

US3452203 (Prod: Lynn Health Science Institute)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:44:45

All time stamps listed in this document are displayed in GMT

US3452203

Form: Participant Creation

Data signed: (b) (4) 16 Apr 2021 03:38:02

Generated On: 11 Aug 2021 22:44:45

[Participant ID](#)

US3452203

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

US3452203

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 04 AUG 2020

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

Folder OID SCRN

US3452203

Folder: Screening

Form: Demographics

Data signed: (b) (4) 17 Feb 2021 18:05:29

Generated On: 11 Aug 2021 22:44:45

Date of Birth (MMM yyyy)	(b) (6) 1940
Age	80
Age Units	YEARS
Age (Derived)	80
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

US3452203

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

Date of Informed Consent (*dd MMM yyyy*) 04 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version
Amendment 1
Amendment 2
Amendment 3
Amendment 4
Amendment 5

Was participant enrolled in the study? Yes
No

If No, indicate reason for screen fail
Withdrew Consent
Inclusion/Exclusion
Cohort Full
Other

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes
No

If Yes, previous participant number _____

Enrollment Trigger 1

US3452203

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

Did the participant meet all eligibility criteria?

Yes

No

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

Condition	GLAUCOMA
Start date (dd MMM yyyy)	UN UNK 2012
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 UNK 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

Condition	GERD
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

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

US3452203

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 1970
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 1970
Start Year (derived)	1970
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

Condition	COMPLETE HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 1985
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 UNK 1985
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1985
Start Year (derived)	1985
Stop Month and Year (derived)	JAN 1985
Stop Year (derived)	1985

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

Condition	CHOLECYSTECTOMY
Start date (dd MMM yyyy)	UN UNK 1994
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 UNK 1994
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1994
Start Year (derived)	1994
Stop Month and Year (derived)	JAN 1994
Stop Year (derived)	1994

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

Condition	LEFT KNEE REPLACEMENT SURGERY
Start date (dd MMM yyyy)	UN UNK 2005
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 UNK 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

Condition	RIGHT KNEE REPLACEMENT
Start date (dd MMM yyyy)	UN UNK 2007
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 UNK 2007
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	JAN 2007
Stop Year (derived)	2007

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

Condition	BOWEL RESECTION
Start date (dd MMM yyyy)	UN UNK 2001
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 UNK 2001
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2001
Start Year (derived)	2001
Stop Month and Year (derived)	JAN 2001
Stop Year (derived)	2001

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

Condition	BUNIONS REMOVED FROM BOTH FEET
Start date (dd MMM yyyy)	UN UNK 2003
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 UNK 2003
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	JAN 2003
Stop Year (derived)	2003

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

Condition	ROTATOR CUFF REPAIR OF RIGHT SHOULDER
Start date (dd MMM yyyy)	UN UNK 2009
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 UNK 2009
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	JAN 2009
Stop Year (derived)	2009

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

Condition	NASAL RECONSTRUCTION DUE TO INJURY
Start date (dd MMM yyyy)	UN UNK 2010
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 UNK 2010
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

Condition	ALLERGY TO SULFA
Start date (dd MMM yyyy)	UN UNK 1976
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 1976
Start Year (derived)	1976
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

Condition	ALLERGY TO CODEINE/MORPHINE
Start date (dd MMM yyyy)	UN UNK 1985
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 1985
Start Year (derived)	1985
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

Condition	ALLERGY TO NAR-CAN
Start date (dd MMM yyyy)	UN UNK 1985
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 1985
Start Year (derived)	1985
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

Condition	GALLSTONES
Start date (dd MMM yyyy)	UN UNK 1994
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 UNK 1994
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1994
Start Year (derived)	1994
Stop Month and Year (derived)	JAN 1994
Stop Year (derived)	1994

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Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

Condition	PAINFUL PERIODS
Start date (dd MMM yyyy)	UN UNK 1985
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 UNK 1985
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1985
Start Year (derived)	1985
Stop Month and Year (derived)	JAN 1985
Stop Year (derived)	1985

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Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

Condition	NON-CANCEROUS GROWTH IN BOWEL
Start date (dd MMM yyyy)	UN UNK 2001
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 UNK 2001
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2001
Start Year (derived)	2001
Stop Month and Year (derived)	JAN 2001
Stop Year (derived)	2001

US3452203

Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

Condition	HIGH BLOOD PRESSURE
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

US3452203

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	04 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	14:35 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 14:35
Height (<i>xxx.x</i>)	61.0 in
Weight (<i>xxx.x</i>)	199.6 lb
BMI (<i>xxx.x</i>)	37.79295 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)	_____

US3452203

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

04 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 17 Feb 2021 18:05:29

Generated On: 11 Aug 2021 22:44:45

Date of assessment (*dd MMM yyyy*) 04 AUG 2020

Is the participant of childbearing potential? Yes
No

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (*dd MMM yyyy*) UN UNK 1985

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: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes No

Specify _____

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 18:05:30

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

US3452203

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 04 AUG 2020

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

Folder OID VISIT1

US3452203

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

What was the date of randomization? (dd MMM yyyy) 04 AUG 2020

What was the participant's randomization number? 184703

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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

Height	ND - Not Done
Weight	ND - Not Done

US3452203

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	04 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	14:35 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 14:35
Temperature (<i>xxx.x</i>)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	57 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3452203

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	04 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	15:39 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 15:39
Temperature (<i>xxx.x</i>)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	56 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	82 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

04 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

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) 04 AUG 2020

What was the treatment time? (00:00-23:59) 14:55 (24 HR)

Treatment Date and Time (derived) 04 AUG 2020 14:55

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) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 04 AUG 2020

Collection time (*00:00-23:59*) 14:39 (24 HR)

Collection date and time (derived) 04 AUG 2020 14:39

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

Collection date (<i>dd MMM yyyy</i>)			04 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:37	04 AUG 2020 14:37
Nasopharyngeal Swab 2	Yes	14:37	04 AUG 2020 14:37

US3452203

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

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 97.9 °F

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 04 AUG 2020 15:35

PC Open Date & Time 04 AUG 2020 15:15

PC Close Date & Time 04 AUG 2020 17:45

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.9 °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 04 AUG 2020 21:20
PC Open Date & Time 04 AUG 2020 18:40
PC Close Date & Time 05 AUG 2020 11:59

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 2

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

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

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

PC Time Stamp	05 AUG 2020 17:43
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.1 °F

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

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

PC Time Stamp 06 AUG 2020 15:59

PC Open Date & Time 06 AUG 2020 12:00

PC Close Date & Time 07 AUG 2020 11:59

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 4

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

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

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

PC Time Stamp	07 AUG 2020 14:22
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 5

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	08 AUG 2020 18:47
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 6

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

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

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 7

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

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

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

PC Time Stamp	10 AUG 2020 12:01
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

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

04 AUG 2020 15:35

PC Open Date & Time

04 AUG 2020 15:15

PC Close Date & Time

04 AUG 2020 17:45

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

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

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.**

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

PC Open Date & Time

04 AUG 2020 18:40

PC Close Date & Time

05 AUG 2020 11:59

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 2

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

Please record - **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	06 AUG 2020 11:35
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 3

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

Please record - **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	06 AUG 2020 16:00
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 4

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	07 AUG 2020 14:23
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 5

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

08 AUG 2020 18:48

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 6

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

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

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 7

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

10 AUG 2020 12:01

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

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

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

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

No

Yes

PC Time stamp	04 AUG 2020 15:36
PC Open Date & Time	04 AUG 2020 15:15
PC Close Date & Time	04 AUG 2020 17:45

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

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

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

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

No

Yes

PC Time stamp

PC Open Date & Time

04 AUG 2020 18:40

PC Close Date & Time

05 AUG 2020 11:59

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:44:45

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

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:44:45

	Yes <input type="checkbox"/>
PC Time stamp	06 AUG 2020 11:36
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:44:45

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

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:44:45

	Yes <input type="checkbox"/>
PC Time stamp	06 AUG 2020 16:00
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:44:45

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

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:44:45

Yes

PC Time stamp	07 AUG 2020 14:23
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:44:45

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

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:44:45

	Yes <input type="checkbox"/>
PC Time stamp	08 AUG 2020 18:48
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:44:45

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

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:44:45

Yes

PC Time stamp	09 AUG 2020 12:01
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:44:45

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

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:44:45

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

US3452203

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 18:05:29

Generated On: 11 Aug 2021 22:44:45

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 11 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3452203

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 18:05:29

Generated On: 11 Aug 2021 22:44:45

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3452203

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 03:38:04

Generated On: 11 Aug 2021 22:44:45

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 18 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3452203

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 03:38:04

Generated On: 11 Aug 2021 22:44:45

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3452203

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 18:05:29

Generated On: 11 Aug 2021 22:44:45

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 25 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3452203

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 18:05:29

Generated On: 11 Aug 2021 22:44:45

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3452203

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3452203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	03 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	13:38 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 13:38
Temperature (<i>xxx.x</i>)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	60 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	154 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3452203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

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)	03 SEP 2020
Time of assessment (00:00-23:59)	14:45 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 14:45
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3452203

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

03 SEP 2020

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

US3452203

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

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) 03 SEP 2020

What was the treatment time? (00:00-23:59) 14:01 (24 HR)

Treatment Date and Time (derived) 03 SEP 2020 14:01

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

US3452203

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 03 SEP 2020

Collection time (*00:00-23:59*) 13:40 (24 HR)

Collection date and time (derived) 03 SEP 2020 13:40

US3452203

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

Collection date (<i>dd MMM yyyy</i>)			03 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:42	03 SEP 2020 13:42
Nasopharyngeal Swab 2	Yes	13:42	03 SEP 2020 13:42

US3452203

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

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 97.9 °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 03 SEP 2020 14:41

PC Open Date & Time 03 SEP 2020 14:21

PC Close Date & Time 03 SEP 2020 16:51

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.6 °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 03 SEP 2020 19:19
PC Open Date & Time 03 SEP 2020 17:46
PC Close Date & Time 04 SEP 2020 11:59

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

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

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

PC Time Stamp	04 SEP 2020 21:18
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

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

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

PC Time Stamp	05 SEP 2020 16:14
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.7 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	06 SEP 2020 19:58
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

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

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

PC Time Stamp	07 SEP 2020 15:56
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.9 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	08 SEP 2020 21:41
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	09 SEP 2020 21:47
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

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

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

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

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

- Yes
- No

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

- Yes
- No

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**
Please select one response below

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

PC Time Stamp

03 SEP 2020 14:41

PC Open Date & Time

03 SEP 2020 14:21

PC Close Date & Time

03 SEP 2020 16:51

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

03 SEP 2020 19:19

PC Open Date & Time

03 SEP 2020 17:46

PC Close Date & Time

04 SEP 2020 11:59

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 2

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

Please record - **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

04 SEP 2020 21:18

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 3

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	05 SEP 2020 16:14
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 4

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	06 SEP 2020 19:58
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 5

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	07 SEP 2020 15:56
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 6

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

08 SEP 2020 21:41

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 7

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

09 SEP 2020 21:48

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

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

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

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

No

Yes

PC Time stamp	03 SEP 2020 14:42
PC Open Date & Time	03 SEP 2020 14:21
PC Close Date & Time	03 SEP 2020 16:51

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

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

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

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

No

Yes

PC Time stamp	03 SEP 2020 19:20
PC Open Date & Time	03 SEP 2020 17:46
PC Close Date & Time	04 SEP 2020 11:59

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:44:45

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

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:44:45

	Yes <input type="checkbox"/>
PC Time stamp	04 SEP 2020 21:19
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:44:45

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

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:44:45

	Yes <input type="checkbox"/>
PC Time stamp	05 SEP 2020 16:14
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:44:45

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

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:44:45

	Yes <input type="checkbox"/>
PC Time stamp	06 SEP 2020 19:59
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:44:45

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

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:44:45

	Yes <input type="checkbox"/>
PC Time stamp	07 SEP 2020 15:57
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:44:45

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

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:44:45

	Yes <input type="checkbox"/>
PC Time stamp	08 SEP 2020 21:42
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:44:45

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

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:44:45

	Yes <input type="checkbox"/>
PC Time stamp	09 SEP 2020 21:48
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3452203

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 18:05:29

Generated On: 11 Aug 2021 22:44:45

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3452203

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 18:05:29

Generated On: 11 Aug 2021 22:44:45

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3452203

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 18:05:29

Generated On: 11 Aug 2021 22:44:45

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 18 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3452203

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 18:05:29

Generated On: 11 Aug 2021 22:44:45

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3452203

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 18:05:29

Generated On: 11 Aug 2021 22:44:45

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 24 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3452203

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 18:05:29

Generated On: 11 Aug 2021 22:44:45

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3452203

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	06 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3452203

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

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) _____

US3452203

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

06 OCT 2020

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

US3452203

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

Was the sample collected? Yes No

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

Collection time (*00:00-23:59*) 13:40 (24 HR)

Collection date and time (derived) 06 OCT 2020 13:40

US3452203

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 18:05:30

Generated On: 11 Aug 2021 22:44:45

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 OCT 2020 19:00:20
Patient Cloud Open Date & Time	04 OCT 2020 00:01
Patient Cloud Close Date & Time	08 OCT 2020 23:59

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 71

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

No

Yes

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

No

Yes

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

Date and time of submission 12 OCT 2020 08:58:50

Patient Cloud Open Date & Time 11 OCT 2020 00:01

Patient Cloud Close Date & Time 15 OCT 2020 23:59

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 78

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

No

Yes

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

No

Yes

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

Date and time of submission 22 OCT 2020 12:23:49

Patient Cloud Open Date & Time 18 OCT 2020 00:01

Patient Cloud Close Date & Time 22 OCT 2020 23:59

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 92

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

No

Yes

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

No

Yes

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

Date and time of submission 02 NOV 2020 08:22:48

Patient Cloud Open Date & Time 01 NOV 2020 00:01

Patient Cloud Close Date & Time 05 NOV 2020 23:59

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

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

Date and time of submission

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 106

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

No

Yes

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

No

Yes

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

Date and time of submission

15 NOV 2020 07:01:13

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	True
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	True
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Please contact your study clinic immediately. Click below to confirm that you have read this 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	19 NOV 2020 09:56:27
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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 27 NOV 2020 10:51:47

Patient Cloud Open Date & Time 26 NOV 2020 00:01

Patient Cloud Close Date & Time 30 NOV 2020 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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	03 DEC 2020 15:59:58
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	10 DEC 2020 07:46:44
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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 17 DEC 2020 18:40:45

Patient Cloud Open Date & Time 17 DEC 2020 00:01

Patient Cloud Close Date & Time 21 DEC 2020 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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 <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	27 DEC 2020 08:06:54
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	31 DEC 2020 11:52:56
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 JAN 2021 12:17:10
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 JAN 2021 23:39:34
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 JAN 2021 08:33:32
Patient Cloud Open Date & Time	21 JAN 2021 00:01
Patient Cloud Close Date & Time	25 JAN 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 180

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

No

Yes

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

No

Yes

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

Date and time of submission 28 JAN 2021 08:52:48

Patient Cloud Open Date & Time 28 JAN 2021 00:01

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

07 FEB 2021 19:52:19

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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	12 FEB 2021 12:57:18
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 FEB 2021 08:45:46
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 208

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

No

Yes

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

No

Yes

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

Date and time of submission 27 FEB 2021 15:53:40

Patient Cloud Open Date & Time 25 FEB 2021 00:01

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 MAR 2021 12:19:44
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	14 MAR 2021 07:13:43
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 229

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

No

Yes

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

No

Yes

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

Date and time of submission 18 MAR 2021 10:27:18

Patient Cloud Open Date & Time 18 MAR 2021 00:01

Patient Cloud Close Date & Time 22 MAR 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 MAR 2021 08:19:40
Patient Cloud Open Date & Time	25 MAR 2021 00:01
Patient Cloud Close Date & Time	29 MAR 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 APR 2021 04:24:57
Patient Cloud Open Date & Time	01 APR 2021 00:01
Patient Cloud Close Date & Time	05 APR 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 APR 2021 07:59:01
Patient Cloud Open Date & Time	08 APR 2021 00:01
Patient Cloud Close Date & Time	12 APR 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 257

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

No

Yes

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

No

Yes

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

Date and time of submission 15 APR 2021 08:30:19

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 APR 2021 09:02:45
Patient Cloud Open Date & Time	22 APR 2021 00:01
Patient Cloud Close Date & Time	26 APR 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 MAY 2021 20:44:23
Patient Cloud Open Date & Time	29 APR 2021 00:01
Patient Cloud Close Date & Time	03 MAY 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 285

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 313

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 320

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 341

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 348

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01
Patient Cloud Close Date & Time	19 JUL 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01
Patient Cloud Close Date & Time	16 AUG 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

Date and time of submission

Patient Cloud Open Date & Time	02 SEP 2021 00:01
Patient Cloud Close Date & Time	06 SEP 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 404

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 411

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 439

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 446

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 460

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01
Patient Cloud Close Date & Time	15 NOV 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	06 DEC 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 495

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

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

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

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

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

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

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	13 DEC 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

Date and time of submission

Patient Cloud Open Date & Time	23 DEC 2021 00:01
Patient Cloud Close Date & Time	27 DEC 2021 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

[Patient Cloud Close Date & Time](#) 03 JAN 2022 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

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10 JAN 2022 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

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17 JAN 2022 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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°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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

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24 JAN 2022 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

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31 JAN 2022 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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°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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

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07 FEB 2022 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 600

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 614

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 621

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

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

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

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

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

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

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

Date and time of submission	
Patient Cloud Open Date & Time	21 APR 2022 00:01
Patient Cloud Close Date & Time	25 APR 2022 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 663

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

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

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

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

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

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

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 670

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 684

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 691

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 712

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 719

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 740

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 768

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

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

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01
Patient Cloud Close Date & Time	19 SEP 2022 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01
Patient Cloud Close Date & Time	26 SEP 2022 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 789

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

DAY 796

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

- Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#) 10 OCT 2022 23:59

US3452203

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:44:45

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 15:54:02

US3452203

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 03:38:05

Generated On: 11 Aug 2021 22:44:45

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

US3452203

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 03:38:05

Generated On: 11 Aug 2021 22:44:45

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3452203

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 03:38:04

Generated On: 11 Aug 2021 22:44:45

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 3 DEC 2020

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3452203

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 03:38:04

Generated On: 11 Aug 2021 22:44:45

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3452203

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 03:38:04

Generated On: 11 Aug 2021 22:44:45

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 30 DEC 2020

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3452203

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 03:38:04

Generated On: 11 Aug 2021 22:44:45

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3452203

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 03:38:05

Generated On: 11 Aug 2021 22:44:45

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 31 JAN 2021

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3452203

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 03:38:05

Generated On: 11 Aug 2021 22:44:45

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3452203

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 03:38:31

Generated On: 11 Aug 2021 22:44:45

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 4 MAR 2021

Was visit performed at the participant's home or at the clinic? Home
Clinic

Folder OID VISIT4

US3452203

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 03:38:31

Generated On: 11 Aug 2021 22:44:45

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) _____

US3452203

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 03:38:31

Generated On: 11 Aug 2021 22:44:45

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

4 MAR 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3452203

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 03:38:31

Generated On: 11 Aug 2021 22:44:45

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 4 MAR 2021

Collection time (*00:00-23:59*) 15:57 (24 HR)

Collection date and time (derived) 4 MAR 2021 15:57

US3452203

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 03:38:31

Generated On: 11 Aug 2021 22:44:45

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3452203

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 03:38:05

Generated On: 11 Aug 2021 22:44:45

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 1 APR 2021

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3452203

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 03:38:05

Generated On: 11 Aug 2021 22:44:45

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3452203

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) 30 Apr 2021 18:38:56

Generated On: 11 Aug 2021 22:44:45

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 30 APR 2021

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3452203

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) 30 Apr 2021 18:38:56

Generated On: 11 Aug 2021 22:44:45

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3452203

Folder: Safety Call Day 299 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) _____

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments _____

If Contact Not Made, please provide Comments _____

US3452203

Folder: Safety Call Day 299 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:45

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 16 Apr 2021 03:38:02

Generated On: 11 Aug 2021 22:44:45

Date of Contact	17 NOV 2020
Time of Contact	14:00
Date and Time of Contact (derived)	17 NOV 2020 14:00
Type of Contact	Clinic Visit - Scheduled <input type="radio"/> Clinical Visit - Unscheduled <input checked="" type="radio"/> Safety Call <input type="radio"/> Convalescent Tele-visit <input type="radio"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="radio"/> No <input type="radio"/>

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

	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 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	93 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.0 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

Not Done

Fatigue

None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

Body Aches

None

Mild

Moderate

Severe

Not Done

Headache

None

Mild

Moderate

Severe

Not Done

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

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

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

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"/>

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

	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 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	92 %
---------------	------

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 checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

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

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

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"/>

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

	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 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	91 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.2 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input 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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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

	Not Done <input type="radio"/>
Fatigue	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Muscle Aches (Myalgia)	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Body Aches	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Headache	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Taste	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Smell	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

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

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

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"/>

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

	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 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	91 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	99.0 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input 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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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

Not Done

Fatigue

None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

Body Aches

None

Mild

Moderate

Severe

Not Done

Headache

None

Mild

Moderate

Severe

Not Done

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

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

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

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"/>

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

	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 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	93 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.7 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

	Not Done <input type="radio"/>
Fatigue	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Muscle Aches (Myalgia)	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Body Aches	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Headache	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Taste	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Smell	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

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

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

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"/>

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

	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 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	93 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.8 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

Not Done

Fatigue

None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

Body Aches

None

Mild

Moderate

Severe

Not Done

Headache

None

Mild

Moderate

Severe

Not Done

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

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

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

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"/>

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

	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 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	93 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.3 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input 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 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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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

Not Done

Fatigue

None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

Body Aches

None

Mild

Moderate

Severe

Not Done

Headache

None

Mild

Moderate

Severe

Not Done

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

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

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

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 17 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

	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 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	93 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.4 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

Not Done

Fatigue

None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

Body Aches

None

Mild

Moderate

Severe

Not Done

Headache

None

Mild

Moderate

Severe

Not Done

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

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

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

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"/>

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

	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 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	93 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.7 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

Not Done

Fatigue

None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

Body Aches

None

Mild

Moderate

Severe

Not Done

Headache

None

Mild

Moderate

Severe

Not Done

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

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

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

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"/>

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

	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 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	93 %
---------------	------

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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

Not Done

Fatigue

None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

Body Aches

None

Mild

Moderate

Severe

Not Done

Headache

None

Mild

Moderate

Severe

Not Done

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

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

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

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"/>

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	27 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	93 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.9 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

Not Done

Fatigue

None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

Body Aches

None

Mild

Moderate

Severe

Not Done

Headache

None

Mild

Moderate

Severe

Not Done

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

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

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

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"/>

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	28 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	93 %
---------------	------

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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EAB) (1725)

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US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

Not Done

Fatigue

None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

Body Aches

None

Mild

Moderate

Severe

Not Done

Headache

None

Mild

Moderate

Severe

Not Done

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

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

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

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"/>

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	29 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	93 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.7 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

Not Done

Fatigue

None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

Body Aches

None

Mild

Moderate

Severe

Not Done

Headache

None

Mild

Moderate

Severe

Not Done

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

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

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

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"/>

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	30 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	96 %
---------------	------

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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

	Not Done <input type="radio"/>
Fatigue	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Muscle Aches (Myalgia)	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Body Aches	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Headache	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Taste	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Smell	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

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

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 16 Apr 2021 03:38:02

Generated On: 11 Aug 2021 22:44:45

Date of Visit 17 NOV 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes
No

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes
No

Date of Test 17 NOV 2020

Type of Test Performed Nasopharyngeal Swab
Nasal Swab
Saliva Test
Other

Other, specify _____

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes
No

If yes, provide lab information below

Lab/ Institution Test Performed _____

CLIA Certified? Yes
No

COVID-19 Positive (CSA Programming Field Only) 1

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 29 Apr 2021 17:43:21

Generated On: 11 Aug 2021 22:44:45

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 17 NOV 2020

End Date 30 NOV 2020

Oxygen Saturation 91 %

Did the subject have PaO₂/FIO₂ Ratio < 300 mm Hg? Yes
No

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes
No

Start Date _____

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes
No

Start Date _____

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 29 Apr 2021 17:43:21

Generated On: 11 Aug 2021 22:44:45

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 _____

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 29 Apr 2021 17:43:21

Generated On: 11 Aug 2021 22:44:45

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 _____

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 16 Apr 2021 03:38:03

Generated On: 11 Aug 2021 22:44:45

[Generate Next COVID-19 Assessment](#)

Yes

No

US3452203

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 16 Apr 2021 03:38:04

Generated On: 11 Aug 2021 22:44:45

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	19 NOV 2020
Day 5	Yes	21 NOV 2020
Day 7	Yes	23 NOV 2020
Day 9	Yes	25 NOV 2020
Day 14	Yes	30 NOV 2020
Day 21	Yes	07 DEC 2020
Day 28	Yes	11 DEC 2020

US3452203

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 03:38:04

Generated On: 11 Aug 2021 22:44:45

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 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	SICKD1

US3452203

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 03:38:04

Generated On: 11 Aug 2021 22:44:45

Were vital signs assessed? Yes
No

Date of assessment (*dd MMM yyyy*) 17 NOV 2020

Time of assessment (*00:00-23:59*) 14:27 (24 HR)

Vital Signs Date and Time (derived) 17 NOV 2020 14:27

Height (*xxx.x*) 61.0 in

Weight (*xxx.x*) 198.0 lb

Temperature (*xxx.x*) 98.0 F

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (*xxx*) 86 beats/min

Pulse units BPM

Respiratory Rate (*xxx*) 20 breaths/min

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (*xxx*) 130 mmHg

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (*xxx*) 65 mmHg

Diastolic Blood Pressure units MMHG

Height (derived) _____

Weight (derived) _____

US3452203

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 03:38:04

Generated On: 11 Aug 2021 22:44:45

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

17 NOV 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3452203

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 16 Apr 2021 03:38:04

Generated On: 11 Aug 2021 22:44:45

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

Yes

No

NA (COVID-19 Negative)

Date of Collection

17 NOV 2020

US3452203

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 03:38:02

Generated On: 11 Aug 2021 22:44:45

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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	SICKD28

US3452203

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 03:38:02

Generated On: 11 Aug 2021 22:44:45

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	11 DEC 2020
Time of assessment (<i>00:00-23:59</i>)	11:01 (24 HR)
Vital Signs Date and Time (derived)	11 DEC 2020 11:01
Height (<i>xxx.x</i>)	61.7 in
Weight (<i>xxx.x</i>)	198.2 lb
Temperature (<i>xxx.x</i>)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	73 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	77 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3452203

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 03:38:02

Generated On: 11 Aug 2021 22:44:45

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

11 DEC 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3452203

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 16 Apr 2021 03:38:02

Generated On: 11 Aug 2021 22:44:45

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes

No

NA (COVID-19 Negative)

Date of Collection

11 DEC 2020

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 03:38:04

Generated On: 11 Aug 2021 22:44:45

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 09 MAR 2021

Was visit performed at the participant's home or at the clinic? Home
Clinic

Folder OID UNBLND_DECIDE

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 03:38:04

Generated On: 11 Aug 2021 22:44:45

Date of updated informed consent (<i>dd MMM yyyy</i>)	09 MAR 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>)	09 MAR 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

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Apr 2021 03:38:04

Generated On: 11 Aug 2021 22:44:45

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Apr 2021 03:38:04

Generated On: 11 Aug 2021 22:44:45

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	09 MAR 2021
Time of assessment (00:00-23:59)	13:45 (24 HR)
Vital Signs Date and Time (derived)	09 MAR 2021 13:45
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)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Apr 2021 03:38:04

Generated On: 11 Aug 2021 22:44:45

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	09 MAR 2021
Time of assessment (00:00-23:59)	14:55 (24 HR)
Vital Signs Date and Time (derived)	09 MAR 2021 14:55
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 03:38:04

Generated On: 11 Aug 2021 22:44:45

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

09 MAR 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 16 Apr 2021 03:38:04

Generated On: 11 Aug 2021 22:44:45

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) 09 MAR 2021

What was the treatment time? (00:00-23:59) 14:24 (24 HR)

Treatment Date and Time (derived) 09 MAR 2021 14:24

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

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 03:38:04

Generated On: 11 Aug 2021 22:44:45

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 09 MAR 2021

Collection time (*00:00-23:59*) 13:49 (24 HR)

Collection date and time (derived) 09 MAR 2021 13:49

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Apr 2021 03:38:04

Generated On: 11 Aug 2021 22:44:45

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 09 MAR 2021

Collection time (*00:00 - 23:59*) 13:47

Collection Date and Time (derived) 09 MAR 2021 13:47

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 03:38:04

Generated On: 11 Aug 2021 22:44:45

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3452203

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 03:38:31

Generated On: 11 Aug 2021 22:44:45

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 16 MAR 2021

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3452203

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 03:38:31

Generated On: 11 Aug 2021 22:44:45

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3452203

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 03:38:04

Generated On: 11 Aug 2021 22:44:45

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 08 APR 2021

Was visit performed at the participant's home or at the clinic? Home
Clinic

Folder OID OLD29

US3452203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Apr 2021 03:38:04

Generated On: 11 Aug 2021 22:44:45

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	08 APR 2021
Time of assessment (<i>00:00-23:59</i>)	13:35 (24 HR)
Vital Signs Date and Time (derived)	08 APR 2021 13:35
Temperature (<i>xxx.x</i>)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	67 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3452203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Apr 2021 03:38:04

Generated On: 11 Aug 2021 22:44:45

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	08 APR 2021
Time of assessment (<i>00:00-23:59</i>)	14:24 (24 HR)
Vital Signs Date and Time (derived)	08 APR 2021 14:24
Temperature (<i>xxx.x</i>)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	58 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3452203

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 03:38:04

Generated On: 11 Aug 2021 22:44:45

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

08 APR 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3452203

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 16 Apr 2021 03:38:04

Generated On: 11 Aug 2021 22:44:45

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) 08 APR 2021

What was the treatment time? (00:00-23:59) 13:53 (24 HR)

Treatment Date and Time (derived) 08 APR 2021 13:53

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

US3452203

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 03:38:04

Generated On: 11 Aug 2021 22:44:45

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3452203

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) _____

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments _____

If Contact Not Made, please provide Comments _____

US3452203

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:45

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3452203

Folder: **Unscheduled 18 Jan 2021**

Form: **Unscheduled Visit Assessment**

Data signed: (b) (4) 16 Apr 2021 03:38:31

Generated On: 11 Aug 2021 22:44:45

Visit Date	18 JAN 2021
------------	-------------

Please check all assessments that apply for this visit

Physical Exam	False
---------------	-------

Vital Signs	False
-------------	-------

Immunogenicity Assessment	True
---------------------------	------

Pregnancy Test	False
----------------	-------

US3452203

Folder: **Unscheduled 18 Jan 2021**

Form: **Immunogenicity Assessment**

Generated On: **11 Aug 2021 22:44:45**

Was the sample collected? Yes
No

Collection date (*dd MMM yyyy*) _____

Collection time (*00:00-23:59*) _____

Collection date and time (derived) _____

US3452203

Folder: **Unscheduled 23 Feb 2021**

Form: **Unscheduled Visit Assessment**

Data signed: (b) (4) 16 Apr 2021 03:38:31

Generated On: 11 Aug 2021 22:44:45

Visit Date	23 FEB 2021
------------	-------------

Please check all assessments that apply for this visit

Physical Exam	True
---------------	------

Vital Signs	False
-------------	-------

Immunogenicity Assessment	False
---------------------------	-------

Pregnancy Test	False
----------------	-------

US3452203

Folder: **Unscheduled 23 Feb 2021**

Form: **Physical Examination**

Generated On: **11 Aug 2021 22:44:45**

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.

US3452203

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 13 Mar 2021 17:15:42

Generated On: 11 Aug 2021 22:44:45

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3452203

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Mar 2021 17:15:42

Generated On: 11 Aug 2021 22:44:45

AEID	USA-US208-2020-MRNA-1273-P30 1000010
Adverse event	COVID 19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	17 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	25 NOV 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 (1)

Data signed: (b) (4) 13 Mar 2021 17:15:42

Generated On: 11 Aug 2021 22:44:45

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
Related
Not Applicable

Relationship to Study Procedure Not Related
Related
Not Applicable

Action taken with investigational product None
Dose Delayed
Investigational Product
Withdrawn
Not Applicable

Other action taken (check all that apply)

None False

Concomitant Medication True

Concomitant Procedure False

Outcome Fatal
Not Recovered/Not Resolved
Recovered/Resolved
Recovered/Resolved with
Sequelae
Recovering/Resolving
Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____

Narrative

US3452203

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Mar 2021 17:15:42

Generated On: 11 Aug 2021 22:44:45

SUBJECT CAME TO SITE WITH SYMPTOMS OF COVID. ILLNESS VISIT WAS CONDUCTED. SUBJECT IS COVID POSITIVE. SUBJECT COMPLETING CONVALESCENT ILLNESS VISITS. CM STARTED AND ADDED TO EDC.

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)	

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 16 Apr 2021 03:11:35

Generated On: 11 Aug 2021 22:44:45

Were any prior/concomitant medications and/or vaccinations taken?

Yes

No

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 03:11:35

Generated On: 11 Aug 2021 22:44:45

Name of Medication ARMOUR THYROID

Prophylaxis Yes
No

Indication HYPOTHYROIDISM

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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EAB) (1725)

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US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 03:11:35

Generated On: 11 Aug 2021 22:44:45

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2016

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 03:11:35

Generated On: 11 Aug 2021 22:44:45

Name of Medication LEVOTHYROXINE

Prophylaxis Yes
No

Indication HYPOTHYROIDISM

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 03:11:35

Generated On: 11 Aug 2021 22:44:45

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 1970

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 03:11:35

Generated On: 11 Aug 2021 22:44:45

Name of Medication SPIRONOLACTONE

Prophylaxis Yes
No

Indication HIGH BLOOD PRESSURE

Dose per administration 50

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 03:11:35

Generated On: 11 Aug 2021 22:44:45

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2016

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 03:11:35

Generated On: 11 Aug 2021 22:44:45

Name of Medication PANTOPRAZOLE

Prophylaxis Yes
No

Indication GERD

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 (4)

Data signed: (b) (4) 16 Apr 2021 03:11:35

Generated On: 11 Aug 2021 22:44:45

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2016

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 03:11:35

Generated On: 11 Aug 2021 22:44:45

Name of Medication DICLOFENIC

Prophylaxis Yes
No

Indication OSTEOARTHRITIS

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 03:11:35

Generated On: 11 Aug 2021 22:44:45

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2018

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 03:11:35

Generated On: 11 Aug 2021 22:44:45

Name of Medication RAPINIROLE

Prophylaxis Yes
No

Indication RLS

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 03:11:35

Generated On: 11 Aug 2021 22:44:45

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2015

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 03:11:35

Generated On: 11 Aug 2021 22:44:45

Name of Medication TRAMADOL

Prophylaxis Yes
No

Indication OSTEOARTHRITIS

Dose per administration 100

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 03:11:35

Generated On: 11 Aug 2021 22:44:45

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2017

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 03:11:35

Generated On: 11 Aug 2021 22:44:45

Name of Medication GABAPENTIN

Prophylaxis Yes
No

Indication SENSORY NEUROPATHY OF BILATERAL EXTREMITIES

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 03:11:35

Generated On: 11 Aug 2021 22:44:45

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input 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 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 (9)

Data signed: (b) (4) 16 Apr 2021 03:11:35

Generated On: 11 Aug 2021 22:44:45

Name of Medication CLARITIN

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 (9)

Data signed: (b) (4) 16 Apr 2021 03:11:35

Generated On: 11 Aug 2021 22:44:45

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2015

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 03:11:35

Generated On: 11 Aug 2021 22:44:45

Name of Medication EZETIMIBE

Prophylaxis Yes
No

Indication HIGH CHOLESTEROL

Dose per administration 10

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 03:11:35

Generated On: 11 Aug 2021 22:44:45

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2015

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 03:11:35

Generated On: 11 Aug 2021 22:44:45

Name of Medication GOLDEN REVIVE (TUMERIC, BROMELAIN, BOSWELLIA, QUERCETIN, MAGNESIUM, PIPERINE)

Prophylaxis Yes
No

Indication JOINT INFLAMMATION ALL JOINTS DUE TO OA

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 03:11:35

Generated On: 11 Aug 2021 22:44:45

	Subcutaneous	<input type="radio"/>
	Transdermal	<input type="radio"/>
	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input 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 APR 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 03:11:35

Generated On: 11 Aug 2021 22:44:45

Name of Medication DICLOFENAC SODIUM

Prophylaxis Yes
No

Indication OA/JOINT INFLAMMATION

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

458 of 2839

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 03:11:35

Generated On: 11 Aug 2021 22:44:45

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN APR 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 16 Apr 2021 03:11:35

Generated On: 11 Aug 2021 22:44:45

Name of Medication PREDNISONE

Prophylaxis Yes
No

Indication SOB CAUSED BY COVID 19

Dose per administration 20

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 16 Apr 2021 03:11:35

Generated On: 11 Aug 2021 22:44:45

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 17 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 24 NOV 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3452203

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 16 Apr 2021 03:38:02

Generated On: 11 Aug 2021 22:44:45

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3452203

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:44:45

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

US3452203

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:44:45

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

US3452203

Folder: SAE USA-US208-2020-MRNA-1273-P301000010

Form: Safety Report Form

Data signed: (b) (4) 16 Apr 2021 03:38:04

Generated On: 11 Aug 2021 22:44:45

SAEID	USA-US208-2020-MRNA-1273-P30 1000010
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	_____
Investigator's Last Name	_____
Site Address: Street	_____
Site Address: City	_____
Site Address: State	_____
Site Address: Postal Code	_____
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3452203

Folder: SAE USA-US208-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Data signed: (b) (4) 16 Apr 2021 03:38:04

Generated On: 11 Aug 2021 22:44:45

SAEID USA-US208-2020-MRNA-1273-P30
1000010

Serious Yes
No

Death Yes
No

Life threatening Yes
No

Requires inpatient or prolongation of existing Hospitalization Yes
No

Persistent or significant disability or incapacity Yes
No

Congenital anomaly or birth defect Yes
No

Other medically important event Yes
No

Investigator's First Name _____

Investigator's Last Name _____

Site Address: Street _____

Site Address: City _____

Site Address: State _____

Site Address: Postal Code _____

Investigator Country US

E2B Transmit Flag (Derived/Hidden) 2

Date of submission (Pre-filled from custom function) 01/DEC/2020 17:11

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

US3452203

Folder: SAE USA-US208-2020-MRNA-1273-P301000010

Form: Safety Report Form (2)

Data signed: (b) (4) 16 Apr 2021 03:38:04

Generated On: 11 Aug 2021 22:44:45

SAEID USA-US208-2020-MRNA-1273-P30
1000010

Serious Yes
No

Death Yes
No

Life threatening Yes
No

Requires inpatient or prolongation of existing Hospitalization Yes
No

Persistent or significant disability or incapacity Yes
No

Congenital anomaly or birth defect Yes
No

Other medically important event Yes
No

Investigator's First Name _____

Investigator's Last Name _____

Site Address: Street _____

Site Address: City _____

Site Address: State _____

Site Address: Postal Code _____

Investigator Country US

E2B Transmit Flag (Derived/Hidden) 2

Date of submission (Pre-filled from custom function) 14/DEC/2020 10:32

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

US3452203 (Prod: Lynn Health Science Institute)

US3452203

Form: Participant Creation

Generated On: 11 Aug 2021 22:44:45

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'US3452203'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 18:59:51

US3452203

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:44:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4) (b) (4)	04 Aug 2020 19:31:51

US3452203

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:44:45

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '04 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 18:59:52

US3452203

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:44:45

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Clinic (Clinic)'	(b) (4) Kim Calloway (b) (4) (b) (4)	04 Aug 2020 19:31:51

US3452203

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:44:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered 'SCRN'	System	04 Aug 2020 19:31:51

US3452203

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:44:45

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered (b) (6) 1940'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 18:59:53

US3452203

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:44:45

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '80'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:50:44

US3452203

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:44:45

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered 'YEARS'	System	04 Aug 2020 21:50:44

US3452203

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:44:45

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered '80'	System	04 Aug 2020 19:32:09

US3452203

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:44:45

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Female (F)'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 21:50:44
	(b) (4)	

US3452203

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:44:45

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:50:44

US3452203

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:44:45

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '1'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:50:44

US3452203

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:44:45

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:50:44

US3452203

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:44:45

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:50:44

US3452203

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:44:45

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:50:44

US3452203

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:44:45

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:50:44

US3452203

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:44:45

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:50:44

US3452203

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:44:45

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered empty.	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:50:44

US3452203

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:44:45

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:50:44

US3452203

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:44:45

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:50:44

US3452203

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:44:45

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '04 Aug 2020'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 19:32:09
	(b) (4)	

US3452203

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:44:45

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered 'Aug 2020'	System	04 Aug 2020 19:32:09

US3452203

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:44:45

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered '2020'	System	04 Aug 2020 19:32:09

US3452203

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:44:45

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Amendment 1 (1)'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 19:32:09

US3452203

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:44:45

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 19:32:09
	(b) (4)	

US3452203

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:44:45

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered empty.	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 19:32:09
	(b) (4)	

US3452203

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:44:45

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered empty.	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 19:32:09
	(b) (4)	

US3452203

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:44:45

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 19:32:09

US3452203

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:44:45

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 18:59:52

US3452203

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:44:45

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered '1'	System	04 Aug 2020 19:32:13

US3452203

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:44:45

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 19:32:13
	(b) (4)	

US3452203

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:44:45

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 21:51:08
	(b) (4)	

US3452203

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:44:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User closed query 'Per CDM: Please clarify which information was updated as there is no concomitant medication listed for this indication. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 08:21:34
Query 'Per CDM: Please clarify which information was updated as there is no concomitant medication listed for this indication. ' answered with 'Subject not on any meds for Glaucoma ' (Site from DM).	Chalimar Rojo (b) (4) (b) (4)	20 Oct 2020 18:35:57
User opened query 'Per CDM: Please clarify which information was updated as there is no concomitant medication listed for this indication. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 19:36:50
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 19:36:50
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'EDC updated' (Site from DM).	Chalimar Rojo (b) (4) (b) (4)	02 Oct 2020 15:37:22
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 13:16:24
User coded data point as SOC: Eye disorders, HLGT: Glaucoma and ocular hypertension, HLT: Glaucomas (excl congenital), PT: Glaucoma, LLT: Glaucoma - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 21:53:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 21:53:09
Data point term sent to Coder	System	04 Aug 2020 21:52:32

US3452203

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:44:45

[Condition](#)

Audit	User	Time (GMT)
User entered 'GLAUCOMA'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:51:33

US3452203

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:44:45

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered 'UN UNK 2012'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:51:33

US3452203

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:44:45

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:51:33

US3452203

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:44:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
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).	System	02 Oct 2020 15:37:37
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	02 Oct 2020 15:37:13
User entered 'No (N)' reason for change: Data Entry Error	Chalimar Rojo (b) (4) (b) (4)	02 Oct 2020 15:37:13
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:51:33

US3452203

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:44:45

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'un UNK 2012' reason for change:	(b) (4)	
Data Entry Error	Chalimar Rojo (b) (4)	02 Oct 2020 15:37:37
User entered empty.	(b) (4)	
	Kim Calloway (b) (4)	04 Aug 2020 21:51:33
	(b) (4)	

US3452203

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:44:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:51:33

US3452203

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:44:45

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered 'Jan 2012'	System	04 Aug 2020 21:51:33

US3452203

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:44:45

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered '2012'	System	04 Aug 2020 21:51:33

US3452203

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:44:45

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered 'Jan 2012'	System	02 Oct 2020 15:37:37
User entered empty.	System	04 Aug 2020 21:51:33

US3452203

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:44:45

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered '2012'	System	02 Oct 2020 15:37:37
User entered empty.	System	04 Aug 2020 21:51:33

US3452203

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:44:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User coded data point as SOC: Immune system disorders, HLG: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:24:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:24:04
Data point term sent to Coder	System	17 Feb 2021 18:06:05
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User coded data point as SOC: Immune system disorders, HLG: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 21:53:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 21:53:09
Data point term sent to Coder	System	04 Aug 2020 21:52:32
User entered 'SEASONAL ALLERGIES'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:51:49

US3452203

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:44:45

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered 'UN UNK 2015'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:51:49

US3452203

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:44:45

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:51:49

US3452203

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:44:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 21:51:49
	(b) (4)	

US3452203

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:44:45

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered empty.	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 21:51:49
	(b) (4)	

US3452203

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:44:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:51:49

US3452203

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:44:45

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered 'Jan 2015'	System	04 Aug 2020 21:51:49

US3452203

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:44:45

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered '2015'	System	04 Aug 2020 21:51:49

US3452203

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:44:45

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered empty.	System	04 Aug 2020 21:51:49

US3452203

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:44:45

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered empty.	System	04 Aug 2020 21:51:49

US3452203

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:44:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: GERD - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:15:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:15:02
Data point term sent to Coder	System	17 Feb 2021 18:06:06
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: GERD - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 21:53:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 21:53:09
Data point term sent to Coder	System	04 Aug 2020 21:52:32
User entered 'GERD'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:52:01

US3452203

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:44:45

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered 'UN UNK 2016'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:52:01

US3452203

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:44:45

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:52:01

US3452203

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:44:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 21:52:01
	(b) (4)	

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:44:45

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered empty.	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 21:52:01
	(b) (4)	

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:44:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:52:01

US3452203

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:44:45

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered 'Jan 2016'	System	04 Aug 2020 21:52:01

US3452203

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:44:45

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered '2016'	System	04 Aug 2020 21:52:01

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:44:45

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered empty.	System	04 Aug 2020 21:52:01

US3452203

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:44:45

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered empty.	System	04 Aug 2020 21:52:01

US3452203

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:44:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Lipid metabolism and deposit disorders NEC, PT: Hypocholesterolaemia, LLT: Hypocholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:22:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:22:10
Data point term sent to Coder	System	17 Feb 2021 18:06:06
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Lipid metabolism and deposit disorders NEC, PT: Hypocholesterolaemia, LLT: Hypocholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 21:53:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 21:53:09
Data point term sent to Coder	System	04 Aug 2020 21:52:32
User entered 'HYPOCHOLESTEROLEMIA'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:52:21

US3452203

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:44:45

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered 'UN UNK 2015'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:52:21

US3452203

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:44:45

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:52:21

US3452203

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:44:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 21:52:21
	(b) (4)	

US3452203

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:44:45

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered empty.	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:52:21

US3452203

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:44:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '0'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 21:52:21
	(b) (4)	

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Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:44:45

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered 'Jan 2015'	System	04 Aug 2020 21:52:21

US3452203

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:44:45

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered '2015'	System	04 Aug 2020 21:52:21

US3452203

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:44:45

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered empty.	System	04 Aug 2020 21:52:21

US3452203

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:44:45

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered empty.	System	04 Aug 2020 21:52:21

US3452203

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:44:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:24:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:24:07
Data point term sent to Coder	System	17 Feb 2021 18:06:06
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 21:55:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 21:55:11
Data point term sent to Coder	System	04 Aug 2020 21:53:33
User entered 'HYPOTHYROIDISM'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:53:15

US3452203

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:44:45

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered 'UN UNK 1970'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:53:15

US3452203

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:44:45

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:53:15

US3452203

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:44:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 21:53:15
	(b) (4)	

US3452203

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:44:45

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered empty.	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:53:15

US3452203

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:44:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:53:15

US3452203

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:44:45

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered 'Jan 1970'	System	04 Aug 2020 21:53:15

US3452203

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:44:45

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered '1970'	System	04 Aug 2020 21:53:15

US3452203

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:44:45

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered empty.	System	04 Aug 2020 21:53:15

US3452203

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:44:45

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered empty.	System	04 Aug 2020 21:53:15

US3452203

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:44:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Peripheral sensory neuropathy, LLT: Sensory peripheral neuropathy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:18:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:18:02
Data point term sent to Coder	System	17 Feb 2021 18:06:06
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User closed query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 02:25:42
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Peripheral sensory neuropathy, LLT: Sensory peripheral neuropathy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 00:45:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 00:45:25
Data point term sent to Coder	System	23 Oct 2020 16:17:23
Query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'updated' (Site from DM).	Chalimar Rojo (b) (4) (b) (4)	23 Oct 2020 16:16:43
Coding entries removed.	Chalimar Rojo (b) (4) (b) (4)	23 Oct 2020 16:16:38
User entered 'sensory NEUROPATHY of bilateral extremities' reason for change: Data Entry Error	Chalimar Rojo (b) (4) (b) (4)	23 Oct 2020 16:16:38

US3452203

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:44:45

Condition

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 09:36:05
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Neuropathy - version MedDRA\23.0.	Coder Import (b) (4)	17 Aug 2020 21:16:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Aug 2020 21:16:14
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Neuropathy - version MedDRA\23.0.	Coder Import (b) (4)	04 Aug 2020 21:55:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	04 Aug 2020 21:55:11
Data point term sent to Coder	System	04 Aug 2020 21:53:33
User entered 'NEUROPATHY'	Kim Calloway (b) (4)	04 Aug 2020 21:53:32

US3452203

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:44:45

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered 'UN UNK 2017'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:53:32

US3452203

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:44:45

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:53:32

US3452203

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:44:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 21:53:32
	(b) (4)	

US3452203

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:44:45

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered empty.	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 21:53:32
	(b) (4)	

US3452203

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:44:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:53:32

US3452203

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:44:45

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered 'Jan 2017'	System	04 Aug 2020 21:53:32

US3452203

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:44:45

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered '2017'	System	04 Aug 2020 21:53:32

US3452203

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:44:45

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered empty.	System	04 Aug 2020 21:53:32

US3452203

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:44:45

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered empty.	System	04 Aug 2020 21:53:32

US3452203

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:44:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Restless legs syndrome, LLT: Restless leg syndrome - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:15:05
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:15:05
Data point term sent to Coder	System	17 Feb 2021 18:06:06
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Restless legs syndrome, LLT: Restless leg syndrome - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 09:34:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 09:34:40
Data point term sent to Coder	System	04 Aug 2020 21:54:34
User entered 'RLS'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:53:51

US3452203

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:44:45

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered 'UN UNK 2015'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:53:51

US3452203

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:44:45

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '0'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 21:53:51
	(b) (4)	

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Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:44:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 21:53:51
	(b) (4)	

US3452203

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:44:45

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered empty.	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 21:53:51
	(b) (4)	

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Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:44:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:53:51

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Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:44:45

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered 'Jan 2015'	System	04 Aug 2020 21:53:51

US3452203

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:44:45

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered '2015'	System	04 Aug 2020 21:53:51

US3452203

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:44:45

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered empty.	System	04 Aug 2020 21:53:51

US3452203

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:44:45

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered empty.	System	04 Aug 2020 21:53:51

US3452203

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:44:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:24:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:24:20
Data point term sent to Coder	System	17 Feb 2021 18:06:06
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 09:07:13
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 09:07:13
Data point term sent to Coder	System	04 Aug 2020 21:54:34
User entered 'OSTEOARTHRITIS ALL JOINTS'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:54:15

US3452203

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:44:45

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered 'UN UNK 2018'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:54:15

US3452203

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:44:45

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '0'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 21:54:15
	(b) (4)	

US3452203

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:44:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:54:15

US3452203

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:44:45

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered empty.	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 21:54:15
	(b) (4)	

US3452203

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:44:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:54:15

US3452203

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:44:45

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered 'Jan 2018'	System	04 Aug 2020 21:54:15

US3452203

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:44:45

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered '2018'	System	04 Aug 2020 21:54:15

US3452203

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:44:45

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered empty.	System	04 Aug 2020 21:54:15

US3452203

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:44:45

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered empty.	System	04 Aug 2020 21:54:15

US3452203

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:44:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Total hysterectomy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:15:07
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:15:07
Data point term sent to Coder	System	17 Feb 2021 18:06:07
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 19:37:23
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'EDC updated' (Site from DM).	Chalimar Rojo (b) (4) (b) (4)	02 Oct 2020 15:39:58
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 13:17:34
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Total hysterectomy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 15:50:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 15:50:38
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 21:57:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 21:57:01
Data point term sent to Coder	System	04 Aug 2020 21:55:35

US3452203

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:44:45

[Condition](#)

Audit	User	Time (GMT)
User entered 'COMPLETE HYSTERECTOMY'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:54:37

US3452203

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:44:45

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered 'UN UNK 1985'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:54:37

US3452203

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:44:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:54:37

US3452203

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:44:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'No (N)'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 21:54:37
	(b) (4)	

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Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:44:45

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'UN UNK 1985'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 21:54:37
	(b) (4)	

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Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:44:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:54:37

US3452203

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:44:45

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered 'Jan 1985'	System	04 Aug 2020 21:54:37

US3452203

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:44:45

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered '1985'	System	04 Aug 2020 21:54:37

US3452203

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:44:45

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered 'Jan 1985'	System	04 Aug 2020 21:54:37

US3452203

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:44:45

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered '1985'	System	04 Aug 2020 21:54:37

US3452203

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:44:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:15:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:15:09
Data point term sent to Coder	System	17 Feb 2021 18:06:06
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 19:37:46
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'EDC updated' (Site from DM).	Chalimar Rojo (b) (4) (b) (4)	02 Oct 2020 15:39:02
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 13:17:56
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 21:57:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 21:57:01
Data point term sent to Coder	System	04 Aug 2020 21:55:35
User entered 'CHOLECYSTECTOMY'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:55:13

US3452203

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:44:45

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered 'UN UNK 1994'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:55:13

US3452203

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:44:45

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:55:13

US3452203

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:44:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'No (N)'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 21:55:13
	(b) (4)	

US3452203

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:44:45

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'UN UNK 1994'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 21:55:13
	(b) (4)	

US3452203

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:44:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:55:13

US3452203

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:44:45

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered 'Jan 1994'	System	04 Aug 2020 21:55:13

US3452203

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:44:45

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered '1994'	System	04 Aug 2020 21:55:13

US3452203

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:44:45

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered 'Jan 1994'	System	04 Aug 2020 21:55:13

US3452203

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:44:45

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered '1994'	System	04 Aug 2020 21:55:13

US3452203

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:44:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee replacement - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:18:06
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:18:06
Data point term sent to Coder	System	17 Feb 2021 18:06:06
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee replacement - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Aug 2020 14:56:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Aug 2020 14:56:21
Data point term sent to Coder	System	04 Aug 2020 21:56:36
User entered 'LEFT KNEE REPLACEMENT SURGERY'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:55:59

US3452203

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:44:45

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered 'UN UNK 2005'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:55:59

US3452203

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:44:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:55:59

US3452203

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:44:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'No (N)'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 21:55:59
	(b) (4)	

US3452203

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:44:45

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'UN UNK 2005'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 21:55:59
	(b) (4)	

US3452203

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:44:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:55:59

US3452203

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:44:45

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered 'Jan 2005'	System	04 Aug 2020 21:55:59

US3452203

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:44:45

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered '2005'	System	04 Aug 2020 21:55:59

US3452203

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:44:45

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered 'Jan 2005'	System	04 Aug 2020 21:55:59

US3452203

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:44:45

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered '2005'	System	04 Aug 2020 21:55:59

US3452203

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:44:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User coded data point as SOC: Surgical and medical procedures, HLG: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee replacement - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:34:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:34:02
Data point term sent to Coder	System	17 Feb 2021 18:06:07
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User coded data point as SOC: Surgical and medical procedures, HLG: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee replacement - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 21:57:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 21:57:02
Data point term sent to Coder	System	04 Aug 2020 21:56:36
User entered 'RIGHT KNEE REPLACEMENT'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:56:20

US3452203

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:44:45

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered 'UN UNK 2007'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:56:20

US3452203

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:44:45

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:56:20

US3452203

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:44:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'No (N)'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 21:56:20
	(b) (4)	

US3452203

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:44:45

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'UN UNK 2007'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 21:56:20
	(b) (4)	

US3452203

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:44:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:56:20

US3452203

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:44:45

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered 'Jan 2007'	System	04 Aug 2020 21:56:20

US3452203

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:44:45

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered '2007'	System	04 Aug 2020 21:56:20

US3452203

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:44:45

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered 'Jan 2007'	System	04 Aug 2020 21:56:20

US3452203

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:44:45

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered '2007'	System	04 Aug 2020 21:56:20

US3452203

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:44:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Gastrointestinal therapeutic procedures NEC, PT: Intestinal resection, LLT: Bowel resection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:24:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 18:24:11
Data point term sent to Coder	System	17 Feb 2021 18:06:07
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 19:38:12
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'EDC updated' (Site from DM).	Chalimar Rojo (b) (4) (b) (4)	02 Oct 2020 15:40:53
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 13:18:15
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Gastrointestinal therapeutic procedures NEC, PT: Intestinal resection, LLT: Bowel resection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 21:59:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Aug 2020 21:59:03
Data point term sent to Coder	System	04 Aug 2020 21:57:36
User entered 'BOWEL RESECTION'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:57:09

US3452203

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:44:45

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered 'UN UNK 2001'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:57:09

US3452203

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:44:45

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '0'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 21:57:09
	(b) (4)	

US3452203

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:44:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'No (N)'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 21:57:09
	(b) (4)	

US3452203

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:44:45

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'UN UNK 2001'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 21:57:09
	(b) (4)	

US3452203

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:44:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:57:09

US3452203

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:44:45

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered 'Jan 2001'	System	04 Aug 2020 21:57:09

US3452203

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:44:45

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered '2001'	System	04 Aug 2020 21:57:09

US3452203

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:44:45

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered 'Jan 2001'	System	04 Aug 2020 21:57:09

US3452203

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:44:45

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered '2001'	System	04 Aug 2020 21:57:09

US3452203

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:44:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Bunion operation, LLT: Bunion operation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:15:06
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:15:06
Data point term sent to Coder	System	17 Feb 2021 18:06:07
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Bunion operation, LLT: Bunion operation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 22:11:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 22:11:37
Data point term sent to Coder	System	04 Aug 2020 21:57:37
User entered 'BUNIONS REMOVED FROM BOTH FEET'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:57:36

US3452203

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:44:45

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered 'UN UNK 2003'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:57:36

US3452203

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:44:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:57:36

US3452203

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:44:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'No (N)'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 21:57:36
	(b) (4)	

US3452203

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:44:45

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'UN UNK 2003'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 21:57:36
	(b) (4)	

US3452203

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:44:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:57:36

US3452203

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:44:45

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered 'Jan 2003'	System	04 Aug 2020 21:57:36

US3452203

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:44:45

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered '2003'	System	04 Aug 2020 21:57:36

US3452203

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:44:45

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered 'Jan 2003'	System	04 Aug 2020 21:57:36

US3452203

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:44:45

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered '2003'	System	04 Aug 2020 21:57:36

US3452203

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:44:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User coded data point as SOC: Surgical and medical procedures, HLG: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Rotator cuff repair, LLT: Rotator cuff repair - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:30:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:30:01
User coded data point as SOC: Surgical and medical procedures, HLG: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Rotator cuff repair, LLT: Rotator cuff repair - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:15:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:15:03
Data point term sent to Coder	System	17 Feb 2021 18:06:08
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User coded data point as SOC: Surgical and medical procedures, HLG: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Rotator cuff repair, LLT: Rotator cuff repair - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 08:47:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 08:47:33
Data point term sent to Coder	System	04 Aug 2020 21:58:37
User entered 'ROTATOR CUFF REPAIR OF RIGHT SHOULDER'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:58:01

US3452203

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:44:45

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered 'UN UNK 2009'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:58:01

US3452203

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:44:45

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:58:01

US3452203

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:44:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'No (N)'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 21:58:01
	(b) (4)	

US3452203

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:44:45

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'UN UNK 2009'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 21:58:01
	(b) (4)	

US3452203

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:44:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:58:01

US3452203

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:44:45

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered 'Jan 2009'	System	04 Aug 2020 21:58:01

US3452203

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:44:45

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered '2009'	System	04 Aug 2020 21:58:01

US3452203

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:44:45

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered 'Jan 2009'	System	04 Aug 2020 21:58:01

US3452203

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:44:45

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered '2009'	System	04 Aug 2020 21:58:01

US3452203

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:44:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Nasal therapeutic procedures, PT: Nasal operation, LLT: Nasal operation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:18:05
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:18:05
Data point term sent to Coder	System	17 Feb 2021 18:06:08
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Nasal therapeutic procedures, PT: Nasal operation, LLT: Nasal operation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 10:39:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 10:39:37
Data point term sent to Coder	System	04 Aug 2020 21:59:38
User entered 'NASAL RECONSTRUCTION DUE TO INJURY'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:58:39

US3452203

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:44:45

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered 'UN UNK 2010'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:58:39

US3452203

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:44:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:58:39

US3452203

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:44:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'No (N)'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 21:58:39
	(b) (4)	

US3452203

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:44:45

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'UN UNK 2010'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 21:58:39
	(b) (4)	

US3452203

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:44:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:58:39

US3452203

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:44:45

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered 'Jan 2010'	System	04 Aug 2020 21:58:39

US3452203

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:44:45

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered '2010'	System	04 Aug 2020 21:58:39

US3452203

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:44:45

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered 'Jan 2010'	System	04 Aug 2020 21:58:39

US3452203

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:44:45

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered '2010'	System	04 Aug 2020 21:58:39

US3452203

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:44:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User coded data point as SOC: Immune system disorders, HLG: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Sulfonamide allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:40:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:40:01
Data point term sent to Coder	System	17 Feb 2021 18:06:07
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User coded data point as SOC: Immune system disorders, HLG: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Sulfonamide allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 22:01:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 22:01:04
Data point term sent to Coder	System	04 Aug 2020 21:59:38
User entered 'ALLERGY TO SULFA'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:58:54

US3452203

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:44:45

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered 'UN UNK 1976'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:58:54

US3452203

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:44:45

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:58:54

US3452203

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:44:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 21:58:54
	(b) (4)	

US3452203

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:44:45

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered empty.	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:58:54

US3452203

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:44:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:58:54

US3452203

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:44:45

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered 'Jan 1976'	System	04 Aug 2020 21:58:54

US3452203

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:44:45

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered '1976'	System	04 Aug 2020 21:58:54

US3452203

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:44:45

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered empty.	System	04 Aug 2020 21:58:54

US3452203

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:44:45

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered empty.	System	04 Aug 2020 21:58:54

US3452203

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:44:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
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) (b) (4)	17 Feb 2021 18:18:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:18:03
Data point term sent to Coder	System	17 Feb 2021 18:06:07
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
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) (b) (4)	04 Aug 2020 22:05:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 22:05:09
Data point term sent to Coder	System	04 Aug 2020 21:59:38
User entered 'ALLERGY TO CODEINE/MORPHINE'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:59:27

US3452203

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:44:45

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'UN UNK 1985'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 21:59:27
	(b) (4)	

US3452203

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:44:45

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '0'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 21:59:27
	(b) (4)	

US3452203

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:44:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 21:59:27
	(b) (4)	

US3452203

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:44:45

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered empty.	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 21:59:27
	(b) (4)	

US3452203

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:44:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:59:27

US3452203

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:44:45

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered 'Jan 1985'	System	04 Aug 2020 21:59:27

US3452203

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:44:45

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered '1985'	System	04 Aug 2020 21:59:27

US3452203

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:44:45

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered empty.	System	04 Aug 2020 21:59:27

US3452203

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:44:45

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered empty.	System	04 Aug 2020 21:59:27

US3452203

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:44:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User coded data point as SOC: Immune system disorders, HLG: 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) (b) (4)	17 Feb 2021 18:24:13
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:24:13
Data point term sent to Coder	System	17 Feb 2021 18:06:09
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User coded data point as SOC: Immune system disorders, HLG: 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) (b) (4)	04 Aug 2020 22:05:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 22:05:59
Data point term sent to Coder	System	04 Aug 2020 22:00:38
User entered 'ALLERGY TO NAR-CAN'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:59:45

US3452203

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:44:45

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered 'UN UNK 1985'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:59:45

US3452203

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:44:45

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:59:45

US3452203

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:44:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 21:59:45
	(b) (4)	

US3452203

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:44:45

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered empty.	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 21:59:45
	(b) (4)	

US3452203

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:44:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 21:59:45

US3452203

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:44:45

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered 'Jan 1985'	System	04 Aug 2020 21:59:45

US3452203

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:44:45

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered '1985'	System	04 Aug 2020 21:59:45

US3452203

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:44:45

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered empty.	System	04 Aug 2020 21:59:45

US3452203

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:44:45

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered empty.	System	04 Aug 2020 21:59:45

US3452203

Folder: Screening

Form: Medical History (20)

Generated On: 11 Aug 2021 22:44:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User coded data point as SOC: Hepatobiliary disorders, HLG: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Gallstones - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:15:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:15:08
Data point term sent to Coder	System	17 Feb 2021 18:06:09
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User coded data point as SOC: Hepatobiliary disorders, HLG: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Gallstones - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 15:39:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 15:39:52
Data point term sent to Coder	System	02 Oct 2020 15:38:53
User entered 'gallstones'	Chalimar Rojo (b) (4) (b) (4)	02 Oct 2020 15:38:47

US3452203

Folder: Screening

Form: Medical History (20)

Generated On: 11 Aug 2021 22:44:45

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'un UNK 1994'	(b) (4) Chalimar Rojo (b) (4)	02 Oct 2020 15:38:47
	(b) (4)	

US3452203

Folder: Screening

Form: Medical History (20)

Generated On: 11 Aug 2021 22:44:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '0'	(b) (4) Chalimar Rojo (b) (4) (b) (4)	02 Oct 2020 15:38:47

US3452203

Folder: Screening

Form: Medical History (20)

Generated On: 11 Aug 2021 22:44:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'No (N)'	(b) (4) Chalimar Rojo (b) (4) (b) (4)	02 Oct 2020 15:38:47

US3452203

Folder: Screening

Form: Medical History (20)

Generated On: 11 Aug 2021 22:44:45

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'un UNK 1994'	(b) (4) Chalimar Rojo (b) (4)	02 Oct 2020 15:38:47
	(b) (4)	

US3452203

Folder: Screening

Form: Medical History (20)

Generated On: 11 Aug 2021 22:44:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '0'	(b) (4) Chalimar Rojo (b) (4) (b) (4)	02 Oct 2020 15:38:47

US3452203

Folder: Screening

Form: Medical History (20)

Generated On: 11 Aug 2021 22:44:45

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered 'Jan 1994'	System	02 Oct 2020 15:38:47

US3452203

Folder: Screening

Form: Medical History (20)

Generated On: 11 Aug 2021 22:44:45

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered '1994'	System	02 Oct 2020 15:38:47

US3452203

Folder: Screening

Form: Medical History (20)

Generated On: 11 Aug 2021 22:44:45

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered 'Jan 1994'	System	02 Oct 2020 15:38:47

US3452203

Folder: Screening

Form: Medical History (20)

Generated On: 11 Aug 2021 22:44:45

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered '1994'	System	02 Oct 2020 15:38:47

US3452203

Folder: Screening

Form: Medical History (21)

Generated On: 11 Aug 2021 22:44:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User coded data point as SOC: Reproductive system and breast disorders, HLG: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation and uterine bleeding NEC, PT: Dysmenorrhoea, LLT: Painful periods - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:18:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:18:05
Data point term sent to Coder	System	17 Feb 2021 18:06:09
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User coded data point as SOC: Reproductive system and breast disorders, HLG: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation and uterine bleeding NEC, PT: Dysmenorrhoea, LLT: Painful periods - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 15:41:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 15:41:43
Data point term sent to Coder	System	02 Oct 2020 15:40:56
User entered 'painful periods'	Chalimar Rojo (b) (4) (b) (4)	02 Oct 2020 15:40:36

US3452203

Folder: Screening

Form: Medical History (21)

Generated On: 11 Aug 2021 22:44:45

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'un UNK 1985'	(b) (4) Chalimar Rojo (b) (4)	02 Oct 2020 15:40:36
	(b) (4)	

US3452203

Folder: Screening

Form: Medical History (21)

Generated On: 11 Aug 2021 22:44:45

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '0'	(b) (4) Chalimar Rojo (b) (4) (b) (4)	02 Oct 2020 15:40:36

US3452203

Folder: Screening

Form: Medical History (21)

Generated On: 11 Aug 2021 22:44:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'No (N)'	(b) (4) Chalimar Rojo (b) (4) (b) (4)	02 Oct 2020 15:40:36

US3452203

Folder: Screening

Form: Medical History (21)

Generated On: 11 Aug 2021 22:44:45

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'un UNK 1985'	(b) (4) Chalimar Rojo (b) (4)	02 Oct 2020 15:40:36
	(b) (4)	

US3452203

Folder: Screening

Form: Medical History (21)

Generated On: 11 Aug 2021 22:44:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '0'	(b) (4) Chalimar Rojo (b) (4) (b) (4)	02 Oct 2020 15:40:36

US3452203

Folder: Screening

Form: Medical History (21)

Generated On: 11 Aug 2021 22:44:45

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered 'Jan 1985'	System	02 Oct 2020 15:40:36

US3452203

Folder: Screening

Form: Medical History (21)

Generated On: 11 Aug 2021 22:44:45

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered '1985'	System	02 Oct 2020 15:40:36

US3452203

Folder: Screening

Form: Medical History (21)

Generated On: 11 Aug 2021 22:44:45

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered 'Jan 1985'	System	02 Oct 2020 15:40:36

US3452203

Folder: Screening

Form: Medical History (21)

Generated On: 11 Aug 2021 22:44:45

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered '1985'	System	02 Oct 2020 15:40:36

US3452203

Folder: Screening

Form: Medical History (22)

Generated On: 11 Aug 2021 22:44:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLT: Gastrointestinal neoplasms benign, HLT: Gastrointestinal neoplasms benign NEC, PT: Benign gastrointestinal neoplasm, LLT: Benign gastrointestinal neoplasm - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:24:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:24:10
Data point term sent to Coder	System	17 Feb 2021 18:06:09
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLT: Gastrointestinal neoplasms benign, HLT: Gastrointestinal neoplasms benign NEC, PT: Benign gastrointestinal neoplasm, LLT: Benign gastrointestinal neoplasm - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 17:58:00
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 17:58:00
Data point term sent to Coder	System	02 Oct 2020 15:41:59
User entered 'non-cancerous growth in bowel'	Chalimar Rojo (b) (4) (b) (4)	02 Oct 2020 15:41:32

US3452203

Folder: Screening

Form: Medical History (22)

Generated On: 11 Aug 2021 22:44:45

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'un UNK 2001'	(b) (4) Chalimar Rojo (b) (4)	02 Oct 2020 15:41:32
	(b) (4)	

US3452203

Folder: Screening

Form: Medical History (22)

Generated On: 11 Aug 2021 22:44:45

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '0'	(b) (4) Chalimar Rojo (b) (4) (b) (4)	02 Oct 2020 15:41:32

US3452203

Folder: Screening

Form: Medical History (22)

Generated On: 11 Aug 2021 22:44:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'No (N)'	(b) (4) Chalimar Rojo (b) (4) (b) (4)	02 Oct 2020 15:41:32

US3452203

Folder: Screening

Form: Medical History (22)

Generated On: 11 Aug 2021 22:44:45

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'un UNK 2001'	(b) (4) Chalimar Rojo (b) (4)	02 Oct 2020 15:41:32
	(b) (4)	

US3452203

Folder: Screening

Form: Medical History (22)

Generated On: 11 Aug 2021 22:44:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '0'	(b) (4) Chalimar Rojo (b) (4) (b) (4)	02 Oct 2020 15:41:32

US3452203

Folder: Screening

Form: Medical History (22)

Generated On: 11 Aug 2021 22:44:45

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered 'Jan 2001'	System	02 Oct 2020 15:41:32

US3452203

Folder: Screening

Form: Medical History (22)

Generated On: 11 Aug 2021 22:44:45

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered '2001'	System	02 Oct 2020 15:41:32

US3452203

Folder: Screening

Form: Medical History (22)

Generated On: 11 Aug 2021 22:44:45

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered 'Jan 2001'	System	02 Oct 2020 15:41:32

US3452203

Folder: Screening

Form: Medical History (22)

Generated On: 11 Aug 2021 22:44:45

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered '2001'	System	02 Oct 2020 15:41:32

US3452203

Folder: Screening

Form: Medical History (23)

Generated On: 11 Aug 2021 22:44:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Blood pressure high - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:18:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:18:04
Data point term sent to Coder	System	17 Feb 2021 18:06:09
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Blood pressure high - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 20:22:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 20:22:34
Data point term sent to Coder	System	19 Oct 2020 20:21:58
Coding entries removed.	Kim Calloway (b) (4) (b) (4)	19 Oct 2020 20:21:41
User entered 'HIGH BLOOD PRESSURE' reason for change: Data Entry Error	Kim Calloway (b) (4) (b) (4)	19 Oct 2020 20:21:41
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Blood pressure high - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 21:20:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 21:20:16
Data point term sent to Coder	System	06 Oct 2020 20:56:11
User entered 'HIHG BLOOD PRESSURE'	Kim Calloway (b) (4) (b) (4)	06 Oct 2020 20:55:58

US3452203

Folder: Screening

Form: Medical History (23)

Generated On: 11 Aug 2021 22:44:45

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered 'UN UNK 2016'	Kim Calloway (b) (4) (b) (4)	06 Oct 2020 20:55:58

US3452203

Folder: Screening

Form: Medical History (23)

Generated On: 11 Aug 2021 22:44:45

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	06 Oct 2020 20:55:58

US3452203

Folder: Screening

Form: Medical History (23)

Generated On: 11 Aug 2021 22:44:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	06 Oct 2020 20:55:58
	(b) (4)	

US3452203

Folder: Screening

Form: Medical History (23)

Generated On: 11 Aug 2021 22:44:45

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered empty.	(b) (4) Kim Calloway (b) (4)	06 Oct 2020 20:55:58
	(b) (4)	

US3452203

Folder: Screening

Form: Medical History (23)

Generated On: 11 Aug 2021 22:44:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	06 Oct 2020 20:55:58

US3452203

Folder: Screening

Form: Medical History (23)

Generated On: 11 Aug 2021 22:44:45

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered 'Jan 2016'	System	06 Oct 2020 20:55:58

US3452203

Folder: Screening

Form: Medical History (23)

Generated On: 11 Aug 2021 22:44:45

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered '2016'	System	06 Oct 2020 20:55:58

US3452203

Folder: Screening

Form: Medical History (23)

Generated On: 11 Aug 2021 22:44:45

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered empty.	System	06 Oct 2020 20:55:58

US3452203

Folder: Screening

Form: Medical History (23)

Generated On: 11 Aug 2021 22:44:45

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered empty.	System	06 Oct 2020 20:55:58

US3452203

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	20 Aug 2020 17:19:29
	(b) (4)	

US3452203

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '04 Aug 2020'	(b) (4) Kim Calloway (b) (4)	20 Aug 2020 17:19:29
	(b) (4)	

US3452203

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '14:35'	(b) (4) Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:19:29

US3452203

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered '04 Aug 2020 14:35'	System	20 Aug 2020 17:19:29

US3452203

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '61.0' in	(b) (4) Kim Calloway (b) (4)	20 Aug 2020 17:19:29
DataPoint set to visible.	(b) (4) System	04 Aug 2020 19:32:13

US3452203

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '199.6' lb	(b) (4) Kim Calloway (b) (4)	20 Aug 2020 17:19:29
DataPoint set to visible.	(b) (4) System	04 Aug 2020 19:32:13

US3452203

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
Amendment Manager: User entered '37.79295'	System	16 Sep 2020 23:42:58
User entered '37.8'	System	20 Aug 2020 17:19:29
DataPoint set to visible.	System	04 Aug 2020 19:32:13

US3452203

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered 'kg/m2'	System	20 Aug 2020 17:19:29
DataPoint set to visible.	System	04 Aug 2020 19:32:13

US3452203

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User closed query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visits performed on the same day then TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP data will be recorded on Predose Vital Sign form of Visit 1 Day 1 visit and will be updated as ND on this form. Please verify and amend the data as appropriate or clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 06:44:50
Query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visits performed on the same day then TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP data will be recorded on Predose Vital Sign form of Visit 1 Day 1 visit and will be updated as ND on this form. Please verify and amend the data as appropriate or clarify.' answered with 'Updated' (Site from DM).	Chalimar Rojo (b) (4) (b) (4)	01 Oct 2020 18:44:44
User entered missing code ND - Not Done; reason for change Data Entry Error	Chalimar Rojo (b) (4) (b) (4)	01 Oct 2020 18:44:40
User opened query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visits performed on the same day then TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP data will be recorded on Predose Vital Sign form of Visit 1 Day 1 visit and will be updated as ND on this form. Please verify and amend the data as appropriate or clarify.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 08:07:23
User entered '97.7' F	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:19:29

US3452203

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered empty; reason for change Data Entry Error	Chalimar Rojo (b) (4) (b) (4)	01 Oct 2020 18:44:40
User entered 'Oral (Oral)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:19:29

US3452203

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:19:29

US3452203

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered missing code ND - Not Done; reason for change Data Entry Error	Chalimar Rojo (b) (4) (b) (4)	01 Oct 2020 18:44:40
User entered '57'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:19:29

US3452203

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered 'bpm'	System	20 Aug 2020 17:19:29

US3452203

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered missing code ND - Not Done; reason for change Data Entry Error	Chalimar Rojo (b) (4) (b) (4)	01 Oct 2020 18:44:40
User entered '20'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:19:29

US3452203

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered 'breaths/min'	System	20 Aug 2020 17:19:29

US3452203

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	01 Oct 2020 18:44:40
User entered '133'	Chalimar Rojo (b) (4)	20 Aug 2020 17:19:29
	(b) (4)	

US3452203

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered 'mmHg'	System	20 Aug 2020 17:19:29

US3452203

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered missing code ND - Not Done; reason for change Data Entry Error	Chalimar Rojo (b) (4) (b) (4)	01 Oct 2020 18:44:40
User entered '65'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:19:29

US3452203

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered 'mmHg'	System	20 Aug 2020 17:19:29

US3452203

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56

US3452203

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56

US3452203

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:44:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 19:32:45
	(b) (4)	

US3452203

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:44:45

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	06 Sep 2020 11:45:20
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		03 Sep 2020 18:25:19
User entered '04 Aug 2020'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 19:32:45

US3452203

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:44:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '04 Aug 2020'	(b) (4) Kim Calloway (b) (4) (b) (4)	04 Aug 2020 22:00:11

US3452203

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:44:45

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 22:00:11

US3452203

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:44:45

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered 'Surgically sterile (SURGICALLY STERILE)'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 22:00:11

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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:44:45

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered empty.	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 22:00:11
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:44:45

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'UN UNK 1985'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 22:00:11
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:44:45

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 22:00:11

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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:44:45

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered empty.	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 22:00:11
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:44:45

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 22:00:11

US3452203

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:44:45

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'No (N)'	(b) (4) Kim Calloway (b) (4) (b) (4)	04 Aug 2020 22:00:37

US3452203

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:44:45

[Emergency Response](#) (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'No (N)'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 22:00:37
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:44:45

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 22:00:37

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:44:45

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 22:00:37

US3452203

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:44:45

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'No (N)'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 22:00:37
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 22:00:37

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:44:45

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 22:00:37

US3452203

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:44:45

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 22:00:37

US3452203

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:44:45

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'No (N)'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 22:00:37
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:44:45

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 22:00:37

US3452203

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:44:45

[Educators and Students](#) (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 22:00:37

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:44:45

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'No (N)'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 22:00:37
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:44:45

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered empty.	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 22:00:37

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:44:45

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '1'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 22:00:37
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:44:45

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '0'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 22:00:37
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:44:45

[Resides in Multi-family dwelling](#) (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 22:00:37

US3452203

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:44:45

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '0'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 22:00:37
	(b) (4)	

US3452203

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:44:45

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 22:00:37

US3452203

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:44:45

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '0'	(b) (4) Kim Calloway (b) (4) (b) (4)	04 Aug 2020 22:00:37

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:44:45

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered '0'	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 22:00:37

US3452203

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:44:45

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User entered empty.	Kim Calloway (b) (4) (b) (4)	04 Aug 2020 22:00:37

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:44:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 19:33:10

US3452203

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:44:45

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '04 Aug 2020'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 19:33:10
	(b) (4)	

US3452203

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:44:45

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Clinic (Clinic)'	Kim Calloway (b) (4)	04 Aug 2020 19:33:10

US3452203

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:44:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered 'VISIT1'	System	04 Aug 2020 19:33:10

US3452203

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:44:45

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '04 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 19:24:43

US3452203

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:44:45

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 02:03:57
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:03:57
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Aug 2020 19:24:43
User entered '184703' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 19:24:43

US3452203

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:44:45

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 19:24:43

US3452203

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:44:45

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)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'No (N)'	Kim Calloway (b) (4)	04 Aug 2020 22:00:50

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:44:45

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)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'No (N)'	Kim Calloway (b) (4)	04 Aug 2020 22:00:50

US3452203

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:44:45

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'No (N)'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 22:00:50

US3452203

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:44:45

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'No (N)'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 22:00:50

US3452203

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:44:45

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'No (N)'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 22:00:50

US3452203

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:44:45

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User closed query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visit performed on the same day then HEIGHT and WEIGHT will be recorded as ND on this form. Please verify and amend the data as appropriate or clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 07:14:59
Query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visit performed on the same day then HEIGHT and WEIGHT will be recorded as ND on this form. Please verify and amend the data as appropriate or clarify.' answered with 'Updated' (Site from DM).	Chalimar Rojo (b) (4) (b) (4)	01 Oct 2020 18:47:50
User entered missing code ND - Not Done; reason for change Data Entry Error	Chalimar Rojo (b) (4) (b) (4)	01 Oct 2020 18:45:50
User opened query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visit performed on the same day then HEIGHT and WEIGHT will be recorded as ND on this form. Please verify and amend the data as appropriate or clarify.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 08:06:51
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:21:12

US3452203

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:44:45

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	01 Oct 2020 18:45:50
User entered empty.	Chalimar Rojo (b) (4)	20 Aug 2020 17:21:12
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:44:45

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User closed query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visit performed on the same day then HEIGHT and WEIGHT will be recorded as ND on this form. Please verify and amend the data as appropriate or clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 07:14:59
Query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visit performed on the same day then HEIGHT and WEIGHT will be recorded as ND on this form. Please verify and amend the data as appropriate or clarify.' answered with 'Updated' (Site from DM).	Chalimar Rojo (b) (4) (b) (4)	01 Oct 2020 18:47:50
User entered missing code ND - Not Done; reason for change Data Entry Error	Chalimar Rojo (b) (4) (b) (4)	01 Oct 2020 18:45:50
User opened query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visit performed on the same day then HEIGHT and WEIGHT will be recorded as ND on this form. Please verify and amend the data as appropriate or clarify.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 08:06:51
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:21:12

US3452203

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:44:45

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	01 Oct 2020 18:45:50
User entered empty.	Chalimar Rojo (b) (4)	20 Aug 2020 17:21:12
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User accepted default value 'Pre-Dose (PREDOSE)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:21:12

US3452203

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Chalimar Rojo (b) (4)	01 Oct 2020 18:45:50
User entered 'No (N)'	(b) (4) Kim Calloway (b) (4)	20 Aug 2020 17:21:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '04 Aug 2020' reason for change: Data Entry Error	(b) (4)	01 Oct 2020 18:45:50
User entered empty.	Chalimar Rojo (b) (4)	20 Aug 2020 17:21:12
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '14:35' reason for change: Data Entry Error	(b) (4)	01 Oct 2020 18:45:50
User entered empty.	Chalimar Rojo (b) (4)	20 Aug 2020 17:21:12
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered '04 Aug 2020 14:35'	System	01 Oct 2020 18:45:50
User entered empty.	System	20 Aug 2020 17:21:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '97.7' F reason for change: Data Entry Error	(b) (4) Chalimar Rojo (b) (4)	01 Oct 2020 18:45:50
User entered empty.	(b) (4) Kim Calloway (b) (4)	20 Aug 2020 17:21:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	01 Oct 2020 18:45:50
User entered empty.	Chalimar Rojo (b) (4)	01 Oct 2020 18:45:50
	(b) (4)	
	Kim Calloway (b) (4)	20 Aug 2020 17:21:12
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered empty.	(b) (4) Kim Calloway (b) (4)	20 Aug 2020 17:21:12

US3452203

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '57' reason for change: Data Entry Error	(b) (4)	
	Chalimar Rojo (b) (4)	01 Oct 2020 18:45:50
User entered empty.	(b) (4)	
	Kim Calloway (b) (4)	20 Aug 2020 17:21:12
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered 'bpm'	System	01 Oct 2020 18:45:50
User entered empty.	System	20 Aug 2020 17:21:12

US3452203

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '20' reason for change: Data Entry Error	(b) (4)	
	Chalimar Rojo (b) (4)	01 Oct 2020 18:45:50
User entered empty.	(b) (4)	
	Kim Calloway (b) (4)	20 Aug 2020 17:21:12
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered 'breaths/min'	System	01 Oct 2020 18:45:50
User entered empty.	System	20 Aug 2020 17:21:12

US3452203

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '133' reason for change: Data Entry Error	(b) (4) Chalimar Rojo (b) (4)	01 Oct 2020 18:45:50
User entered empty.	(b) (4) Kim Calloway (b) (4)	20 Aug 2020 17:21:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered 'mmHg'	System	01 Oct 2020 18:45:50
User entered empty.	System	20 Aug 2020 17:21:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '65' reason for change: Data Entry Error	(b) (4)	
	Chalimar Rojo (b) (4)	01 Oct 2020 18:45:50
User entered empty.	(b) (4)	
	Kim Calloway (b) (4)	20 Aug 2020 17:21:12
	(b) (4)	

US3452203

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered 'mmHg'	System	01 Oct 2020 18:45:50
User entered empty.	System	20 Aug 2020 17:21:12

US3452203

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:44:45

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User closed query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visit performed on the same day then HEIGHT and WEIGHT will be recorded as ND on this form. Please verify and amend the data as appropriate or clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 07:14:59
Query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visit performed on the same day then HEIGHT and WEIGHT will be recorded as ND on this form. Please verify and amend the data as appropriate or clarify.' answered with 'Updated' (Site from DM).	Chalimar Rojo (b) (4) (b) (4)	01 Oct 2020 18:47:50
User entered missing code ND - Not Done; reason for change Data Entry Error	Chalimar Rojo (b) (4) (b) (4)	01 Oct 2020 18:45:50
User opened query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visit performed on the same day then HEIGHT and WEIGHT will be recorded as ND on this form. Please verify and amend the data as appropriate or clarify.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 08:06:51
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:21:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:44:45

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	01 Oct 2020 18:45:50
User entered empty.	Chalimar Rojo (b) (4)	20 Aug 2020 17:21:12
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User accepted default value 'Post-Dose (POSTDOSE)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:26:15

US3452203

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	20 Aug 2020 17:26:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '04 Aug 2020'	(b) (4) Kim Calloway (b) (4)	20 Aug 2020 17:26:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:05:14
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'CORRECT' (Site from System).	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:26:23
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	System	20 Aug 2020 17:26:15
User entered '15:39'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:26:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered '04 Aug 2020 15:39'	System	20 Aug 2020 17:26:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '97.9' F	(b) (4) Kim Calloway (b) (4)	20 Aug 2020 17:26:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Oral (Oral)'	(b) (4) Kim Calloway (b) (4)	20 Aug 2020 17:26:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered empty.	(b) (4) Kim Calloway (b) (4)	20 Aug 2020 17:26:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '56'	(b) (4) Kim Calloway (b) (4)	20 Aug 2020 17:26:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered 'bpm'	System	20 Aug 2020 17:26:15

US3452203

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '14'	(b) (4) Kim Calloway (b) (4)	20 Aug 2020 17:26:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered 'breaths/min'	System	20 Aug 2020 17:26:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '136'	(b) (4) Kim Calloway (b) (4)	20 Aug 2020 17:26:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered 'mmHg'	System	20 Aug 2020 17:26:15

US3452203

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '82'	(b) (4) Kim Calloway (b) (4)	20 Aug 2020 17:26:15

US3452203

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered 'mmHg'	System	20 Aug 2020 17:26:15

US3452203

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:44:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 19:33:24

US3452203

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:44:45

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '04 Aug 2020'	(b) (4) Kim Calloway (b) (4) (b) (4)	04 Aug 2020 19:33:24

US3452203

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:44:45

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 20:04:25

US3452203

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:44:45

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered empty.	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 20:04:25

US3452203

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:44:45

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)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered empty.	Kim Calloway (b) (4)	04 Aug 2020 20:04:25

US3452203

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:44:45

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered 'MRNA-1273 OR PLACEBO'	System	04 Aug 2020 20:04:25

US3452203

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:44:45

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '04 Aug 2020'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 20:04:25

US3452203

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:44:45

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '14:55'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 20:04:25

US3452203

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:44:45

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered '04 Aug 2020 14:55'	System	04 Aug 2020 20:04:25

US3452203

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:44:45

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Right Arm (RIGHT ARM)' reason for change: Data Entry Error	(b) (4)	03 Sep 2020 19:08:54
User entered 'Left Arm (LEFT ARM)'	Kim Calloway (b) (4)	04 Aug 2020 20:04:25
	(b) (4)	

US3452203

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:44:45

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered 'ONCE'	System	04 Aug 2020 20:04:25

US3452203

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:44:45

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered 'INTRAMUSCULAR'	System	04 Aug 2020 20:04:25

US3452203

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:44:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	20 Aug 2020 17:28:12

US3452203

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:44:45

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '04 Aug 2020'	(b) (4) Kim Calloway (b) (4)	20 Aug 2020 17:28:12
	(b) (4)	

US3452203

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:44:45

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '14:39'	(b) (4) Kim Calloway (b) (4)	20 Aug 2020 17:28:12

US3452203

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:44:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered '04 Aug 2020 14:39'	System	20 Aug 2020 17:28:12

US3452203

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:44:45

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '04 Aug 2020'	(b) (4) Kim Calloway (b) (4)	20 Aug 2020 17:28:34
	(b) (4)	

US3452203

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:44:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:28:34

US3452203

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:44:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	20 Aug 2020 17:28:34

US3452203

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:44:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '14:37'	(b) (4) Kim Calloway (b) (4)	20 Aug 2020 17:28:34

US3452203

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:44:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered '04 Aug 2020 14:37'	System	20 Aug 2020 17:28:34

US3452203

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:44:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:28:43

US3452203

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:44:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	20 Aug 2020 17:28:43

US3452203

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:44:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '14:37'	(b) (4) Kim Calloway (b) (4)	20 Aug 2020 17:28:43
	(b) (4)	

US3452203

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:44:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered '04 Aug 2020 14:37'	System	20 Aug 2020 17:28:43

US3452203

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:44:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	04 Aug 2020 19:33:32
	(b) (4)	

US3452203

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:44:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered '1'	System	04 Aug 2020 19:33:32

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	04 Aug 2020 20:04:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-04T15:34:03', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'ac9e38b2-5caf-4799-b330-d8fcb88ea005' User entered 'Yes (Y)'	System	04 Aug 2020 20:35:09
	System	04 Aug 2020 20:35:09

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-04T15:34:16', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'ac9e38b2-5caf-4799-b330-d8fcb88ea005' User entered '97.9'	System	04 Aug 2020 20:35:09
	System	04 Aug 2020 20:35:09

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-04T15:34:33', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'ac9e38b2-5caf-4799-b330-d8fcb88ea005'	System	04 Aug 2020 20:35:09
User entered 'Yes (Y)'	System	04 Aug 2020 20:35:09

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'SUBJECT WAS CONTACTED' (Site from System).	(b) (4), (b) (6)	27 Aug 2020 11:05:41
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Kim Calloway (b) (4) (b) (4)	26 Aug 2020 17:14:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-04T15:34:51', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'ac9e38b2-5caf-4799-b330-d8fcb88ea005'	System	04 Aug 2020 20:35:09
User entered '1'	System	04 Aug 2020 20:35:09

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-04T15:34:51', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'ac9e38b2-5caf-4799-b330-d8fcb88ea005' User entered '0'	System	04 Aug 2020 20:35:09
	System	04 Aug 2020 20:35:09

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-04T15:35:05', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'ac9e38b2-5caf-4799-b330-d8fcb88ea005' User entered '04 Aug 2020 15:35'	System	04 Aug 2020 20:35:09
	System	04 Aug 2020 20:35:09

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '04 Aug 2020 15:15'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '04 Aug 2020 17:45'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	04 Aug 2020 20:04:25
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-04T21:19:30', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '6ed40b47-a731-4ad9-8ac0-f409b413e851' User entered 'Yes (Y)'	System	05 Aug 2020 02:20:19
	System	05 Aug 2020 02:20:19

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-04T21:19:49', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '6ed40b47-a731-4ad9-8ac0-f409b413e851' User entered '97.9'	System	05 Aug 2020 02:20:19
	System	05 Aug 2020 02:20:19

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-04T21:19:57', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '6ed40b47-a731-4ad9-8ac0-f409b413e851' User entered 'No (N)'	System	05 Aug 2020 02:20:19
	System	05 Aug 2020 02:20:19

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-04T21:20:16', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '6ed40b47-a731-4ad9-8ac0-f409b413e851' User entered '04 Aug 2020 21:20'	System	05 Aug 2020 02:20:19
	System	05 Aug 2020 02:20:19

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '04 Aug 2020 18:40'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	04 Aug 2020 20:04:25
User entered 'Day 2'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:44:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-05T17:42:38', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'f312a08b-4ac4-48d6-a244-a42c490631f7' User entered 'Yes (Y)'	System	05 Aug 2020 22:43:03
	System	05 Aug 2020 22:43:03

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:44:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-05T17:42:47', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'f312a08b-4ac4-48d6-a244-a42c490631f7' User entered '97.4'	System	05 Aug 2020 22:43:03
	System	05 Aug 2020 22:43:03

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:44:45

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-05T17:42:52', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'f312a08b-4ac4-48d6-a244-a42c490631f7'	System	05 Aug 2020 22:43:03
User entered 'No (N)'	System	05 Aug 2020 22:43:03

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-05T17:43:01', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'f312a08b-4ac4-48d6-a244-a42c490631f7' User entered '05 Aug 2020 17:43'	System	05 Aug 2020 22:43:03
	System	05 Aug 2020 22:43:03

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	04 Aug 2020 20:04:25
User entered 'Day 3'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:44:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-06T15:59:26', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'd09acce6-6437-44e0-9b20-7084e5b15459' User entered 'Yes (Y)'	System	06 Aug 2020 20:59:49
	System	06 Aug 2020 20:59:49

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:44:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-06T15:59:34', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'd09acce6-6437-44e0-9b20-7084e5b15459' User entered '98.1'	System	06 Aug 2020 20:59:49
	System	06 Aug 2020 20:59:49

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:44:45

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-06T15:59:40', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'd09acce6-6437-44e0-9b20-7084e5b15459' User entered 'No (N)'	System	06 Aug 2020 20:59:49
	System	06 Aug 2020 20:59:49

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-06T15:59:46', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'd09acce6-6437-44e0-9b20-7084e5b15459' User entered '06 Aug 2020 15:59'	System	06 Aug 2020 20:59:49
	System	06 Aug 2020 20:59:49

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	04 Aug 2020 20:04:25
User entered 'Day 4'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:44:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-07T14:22:15', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '5e7c5b9d-a328-4715-bc6a-c084f58d495b' User entered 'Yes (Y)'	System	07 Aug 2020 19:22:39
	System	07 Aug 2020 19:22:39

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:44:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-07T14:22:24', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '5e7c5b9d-a328-4715-bc6a-c084f58d495b' User entered '97.5'	System	07 Aug 2020 19:22:39
	System	07 Aug 2020 19:22:39

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:44:45

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-07T14:22:30', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '5e7c5b9d-a328-4715-bc6a-c084f58d495b' User entered 'No (N)'	System	07 Aug 2020 19:22:39
	System	07 Aug 2020 19:22:39

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-07T14:22:37', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '5e7c5b9d-a328-4715-bc6a-c084f58d495b' User entered '07 Aug 2020 14:22'	System	07 Aug 2020 19:22:39
	System	07 Aug 2020 19:22:39

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	04 Aug 2020 20:04:25
User entered 'Day 5'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:44:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-08T18:47:24', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'ec407cef-206b-4025-a700-b8358448f049' User entered 'Yes (Y)'	System	08 Aug 2020 23:47:51
	System	08 Aug 2020 23:47:51

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:44:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-08T18:47:35', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'ec407cef-206b-4025-a700-b8358448f049' User entered '97.8'	System	08 Aug 2020 23:47:51
	System	08 Aug 2020 23:47:51

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:44:45

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-08T18:47:39', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'ec407cef-206b-4025-a700-b8358448f049'	System	08 Aug 2020 23:47:51
User entered 'No (N)'	System	08 Aug 2020 23:47:51

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-08T18:47:47', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'ec407cef-206b-4025-a700-b8358448f049' User entered '08 Aug 2020 18:47'	System	08 Aug 2020 23:47:51
	System	08 Aug 2020 23:47:51

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	04 Aug 2020 20:04:25
User entered 'Day 6'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:44:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-09T12:00:45', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '87c5b294-715d-4627-a0fd-c1b14ebd6732' User entered 'Yes (Y)'	System	09 Aug 2020 17:01:10
	System	09 Aug 2020 17:01:10

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:44:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-09T12:00:57', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '87c5b294-715d-4627-a0fd-c1b14ebd6732' User entered '97.6'	System	09 Aug 2020 17:01:10
	System	09 Aug 2020 17:01:10

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:44:45

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-09T12:01:02', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '87c5b294-715d-4627-a0fd-c1b14ebd6732'	System	09 Aug 2020 17:01:10
User entered 'No (N)'	System	09 Aug 2020 17:01:10

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-09T12:01:07', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '87c5b294-715d-4627-a0fd-c1b14ebd6732' User entered '09 Aug 2020 12:01'	System	09 Aug 2020 17:01:10
	System	09 Aug 2020 17:01:10

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	04 Aug 2020 20:04:25
User entered 'Day 7'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:44:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-10T12:00:54', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '6d83e444-a1d3-4140-9f6e-c26a631003cd' User entered 'Yes (Y)'	System	10 Aug 2020 17:01:13
	System	10 Aug 2020 17:01:13

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:44:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-10T12:01:02', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '6d83e444-a1d3-4140-9f6e-c26a631003cd' User entered '97.3'	System	10 Aug 2020 17:01:13
	System	10 Aug 2020 17:01:13

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:44:45

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-10T12:01:06', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '6d83e444-a1d3-4140-9f6e-c26a631003cd' User entered 'No (N)'	System	10 Aug 2020 17:01:13
	System	10 Aug 2020 17:01:13

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-10T12:01:10', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '6d83e444-a1d3-4140-9f6e-c26a631003cd' User entered '10 Aug 2020 12:01'	System	10 Aug 2020 17:01:13
	System	10 Aug 2020 17:01:13

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	04 Aug 2020 20:04:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-04T15:35:15', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'dc3a73a9-9fb6-4d0c-b754-b9a48200eda6'	System	04 Aug 2020 20:35:59
User entered 'None (1)'	System	04 Aug 2020 20:35:59

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-04T15:35:28', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'dc3a73a9-9fb6-4d0c-b754-b9a48200eda6'	System	04 Aug 2020 20:35:59
User entered 'No (N)'	System	04 Aug 2020 20:35:59

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-04T15:35:39', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'dc3a73a9-9fb6-4d0c-b754-b9a48200eda6' User entered 'No (N)'	System	04 Aug 2020 20:35:59
	System	04 Aug 2020 20:35:59

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-04T15:35:50', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'dc3a73a9-9fb6-4d0c-b754-b9a48200eda6'	System	04 Aug 2020 20:35:59
User entered 'None (1)'	System	04 Aug 2020 20:35:59

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-04T15:35:57', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'dc3a73a9-9fb6-4d0c-b754-b9a48200eda6' User entered '04 Aug 2020 15:35'	System	04 Aug 2020 20:35:59
	System	04 Aug 2020 20:35:59

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '04 Aug 2020 15:15'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '04 Aug 2020 17:45'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	04 Aug 2020 20:04:25
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '04 Aug 2020 18:40'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	04 Aug 2020 20:04:25
User entered 'Day 2'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-06T11:35:09', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'c25c7dd7-5b45-4890-ac34-68615aef18a3'	System	06 Aug 2020 16:35:33
User entered 'None (1)'	System	06 Aug 2020 16:35:33

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:44:45

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-06T11:35:13', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'c25c7dd7-5b45-4890-ac34-68615aef18a3'	System	06 Aug 2020 16:35:33
User entered 'No (N)'	System	06 Aug 2020 16:35:33

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:44:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-06T11:35:16', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'c25c7dd7-5b45-4890-ac34-68615aef18a3' User entered 'No (N)'	System	06 Aug 2020 16:35:33
	System	06 Aug 2020 16:35:33

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-06T11:35:25', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'c25c7dd7-5b45-4890-ac34-68615aef18a3'	System	06 Aug 2020 16:35:33
User entered 'None (1)'	System	06 Aug 2020 16:35:33

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-06T11:35:30', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'c25c7dd7-5b45-4890-ac34-68615aef18a3' User entered '06 Aug 2020 11:35'	System	06 Aug 2020 16:35:33
	System	06 Aug 2020 16:35:33

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	04 Aug 2020 20:04:25
User entered 'Day 3'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-06T15:59:53', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '15fb7524-d7d3-4413-b066-21c0ba1b7909'	System	06 Aug 2020 21:00:19
User entered 'None (1)'	System	06 Aug 2020 21:00:19

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:44:45

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-06T15:59:56', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '15fb7524-d7d3-4413-b066-21c0ba1b7909'	System	06 Aug 2020 21:00:19
User entered 'No (N)'	System	06 Aug 2020 21:00:19

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:44:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-06T15:59:59', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '15fb7524-d7d3-4413-b066-21c0ba1b7909'	System	06 Aug 2020 21:00:19
User entered 'No (N)'	System	06 Aug 2020 21:00:19

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-06T16:00:05', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '15fb7524-d7d3-4413-b066-21c0ba1b7909'	System	06 Aug 2020 21:00:19
User entered 'None (1)'	System	06 Aug 2020 21:00:19

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-06T16:00:13', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '15fb7524-d7d3-4413-b066-21c0ba1b7909' User entered '06 Aug 2020 16:00'	System	06 Aug 2020 21:00:19
	System	06 Aug 2020 21:00:19

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	04 Aug 2020 20:04:25
User entered 'Day 4'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-07T14:21:54', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '3643d81d-285b-41ae-a74b-36c0187533ae' User entered 'None (1)'	System	07 Aug 2020 19:23:22
	System	07 Aug 2020 19:23:22

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:44:45

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-07T14:23:02', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '3643d81d-285b-41ae-a74b-36c0187533ae' User entered 'No (N)'	System	07 Aug 2020 19:23:22
	System	07 Aug 2020 19:23:22

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:44:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-07T14:23:06', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '3643d81d-285b-41ae-a74b-36c0187533ae' User entered 'No (N)'	System	07 Aug 2020 19:23:22
	System	07 Aug 2020 19:23:22

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-07T14:23:11', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '3643d81d-285b-41ae-a74b-36c0187533ae' User entered 'None (1)'	System	07 Aug 2020 19:23:22
	System	07 Aug 2020 19:23:22

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-07T14:23:18', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '3643d81d-285b-41ae-a74b-36c0187533ae' User entered '07 Aug 2020 14:23'	System	07 Aug 2020 19:23:22
	System	07 Aug 2020 19:23:22

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	04 Aug 2020 20:04:25
User entered 'Day 5'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-08T18:47:52', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'b0aa32f7-29a0-4e7c-92d3-2c223d6354d8'	System	08 Aug 2020 23:48:14
User entered 'None (1)'	System	08 Aug 2020 23:48:14

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:44:45

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-08T18:47:56', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'b0aa32f7-29a0-4e7c-92d3-2c223d6354d8' User entered 'No (N)'	System	08 Aug 2020 23:48:14
	System	08 Aug 2020 23:48:14

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:44:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-08T18:48:00', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'b0aa32f7-29a0-4e7c-92d3-2c223d6354d8' User entered 'No (N)'	System	08 Aug 2020 23:48:14
	System	08 Aug 2020 23:48:14

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-08T18:48:04', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'b0aa32f7-29a0-4e7c-92d3-2c223d6354d8'	System	08 Aug 2020 23:48:14
User entered 'None (1)'	System	08 Aug 2020 23:48:14

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-08T18:48:09', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'b0aa32f7-29a0-4e7c-92d3-2c223d6354d8' User entered '08 Aug 2020 18:48'	System	08 Aug 2020 23:48:14
	System	08 Aug 2020 23:48:14

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	04 Aug 2020 20:04:25
User entered 'Day 6'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-09T12:01:11', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'e706a1ac-a944-4b86-a637-8ebb8f9e447d'	System	09 Aug 2020 17:01:26
User entered 'None (1)'	System	09 Aug 2020 17:01:26

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:44:45

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-09T12:01:14', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'e706a1ac-a944-4b86-a637-8ebb8f9e447d' User entered 'No (N)'	System	09 Aug 2020 17:01:26
	System	09 Aug 2020 17:01:26

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:44:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-09T12:01:17', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'e706a1ac-a944-4b86-a637-8ebb8f9e447d' User entered 'No (N)'	System	09 Aug 2020 17:01:26
	System	09 Aug 2020 17:01:26

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-09T12:01:20', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'e706a1ac-a944-4b86-a637-8ebb8f9e447d'	System	09 Aug 2020 17:01:26
User entered 'None (1)'	System	09 Aug 2020 17:01:26

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-09T12:01:24', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'e706a1ac-a944-4b86-a637-8ebb8f9e447d' User entered '09 Aug 2020 12:01'	System	09 Aug 2020 17:01:26
	System	09 Aug 2020 17:01:26

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	04 Aug 2020 20:04:25
User entered 'Day 7'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-10T12:01:14', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'b2b2f284-efc8-42f4-8980-f823310e9ed5'	System	10 Aug 2020 17:01:31
User entered 'None (1)'	System	10 Aug 2020 17:01:31

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:44:45

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-10T12:01:17', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'b2b2f284-efc8-42f4-8980-f823310e9ed5'	System	10 Aug 2020 17:01:31
User entered 'No (N)'	System	10 Aug 2020 17:01:31

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:44:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-10T12:01:19', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'b2b2f284-efc8-42f4-8980-f823310e9ed5' User entered 'No (N)'	System	10 Aug 2020 17:01:31
	System	10 Aug 2020 17:01:31

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-10T12:01:22', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'b2b2f284-efc8-42f4-8980-f823310e9ed5'	System	10 Aug 2020 17:01:31
User entered 'None (1)'	System	10 Aug 2020 17:01:31

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-10T12:01:27', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'b2b2f284-efc8-42f4-8980-f823310e9ed5' User entered '10 Aug 2020 12:01'	System	10 Aug 2020 17:01:31
	System	10 Aug 2020 17:01:31

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	04 Aug 2020 20:04:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-04T15:36:09', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '445b4da5-2b4a-4435-9be5-bbd913aabf15' User entered 'None (0)'	System	04 Aug 2020 20:36:40
	System	04 Aug 2020 20:36:40

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-04T15:36:13', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '445b4da5-2b4a-4435-9be5-bbd913aabf15' User entered 'None (0)'	System	04 Aug 2020 20:36:40
	System	04 Aug 2020 20:36:40

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-04T15:36:17', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '445b4da5-2b4a-4435-9be5-bbd913aabf15' User entered 'None (0)'	System	04 Aug 2020 20:36:40
	System	04 Aug 2020 20:36:40

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-04T15:36:21', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '445b4da5-2b4a-4435-9be5-bbd913aabf15' User entered 'None (0)'	System	04 Aug 2020 20:36:40
	System	04 Aug 2020 20:36:40

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-04T15:36:24', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '445b4da5-2b4a-4435-9be5-bbd913aabf15' User entered 'None (0)'	System	04 Aug 2020 20:36:40
	System	04 Aug 2020 20:36:40

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-04T15:36:26', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '445b4da5-2b4a-4435-9be5-bbd913aabf15' User entered 'None (0)'	System	04 Aug 2020 20:36:40
	System	04 Aug 2020 20:36:40

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-04T15:36:32', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '445b4da5-2b4a-4435-9be5-bbd913aabf15' User entered 'No (N)'	System	04 Aug 2020 20:36:40
	System	04 Aug 2020 20:36:40

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-04T15:36:38', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '445b4da5-2b4a-4435-9be5-bbd913aabf15' User entered '04 Aug 2020 15:36'	System	04 Aug 2020 20:36:40
	System	04 Aug 2020 20:36:40

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '04 Aug 2020 15:15'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '04 Aug 2020 17:45'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	04 Aug 2020 20:04:25
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '04 Aug 2020 18:40'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	04 Aug 2020 20:04:25
User entered 'Day 2'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:44:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-06T11:35:51', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'dd117c43-73cd-45ad-8a74-e9ce1d9ee665' User entered 'None (0)'	System	06 Aug 2020 16:36:19
	System	06 Aug 2020 16:36:19

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:44:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-06T11:35:54', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'dd117c43-73cd-45ad-8a74-e9ce1d9ee665' User entered 'None (0)'	System	06 Aug 2020 16:36:19
	System	06 Aug 2020 16:36:19

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:44:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-06T11:35:57', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'dd117c43-73cd-45ad-8a74-e9ce1d9ee665' User entered 'None (0)'	System	06 Aug 2020 16:36:19
	System	06 Aug 2020 16:36:19

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:44:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-06T11:36:00', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'dd117c43-73cd-45ad-8a74-e9ce1d9ee665' User entered 'None (0)'	System	06 Aug 2020 16:36:19
	System	06 Aug 2020 16:36:19

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:44:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-06T11:36:02', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'dd117c43-73cd-45ad-8a74-e9ce1d9ee665' User entered 'None (0)'	System	06 Aug 2020 16:36:19
	System	06 Aug 2020 16:36:19

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:44:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-06T11:36:04', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'dd117c43-73cd-45ad-8a74-e9ce1d9ee665' User entered 'None (0)'	System	06 Aug 2020 16:36:19
	System	06 Aug 2020 16:36:19

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-06T11:36:11', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'dd117c43-73cd-45ad-8a74-e9ce1d9ee665' User entered 'No (N)'	System	06 Aug 2020 16:36:19
	System	06 Aug 2020 16:36:19

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:44:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-06T11:36:17', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'dd117c43-73cd-45ad-8a74-e9ce1d9ee665' User entered '06 Aug 2020 11:36'	System	06 Aug 2020 16:36:19
	System	06 Aug 2020 16:36:19

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	04 Aug 2020 20:04:25
User entered 'Day 3'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:44:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-06T16:00:20', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'b689351a-e814-407d-ab14-988eadd9f9e8' User entered 'None (0)'	System	06 Aug 2020 21:00:48
	System	06 Aug 2020 21:00:48

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:44:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-06T16:00:25', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'b689351a-e814-407d-ab14-988eadd9f9e8' User entered 'None (0)'	System	06 Aug 2020 21:00:48
	System	06 Aug 2020 21:00:48

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:44:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-06T16:00:28', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'b689351a-e814-407d-ab14-988eadd9f9e8' User entered 'None (0)'	System	06 Aug 2020 21:00:48
	System	06 Aug 2020 21:00:48

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:44:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-06T16:00:31', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'b689351a-e814-407d-ab14-988eadd9f9e8' User entered 'None (0)'	System	06 Aug 2020 21:00:48
	System	06 Aug 2020 21:00:48

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:44:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-06T16:00:33', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'b689351a-e814-407d-ab14-988eadd9f9e8' User entered 'None (0)'	System	06 Aug 2020 21:00:48
	System	06 Aug 2020 21:00:48

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:44:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-06T16:00:35', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'b689351a-e814-407d-ab14-988eadd9f9e8' User entered 'None (0)'	System	06 Aug 2020 21:00:48
	System	06 Aug 2020 21:00:48

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-06T16:00:41', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'b689351a-e814-407d-ab14-988eadd9f9e8' User entered 'No (N)'	System	06 Aug 2020 21:00:48
	System	06 Aug 2020 21:00:48

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:44:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-06T16:00:45', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'b689351a-e814-407d-ab14-988eadd9f9e8' User entered '06 Aug 2020 16:00'	System	06 Aug 2020 21:00:48
	System	06 Aug 2020 21:00:48

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	04 Aug 2020 20:04:25
User entered 'Day 4'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:44:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-07T14:23:28', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'c0435729-7df4-453d-9f81-366e31afcc97'	System	07 Aug 2020 19:23:59
User entered 'None (0)'	System	07 Aug 2020 19:23:59

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:44:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-07T14:23:30', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'c0435729-7df4-453d-9f81-366e31afcc97' User entered 'None (0)'	System	07 Aug 2020 19:23:59
	System	07 Aug 2020 19:23:59

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:44:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-07T14:23:33', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'c0435729-7df4-453d-9f81-366e31afcc97'	System	07 Aug 2020 19:23:59
User entered 'None (0)'	System	07 Aug 2020 19:23:59

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:44:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-07T14:23:35', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'c0435729-7df4-453d-9f81-366e31afcc97' User entered 'None (0)'	System	07 Aug 2020 19:23:59
	System	07 Aug 2020 19:23:59

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:44:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-07T14:23:38', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'c0435729-7df4-453d-9f81-366e31afcc97'	System	07 Aug 2020 19:23:59
User entered 'None (0)'	System	07 Aug 2020 19:23:59

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:44:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-07T14:23:40', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'c0435729-7df4-453d-9f81-366e31afcc97'	System	07 Aug 2020 19:23:59
User entered 'None (0)'	System	07 Aug 2020 19:23:59

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-07T14:23:46', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'c0435729-7df4-453d-9f81-366e31afcc97'	System	07 Aug 2020 19:23:59
User entered 'No (N)'	System	07 Aug 2020 19:23:59

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:44:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-07T14:23:57', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'c0435729-7df4-453d-9f81-366e31afcc97' User entered '07 Aug 2020 14:23'	System	07 Aug 2020 19:23:59
	System	07 Aug 2020 19:23:59

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	04 Aug 2020 20:04:25
User entered 'Day 5'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:44:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-08T18:48:15', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'ae9604b6-b32b-4697-a071-ecf0f953a3ba' User entered 'None (0)'	System	08 Aug 2020 23:48:43
	System	08 Aug 2020 23:48:43

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:44:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-08T18:48:17', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'ae9604b6-b32b-4697-a071-ecf0f953a3ba' User entered 'None (0)'	System	08 Aug 2020 23:48:43
	System	08 Aug 2020 23:48:43

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:44:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-08T18:48:21', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'ae9604b6-b32b-4697-a071-ecf0f953a3ba' User entered 'None (0)'	System	08 Aug 2020 23:48:43
	System	08 Aug 2020 23:48:43

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:44:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-08T18:48:25', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'ae9604b6-b32b-4697-a071-ecf0f953a3ba' User entered 'None (0)'	System	08 Aug 2020 23:48:43
	System	08 Aug 2020 23:48:43

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:44:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-08T18:48:27', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'ae9604b6-b32b-4697-a071-ecf0f953a3ba' User entered 'None (0)'	System	08 Aug 2020 23:48:43
	System	08 Aug 2020 23:48:43

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:44:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-08T18:48:30', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'ae9604b6-b32b-4697-a071-ecf0f953a3ba' User entered 'None (0)'	System	08 Aug 2020 23:48:43
	System	08 Aug 2020 23:48:43

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-08T18:48:33', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'ae9604b6-b32b-4697-a071-ecf0f953a3ba' User entered 'No (N)'	System	08 Aug 2020 23:48:43
	System	08 Aug 2020 23:48:43

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:44:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-08T18:48:41', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'ae9604b6-b32b-4697-a071-ecf0f953a3ba' User entered '08 Aug 2020 18:48'	System	08 Aug 2020 23:48:43
	System	08 Aug 2020 23:48:43

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	04 Aug 2020 20:04:25
User entered 'Day 6'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:44:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-09T12:01:29', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '28094fd5-c528-4dc7-a480-9cb21ceefc72'	System	09 Aug 2020 17:01:50
User entered 'None (0)'	System	09 Aug 2020 17:01:50

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:44:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-09T12:01:31', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '28094fd5-c528-4dc7-a480-9cb21ceefc72'	System	09 Aug 2020 17:01:50
User entered 'None (0)'	System	09 Aug 2020 17:01:50

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:44:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-09T12:01:33', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '28094fd5-c528-4dc7-a480-9cb21ceefc72'	System	09 Aug 2020 17:01:50
User entered 'None (0)'	System	09 Aug 2020 17:01:50

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:44:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-09T12:01:36', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '28094fd5-c528-4dc7-a480-9cb21ceefc72'	System	09 Aug 2020 17:01:50
User entered 'None (0)'	System	09 Aug 2020 17:01:50

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:44:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-09T12:01:39', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '28094fd5-c528-4dc7-a480-9cb21ceefc72'	System	09 Aug 2020 17:01:50
User entered 'None (0)'	System	09 Aug 2020 17:01:50

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:44:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-09T12:01:40', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '28094fd5-c528-4dc7-a480-9cb21ceefc72'	System	09 Aug 2020 17:01:50
User entered 'None (0)'	System	09 Aug 2020 17:01:50

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-09T12:01:44', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '28094fd5-c528-4dc7-a480-9cb21ceefc72'	System	09 Aug 2020 17:01:50
User entered 'No (N)'	System	09 Aug 2020 17:01:50

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:44:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-09T12:01:47', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '28094fd5-c528-4dc7-a480-9cb21ceefc72' User entered '09 Aug 2020 12:01'	System	09 Aug 2020 17:01:50
	System	09 Aug 2020 17:01:50

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	04 Aug 2020 20:04:25
User entered 'Day 7'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:44:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-10T12:01:31', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '13307e3f-a1c4-4e06-9e31-ed51c1b0b0db' User entered 'None (0)'	System	10 Aug 2020 17:02:05
	System	10 Aug 2020 17:02:05

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:44:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-10T12:01:34', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '13307e3f-a1c4-4e06-9e31-ed51c1b0b0db' User entered 'None (0)'	System	10 Aug 2020 17:02:05
	System	10 Aug 2020 17:02:05

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:44:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-10T12:01:36', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '13307e3f-a1c4-4e06-9e31-ed51c1b0b0db' User entered 'None (0)'	System	10 Aug 2020 17:02:05
	System	10 Aug 2020 17:02:05

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:44:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-10T12:01:39', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '13307e3f-a1c4-4e06-9e31-ed51c1b0b0db' User entered 'None (0)'	System	10 Aug 2020 17:02:05
	System	10 Aug 2020 17:02:05

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:44:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-10T12:01:41', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '13307e3f-a1c4-4e06-9e31-ed51c1b0b0db' User entered 'None (0)'	System	10 Aug 2020 17:02:05
	System	10 Aug 2020 17:02:05

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:44:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-10T12:01:43', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '13307e3f-a1c4-4e06-9e31-ed51c1b0b0db' User entered 'None (0)'	System	10 Aug 2020 17:02:05
	System	10 Aug 2020 17:02:05

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-10T12:01:53', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '13307e3f-a1c4-4e06-9e31-ed51c1b0b0db' User entered 'No (N)'	System	10 Aug 2020 17:02:05
	System	10 Aug 2020 17:02:05

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:44:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-08-10T12:02:03', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '13307e3f-a1c4-4e06-9e31-ed51c1b0b0db' User entered '10 Aug 2020 12:02'	System	10 Aug 2020 17:02:05
	System	10 Aug 2020 17:02:05

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 20:04:25

US3452203

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 20:04:25

US3452203

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Chalimar Rojo (b) (4) (b) (4)	24 Aug 2020 20:31:10

US3452203

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '11 Aug 2020'	(b) (4) Chalimar Rojo (b) (4)	24 Aug 2020 20:31:10
	(b) (4)	

US3452203

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Contact Made (CONTACT MADE)'	Chalimar Rojo (b) (4)	24 Aug 2020 20:31:10

US3452203

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered empty.	(b) (4) Chalimar Rojo (b) (4) (b) (4)	24 Aug 2020 20:31:10

US3452203

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Chalimar Rojo (b) (4) (b) (4)	24 Aug 2020 20:31:15

US3452203

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered 'I'	System	24 Aug 2020 20:31:15

US3452203

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:00
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Yes (Y)'	(b) (4) Chalimar Rojo (b) (4)	24 Aug 2020 20:31:25
	(b) (4)	

US3452203

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:00
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered '18 Aug 2020'	(b) (4) Chalimar Rojo (b) (4) (b) (4)	24 Aug 2020 20:31:25

US3452203

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:00
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Contact Made (CONTACT MADE)'	Chalimar Rojo (b) (4)	24 Aug 2020 20:31:25

US3452203

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:00
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered empty.	(b) (4) Chalimar Rojo (b) (4) (b) (4)	24 Aug 2020 20:31:25

US3452203

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:00
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Yes (Y)'	(b) (4) Chalimar Rojo (b) (4)	24 Aug 2020 20:31:30
	(b) (4)	

US3452203

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:00
User entered '1'	System	24 Aug 2020 20:31:30

US3452203

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:00
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Chalimar Rojo (b) (4) (b) (4)	25 Aug 2020 17:11:34

US3452203

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:00
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '25 Aug 2020'	(b) (4) Chalimar Rojo (b) (4) (b) (4)	25 Aug 2020 17:11:34

US3452203

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:00
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Contact Made (CONTACT MADE)'	Chalimar Rojo (b) (4)	25 Aug 2020 17:11:34

US3452203

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:00
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered empty.	(b) (4) Chalimar Rojo (b) (4) (b) (4)	25 Aug 2020 17:11:34

US3452203

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:00
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	03 Sep 2020 18:25:02

US3452203

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:00
User entered '1'	System	03 Sep 2020 18:25:02

US3452203

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	03 Sep 2020 18:25:19

US3452203

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:45

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '03 Sep 2020'	(b) (4) Kim Calloway (b) (4)	03 Sep 2020 18:25:19

US3452203

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:45

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Clinic (Clinic)'	Kim Calloway (b) (4)	03 Sep 2020 18:25:19

US3452203

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered 'VISIT2'	System	03 Sep 2020 18:25:19

US3452203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User accepted default value 'Pre-Dose (PREDOSE)'	Kim Calloway (b) (4) (b) (4)	03 Sep 2020 19:07:48

US3452203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	03 Sep 2020 19:07:48

US3452203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '03 Sep 2020'	(b) (4) Kim Calloway (b) (4)	03 Sep 2020 19:07:48
	(b) (4)	

US3452203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '13:38'	(b) (4) Kim Calloway (b) (4)	03 Sep 2020 19:07:48

US3452203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered '03 Sep 2020 13:38'	System	03 Sep 2020 19:07:48

US3452203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '97.5' F	(b) (4) Kim Calloway (b) (4)	03 Sep 2020 19:07:48

US3452203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Oral (Oral)'	(b) (4) Kim Calloway (b) (4)	03 Sep 2020 19:07:48

US3452203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered empty.	(b) (4) Kim Calloway (b) (4)	03 Sep 2020 19:07:48

US3452203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '60'	(b) (4) Kim Calloway (b) (4)	03 Sep 2020 19:07:48

US3452203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered 'bpm'	System	03 Sep 2020 19:07:48

US3452203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '16'	(b) (4) Kim Calloway (b) (4)	03 Sep 2020 19:07:48

US3452203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered 'breaths/min'	System	03 Sep 2020 19:07:48

US3452203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '154'	(b) (4) Kim Calloway (b) (4)	03 Sep 2020 19:07:48

US3452203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered 'mmHg'	System	03 Sep 2020 19:07:48

US3452203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '80'	(b) (4) Kim Calloway (b) (4)	03 Sep 2020 19:07:48

US3452203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered 'mmHg'	System	03 Sep 2020 19:07:48

US3452203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User accepted default value 'Post-Dose (POSTDOSE)'	Kim Calloway (b) (4) (b) (4)	03 Sep 2020 19:51:49

US3452203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	03 Sep 2020 19:51:49

US3452203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '03 Sep 2020'	(b) (4) Kim Calloway (b) (4)	03 Sep 2020 19:51:49
	(b) (4)	

US3452203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '14:45' reason for change: Data Entry Error	(b) (4)	09 Oct 2020 16:58:59
User entered '14:31'	Chalimar Rojo (b) (4)	03 Sep 2020 19:51:49
	(b) (4)	

US3452203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered '03 Sep 2020 14:45'	System	09 Oct 2020 16:58:59
User entered '03 Sep 2020 14:31'	System	03 Sep 2020 19:51:49

US3452203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '97.9' F	(b) (4) Kim Calloway (b) (4)	03 Sep 2020 19:51:49

US3452203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Oral (Oral)'	(b) (4) Kim Calloway (b) (4)	03 Sep 2020 19:51:49

US3452203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered empty.	(b) (4) Kim Calloway (b) (4)	03 Sep 2020 19:51:49

US3452203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '71'	(b) (4) Kim Calloway (b) (4)	03 Sep 2020 19:51:49

US3452203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered 'bpm'	System	03 Sep 2020 19:51:49

US3452203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '13'	(b) (4) Kim Calloway (b) (4)	03 Sep 2020 19:51:49

US3452203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered 'breaths/min'	System	03 Sep 2020 19:51:49

US3452203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '121'	(b) (4) Kim Calloway (b) (4)	03 Sep 2020 19:51:49

US3452203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered 'mmHg'	System	03 Sep 2020 19:51:49

US3452203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '69'	(b) (4) Kim Calloway (b) (4)	03 Sep 2020 19:51:49

US3452203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered 'mmHg'	System	03 Sep 2020 19:51:49

US3452203

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:44:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	03 Sep 2020 18:25:32

US3452203

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:44:45

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '03 Sep 2020'	(b) (4) Kim Calloway (b) (4)	03 Sep 2020 18:25:32
	(b) (4)	

US3452203

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:45

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	03 Sep 2020 19:08:07

US3452203

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:45

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered empty.	(b) (4) Kim Calloway (b) (4)	03 Sep 2020 19:08:07

US3452203

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:45

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)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered empty.	(b) (4) Kim Calloway (b) (4)	03 Sep 2020 19:08:07

US3452203

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:45

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 19:08:07

US3452203

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:45

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '03 Sep 2020'	(b) (4) Kim Calloway (b) (4)	03 Sep 2020 19:08:07

US3452203

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:45

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '14:01'	(b) (4) Kim Calloway (b) (4)	03 Sep 2020 19:08:07

US3452203

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:45

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered '03 Sep 2020 14:01'	System	03 Sep 2020 19:08:07

US3452203

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:45

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:05:31
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	03 Sep 2020 19:08:54
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered by data change (Site from System).	System	03 Sep 2020 19:08:54
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	03 Sep 2020 19:08:07
User entered 'Right Arm (RIGHT ARM)'	Kim Calloway (b) (4) (b) (4)	03 Sep 2020 19:08:07

US3452203

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:45

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered 'ONCE'	System	03 Sep 2020 19:08:07

US3452203

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:45

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 19:08:07

US3452203

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:44:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	03 Sep 2020 19:09:42

US3452203

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:44:45

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '03 Sep 2020'	(b) (4) Kim Calloway (b) (4) (b) (4)	03 Sep 2020 19:09:42

US3452203

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:44:45

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '13:40'	(b) (4) Kim Calloway (b) (4)	03 Sep 2020 19:09:42

US3452203

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:44:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered '03 Sep 2020 13:40'	System	03 Sep 2020 19:09:42

US3452203

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:44:45

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '03 Sep 2020'	(b) (4) Kim Calloway (b) (4)	03 Sep 2020 19:10:03
	(b) (4)	

US3452203

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:44:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kim Calloway (b) (4) (b) (4)	03 Sep 2020 19:10:03

US3452203

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:44:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	03 Sep 2020 19:10:03

US3452203

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:44:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '13:42'	(b) (4) Kim Calloway (b) (4) (b) (4)	03 Sep 2020 19:10:03

US3452203

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:44:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered '03 Sep 2020 13:42'	System	03 Sep 2020 19:10:03

US3452203

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:44:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kim Calloway (b) (4) (b) (4)	03 Sep 2020 19:10:03

US3452203

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:44:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	12 Oct 2020 03:30:01
User entered 'No (N)' reason for change: Data Entry Error	Chalimar Rojo (b) (4)	12 Oct 2020 03:30:01
User entered 'Yes (Y)'	(b) (4)	09 Oct 2020 14:58:04
	Kim Hamilton (b) (4)	09 Oct 2020 14:58:04
	(b) (4)	03 Sep 2020 19:10:03
	Kim Calloway (b) (4)	03 Sep 2020 19:10:03
	(b) (4)	

US3452203

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:44:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
	(b) (4)	
User entered '13:42' reason for change: Data Entry Error	Chalimar Rojo (b) (4)	12 Oct 2020 03:30:01
	(b) (4)	
User entered empty; reason for change Data Entry Error	Kim Hamilton (b) (4)	09 Oct 2020 14:58:04
User entered '13:42'	Kim Calloway (b) (4)	03 Sep 2020 19:10:03
	(b) (4)	

US3452203

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:44:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered '03 Sep 2020 13:42'	System	12 Oct 2020 03:30:01
User entered empty.	System	09 Oct 2020 14:58:04
User entered '03 Sep 2020 13:42'	System	03 Sep 2020 19:10:03

US3452203

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Chalimar Rojo (b) (4)	11 Sep 2020 16:12:09

US3452203

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered '1'	System	11 Sep 2020 16:12:09

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	03 Sep 2020 19:08:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-03T14:40:46', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '92ec026c-b51f-4b2e-9684-0293f2e3f168'	System	03 Sep 2020 19:41:18
User entered 'Yes (Y)'	System	03 Sep 2020 19:41:18

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-03T14:40:53', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '92ec026c-b51f-4b2e-9684-0293f2e3f168' User entered '97.9'	System	03 Sep 2020 19:41:18
	System	03 Sep 2020 19:41:18

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-03T14:40:58', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '92ec026c-b51f-4b2e-9684-0293f2e3f168'	System	03 Sep 2020 19:41:18
User entered 'No (N)'	System	03 Sep 2020 19:41:18

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-03T14:41:04', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '92ec026c-b51f-4b2e-9684-0293f2e3f168' User entered '03 Sep 2020 14:41'	System	03 Sep 2020 19:41:18
	System	03 Sep 2020 19:41:18

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '03 Sep 2020 14:21'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '03 Sep 2020 16:51'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	03 Sep 2020 19:08:07
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-03T19:19:15', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '4de9bd3e-af90-4684-b75f-8d72e53ff27d' User entered 'Yes (Y)'	System	04 Sep 2020 00:19:33
	System	04 Sep 2020 00:19:33

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-03T19:19:22', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '4de9bd3e-af90-4684-b75f-8d72e53ff27d' User entered '97.6'	System	04 Sep 2020 00:19:33
	System	04 Sep 2020 00:19:33

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-03T19:19:26', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '4de9bd3e-af90-4684-b75f-8d72e53ff27d'	System	04 Sep 2020 00:19:33
User entered 'No (N)'	System	04 Sep 2020 00:19:33

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-03T19:19:30', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '4de9bd3e-af90-4684-b75f-8d72e53ff27d' User entered '03 Sep 2020 19:19'	System	04 Sep 2020 00:19:33
	System	04 Sep 2020 00:19:33

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '03 Sep 2020 17:46'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	03 Sep 2020 19:08:07
User entered 'Day 2'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:44:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-04T21:17:52', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '09beddd5-1c6f-4684-bf0e-d866083d46b0' User entered 'Yes (Y)'	System	05 Sep 2020 02:18:18
	System	05 Sep 2020 02:18:18

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:44:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-04T21:18:08', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '09beddd5-1c6f-4684-bf0e-d866083d46b0' User entered '97.5'	System	05 Sep 2020 02:18:18
	System	05 Sep 2020 02:18:18

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:44:45

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-04T21:18:12', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '09beddd5-1c6f-4684-bf0e-d866083d46b0' User entered 'No (N)'	System	05 Sep 2020 02:18:18
	System	05 Sep 2020 02:18:18

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-04T21:18:17', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '09beddd5-1c6f-4684-bf0e-d866083d46b0' User entered '04 Sep 2020 21:18'	System	05 Sep 2020 02:18:18
	System	05 Sep 2020 02:18:18

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	03 Sep 2020 19:08:07
User entered 'Day 3'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:44:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-05T16:13:52', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '72b9db13-be9f-499f-8cde-1b3539efef2f' User entered 'Yes (Y)'	System	05 Sep 2020 21:14:11
	System	05 Sep 2020 21:14:11

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:44:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-05T16:13:58', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '72b9db13-be9f-499f-8cde-1b3539efef2f' User entered '97.4'	System	05 Sep 2020 21:14:11
	System	05 Sep 2020 21:14:11

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:44:45

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-05T16:14:01', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '72b9db13-be9f-499f-8cde-1b3539efef2f'	System	05 Sep 2020 21:14:11
User entered 'No (N)'	System	05 Sep 2020 21:14:11

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-05T16:14:06', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '72b9db13-be9f-499f-8cde-1b3539efef2f' User entered '05 Sep 2020 16:14'	System	05 Sep 2020 21:14:11
	System	05 Sep 2020 21:14:11

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	03 Sep 2020 19:08:07
User entered 'Day 4'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:44:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-06T19:57:35', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '97bcfb62-0f17-4b24-95ec-9347dcea9e8f' User entered 'Yes (Y)'	System	07 Sep 2020 00:58:21
	System	07 Sep 2020 00:58:21

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:44:45

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-06T19:58:03', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '97bcfb62-0f17-4b24-95ec-9347dcea9e8f' User entered '96.7'	System	07 Sep 2020 00:58:21
	System	07 Sep 2020 00:58:21

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:44:45

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-06T19:58:09', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '97bcfb62-0f17-4b24-95ec-9347dcea9e8f' User entered 'No (N)'	System	07 Sep 2020 00:58:21
	System	07 Sep 2020 00:58:21

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-06T19:58:17', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '97bcfb62-0f17-4b24-95ec-9347dcea9e8f' User entered '06 Sep 2020 19:58'	System	07 Sep 2020 00:58:21
	System	07 Sep 2020 00:58:21

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	03 Sep 2020 19:08:07
User entered 'Day 5'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:44:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-07T15:55:45', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'a560c2de-2fb8-468c-b881-19e295d76d51' User entered 'Yes (Y)'	System	07 Sep 2020 20:56:13
	System	07 Sep 2020 20:56:13

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:44:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-07T15:55:53', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'a560c2de-2fb8-468c-b881-19e295d76d51' User entered '98.0'	System	07 Sep 2020 20:56:13
	System	07 Sep 2020 20:56:13

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:44:45

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-07T15:56:01', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'a560c2de-2fb8-468c-b881-19e295d76d51'	System	07 Sep 2020 20:56:13
User entered 'No (N)'	System	07 Sep 2020 20:56:13

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-07T15:56:09', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'a560c2de-2fb8-468c-b881-19e295d76d51' User entered '07 Sep 2020 15:56'	System	07 Sep 2020 20:56:13
	System	07 Sep 2020 20:56:13

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	03 Sep 2020 19:08:07
User entered 'Day 6'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:44:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-08T21:40:10', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'c54b8c94-f675-4d61-8470-3ad6af898eaf' User entered 'Yes (Y)'	System	09 Sep 2020 02:41:26
	System	09 Sep 2020 02:41:26

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:44:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-08T21:41:07', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'c54b8c94-f675-4d61-8470-3ad6af898eaf' User entered '97.9'	System	09 Sep 2020 02:41:26
	System	09 Sep 2020 02:41:26

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:44:45

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-08T21:41:19', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'c54b8c94-f675-4d61-8470-3ad6af898eaf' User entered 'No (N)'	System	09 Sep 2020 02:41:26
	System	09 Sep 2020 02:41:26

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-08T21:41:23', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'c54b8c94-f675-4d61-8470-3ad6af898eaf' User entered '08 Sep 2020 21:41'	System	09 Sep 2020 02:41:26
	System	09 Sep 2020 02:41:26

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	03 Sep 2020 19:08:07
User entered 'Day 7'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:44:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-09T21:47:17', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '6d94545f-799f-444b-ac48-858db490bf26' User entered 'Yes (Y)'	System	10 Sep 2020 02:48:00
	System	10 Sep 2020 02:48:00

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:44:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-09T21:47:51', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '6d94545f-799f-444b-ac48-858db490bf26' User entered '98.1'	System	10 Sep 2020 02:48:00
	System	10 Sep 2020 02:48:00

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:44:45

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-09T21:47:54', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '6d94545f-799f-444b-ac48-858db490bf26' User entered 'No (N)'	System	10 Sep 2020 02:48:00
	System	10 Sep 2020 02:48:00

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-09T21:47:58', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '6d94545f-799f-444b-ac48-858db490bf26' User entered '09 Sep 2020 21:47'	System	10 Sep 2020 02:48:00
	System	10 Sep 2020 02:48:00

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	03 Sep 2020 19:08:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-03T14:41:12', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '10671859-e313-46d8-9ec2-6b46be44dc57'	System	03 Sep 2020 19:41:42
User entered 'None (1)'	System	03 Sep 2020 19:41:42

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-03T14:41:23', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '10671859-e313-46d8-9ec2-6b46be44dc57'	System	03 Sep 2020 19:41:42
User entered 'No (N)'	System	03 Sep 2020 19:41:42

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-03T14:41:26', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '10671859-e313-46d8-9ec2-6b46be44dc57'	System	03 Sep 2020 19:41:42
User entered 'No (N)'	System	03 Sep 2020 19:41:42

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-03T14:41:33', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '10671859-e313-46d8-9ec2-6b46be44dc57'	System	03 Sep 2020 19:41:42
User entered 'None (1)'	System	03 Sep 2020 19:41:42

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-03T14:41:41', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '10671859-e313-46d8-9ec2-6b46be44dc57'	System	03 Sep 2020 19:41:42
User entered '03 Sep 2020 14:41'	System	03 Sep 2020 19:41:42

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '03 Sep 2020 14:21'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '03 Sep 2020 16:51'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	03 Sep 2020 19:08:07
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-03T19:19:36', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'b853e0d9-8cc1-4475-8e58-7a465c99e1da' User entered 'None (1)'	System	04 Sep 2020 00:19:53
	System	04 Sep 2020 00:19:53

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-03T19:19:39', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'b853e0d9-8cc1-4475-8e58-7a465c99e1da' User entered 'No (N)'	System	04 Sep 2020 00:19:53
	System	04 Sep 2020 00:19:53

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-03T19:19:42', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'b853e0d9-8cc1-4475-8e58-7a465c99e1da' User entered 'No (N)'	System	04 Sep 2020 00:19:53
	System	04 Sep 2020 00:19:53

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-03T19:19:46', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'b853e0d9-8cc1-4475-8e58-7a465c99e1da' User entered 'None (1)'	System	04 Sep 2020 00:19:53
	System	04 Sep 2020 00:19:53

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-03T19:19:50', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'b853e0d9-8cc1-4475-8e58-7a465c99e1da' User entered '03 Sep 2020 19:19'	System	04 Sep 2020 00:19:53
	System	04 Sep 2020 00:19:53

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '03 Sep 2020 17:46'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	03 Sep 2020 19:08:07
User entered 'Day 2'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-04T21:18:21', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '23181926-41d5-4d6b-9595-3d2616799c1d'	System	05 Sep 2020 02:18:38
User entered 'None (1)'	System	05 Sep 2020 02:18:38

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:44:45

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-04T21:18:25', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '23181926-41d5-4d6b-9595-3d2616799c1d' User entered 'No (N)'	System	05 Sep 2020 02:18:38
	System	05 Sep 2020 02:18:38

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:44:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-04T21:18:28', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '23181926-41d5-4d6b-9595-3d2616799c1d' User entered 'No (N)'	System	05 Sep 2020 02:18:38
	System	05 Sep 2020 02:18:38

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-04T21:18:31', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '23181926-41d5-4d6b-9595-3d2616799c1d'	System	05 Sep 2020 02:18:38
User entered 'None (1)'	System	05 Sep 2020 02:18:38

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-04T21:18:34', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '23181926-41d5-4d6b-9595-3d2616799c1d' User entered '04 Sep 2020 21:18'	System	05 Sep 2020 02:18:38
	System	05 Sep 2020 02:18:38

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	03 Sep 2020 19:08:07
User entered 'Day 3'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-05T16:14:11', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '131f6e4b-4a94-4717-a12d-959b14414af6'	System	05 Sep 2020 21:14:29
User entered 'None (1)'	System	05 Sep 2020 21:14:29

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:44:45

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-05T16:14:14', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '131f6e4b-4a94-4717-a12d-959b14414af6'	System	05 Sep 2020 21:14:29
User entered 'No (N)'	System	05 Sep 2020 21:14:29

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:44:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-05T16:14:17', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '131f6e4b-4a94-4717-a12d-959b14414af6'	System	05 Sep 2020 21:14:29
User entered 'No (N)'	System	05 Sep 2020 21:14:29

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-05T16:14:20', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '131f6e4b-4a94-4717-a12d-959b14414af6'	System	05 Sep 2020 21:14:29
User entered 'None (1)'	System	05 Sep 2020 21:14:29

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-05T16:14:24', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '131f6e4b-4a94-4717-a12d-959b14414af6' User entered '05 Sep 2020 16:14'	System	05 Sep 2020 21:14:29
	System	05 Sep 2020 21:14:29

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	03 Sep 2020 19:08:07
User entered 'Day 4'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-06T19:58:23', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '312e323c-c331-4ddf-b87c-ff6c4209e618'	System	07 Sep 2020 00:58:43
User entered 'None (1)'	System	07 Sep 2020 00:58:43

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:44:45

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-06T19:58:26', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '312e323c-c331-4ddf-b87c-ff6c4209e618'	System	07 Sep 2020 00:58:43
User entered 'No (N)'	System	07 Sep 2020 00:58:43

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:44:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-06T19:58:29', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '312e323c-c331-4ddf-b87c-ff6c4209e618' User entered 'No (N)'	System	07 Sep 2020 00:58:43
	System	07 Sep 2020 00:58:43

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-06T19:58:32', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '312e323c-c331-4ddf-b87c-ff6c4209e618'	System	07 Sep 2020 00:58:43
User entered 'None (1)'	System	07 Sep 2020 00:58:43

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-06T19:58:38', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '312e323c-c331-4ddf-b87c-ff6c4209e618' User entered '06 Sep 2020 19:58'	System	07 Sep 2020 00:58:43
	System	07 Sep 2020 00:58:43

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	03 Sep 2020 19:08:07
User entered 'Day 5'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-07T15:56:13', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '7e5165d9-2b33-4e7d-b717-b4c7c1182a3a'	System	07 Sep 2020 20:56:36
User entered 'None (1)'	System	07 Sep 2020 20:56:36

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:44:45

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-07T15:56:16', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '7e5165d9-2b33-4e7d-b717-b4c7c1182a3a' User entered 'No (N)'	System	07 Sep 2020 20:56:36
	System	07 Sep 2020 20:56:36

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:44:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-07T15:56:22', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '7e5165d9-2b33-4e7d-b717-b4c7c1182a3a' User entered 'No (N)'	System	07 Sep 2020 20:56:36
	System	07 Sep 2020 20:56:36

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-07T15:56:25', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '7e5165d9-2b33-4e7d-b717-b4c7c1182a3a'	System	07 Sep 2020 20:56:36
User entered 'None (1)'	System	07 Sep 2020 20:56:36

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-07T15:56:34', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '7e5165d9-2b33-4e7d-b717-b4c7c1182a3a' User entered '07 Sep 2020 15:56'	System	07 Sep 2020 20:56:36
	System	07 Sep 2020 20:56:36

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	03 Sep 2020 19:08:07
User entered 'Day 6'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-08T21:41:27', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '549b0e57-65da-4594-9040-a8e65da42c4c'	System	09 Sep 2020 02:41:44
User entered 'None (1)'	System	09 Sep 2020 02:41:44

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:44:45

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-08T21:41:31', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '549b0e57-65da-4594-9040-a8e65da42c4c' User entered 'No (N)'	System	09 Sep 2020 02:41:44
	System	09 Sep 2020 02:41:44

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:44:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-08T21:41:34', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '549b0e57-65da-4594-9040-a8e65da42c4c' User entered 'No (N)'	System	09 Sep 2020 02:41:44
	System	09 Sep 2020 02:41:44

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-08T21:41:38', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '549b0e57-65da-4594-9040-a8e65da42c4c'	System	09 Sep 2020 02:41:44
User entered 'None (1)'	System	09 Sep 2020 02:41:44

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-08T21:41:42', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '549b0e57-65da-4594-9040-a8e65da42c4c' User entered '08 Sep 2020 21:41'	System	09 Sep 2020 02:41:44
	System	09 Sep 2020 02:41:44

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	03 Sep 2020 19:08:07
User entered 'Day 7'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-09T21:48:02', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '6a687fd7-fe75-4e0d-a41b-888deea28fe1' User entered 'None (1)'	System	10 Sep 2020 02:48:16
	System	10 Sep 2020 02:48:16

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:44:45

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-09T21:48:05', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '6a687fd7-fe75-4e0d-a41b-888deea28fe1' User entered 'No (N)'	System	10 Sep 2020 02:48:16
	System	10 Sep 2020 02:48:16

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:44:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-09T21:48:08', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '6a687fd7-fe75-4e0d-a41b-888deea28fe1' User entered 'No (N)'	System	10 Sep 2020 02:48:16
	System	10 Sep 2020 02:48:16

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-09T21:48:10', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '6a687fd7-fe75-4e0d-a41b-888deea28fe1' User entered 'None (1)'	System	10 Sep 2020 02:48:16
	System	10 Sep 2020 02:48:16

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-09T21:48:14', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '6a687fd7-fe75-4e0d-a41b-888deea28fe1' User entered '09 Sep 2020 21:48'	System	10 Sep 2020 02:48:16
	System	10 Sep 2020 02:48:16

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	03 Sep 2020 19:08:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-03T14:41:49', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '8f3737b0-010f-4ae8-8c08-a0ef5e980c8c' User entered 'None (0)'	System	03 Sep 2020 19:42:24
	System	03 Sep 2020 19:42:24

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-03T14:41:52', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '8f3737b0-010f-4ae8-8c08-a0ef5e980c8c' User entered 'None (0)'	System	03 Sep 2020 19:42:24
	System	03 Sep 2020 19:42:24

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-03T14:41:55', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '8f3737b0-010f-4ae8-8c08-a0ef5e980c8c' User entered 'None (0)'	System	03 Sep 2020 19:42:24
	System	03 Sep 2020 19:42:24

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-03T14:41:58', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '8f3737b0-010f-4ae8-8c08-a0ef5e980c8c' User entered 'None (0)'	System	03 Sep 2020 19:42:24
	System	03 Sep 2020 19:42:24

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-03T14:42:00', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '8f3737b0-010f-4ae8-8c08-a0ef5e980c8c' User entered 'None (0)'	System	03 Sep 2020 19:42:24
	System	03 Sep 2020 19:42:24

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-03T14:42:02', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '8f3737b0-010f-4ae8-8c08-a0ef5e980c8c' User entered 'None (0)'	System	03 Sep 2020 19:42:24
	System	03 Sep 2020 19:42:24

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-03T14:42:13', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '8f3737b0-010f-4ae8-8c08-a0ef5e980c8c' User entered 'No (N)'	System	03 Sep 2020 19:42:24
	System	03 Sep 2020 19:42:24

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-03T14:42:20', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '8f3737b0-010f-4ae8-8c08-a0ef5e980c8c' User entered '03 Sep 2020 14:42'	System	03 Sep 2020 19:42:24
	System	03 Sep 2020 19:42:24

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '03 Sep 2020 14:21'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '03 Sep 2020 16:51'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	03 Sep 2020 19:08:07
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-03T19:20:02', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '5f2fbb7e-97ba-449d-ba7f-19cf3b6bb06c' User entered 'None (0)'	System	04 Sep 2020 00:20:29
	System	04 Sep 2020 00:20:29

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-03T19:20:04', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '5f2fbb7e-97ba-449d-ba7f-19cf3b6bb06c' User entered 'None (0)'	System	04 Sep 2020 00:20:29
	System	04 Sep 2020 00:20:29

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-03T19:20:08', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '5f2fbb7e-97ba-449d-ba7f-19cf3b6bb06c' User entered 'None (0)'	System	04 Sep 2020 00:20:29
	System	04 Sep 2020 00:20:29

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-03T19:20:10', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '5f2fbb7e-97ba-449d-ba7f-19cf3b6bb06c' User entered 'None (0)'	System	04 Sep 2020 00:20:29
	System	04 Sep 2020 00:20:29

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-03T19:20:13', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '5f2fbb7e-97ba-449d-ba7f-19cf3b6bb06c' User entered 'None (0)'	System	04 Sep 2020 00:20:29
	System	04 Sep 2020 00:20:29

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-03T19:20:15', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '5f2fbb7e-97ba-449d-ba7f-19cf3b6bb06c' User entered 'None (0)'	System	04 Sep 2020 00:20:29
	System	04 Sep 2020 00:20:29

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-03T19:20:22', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '5f2fbb7e-97ba-449d-ba7f-19cf3b6bb06c' User entered 'No (N)'	System	04 Sep 2020 00:20:29
	System	04 Sep 2020 00:20:29

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-03T19:20:27', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '5f2fbb7e-97ba-449d-ba7f-19cf3b6bb06c' User entered '03 Sep 2020 19:20'	System	04 Sep 2020 00:20:29
	System	04 Sep 2020 00:20:29

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '03 Sep 2020 17:46'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	03 Sep 2020 19:08:07
User entered 'Day 2'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:44:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-04T21:18:42', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'e8cfae82-2ea3-4a25-a655-2c5de9baef7d' User entered 'None (0)'	System	05 Sep 2020 02:19:06
	System	05 Sep 2020 02:19:06

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:44:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-04T21:18:44', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'e8cfae82-2ea3-4a25-a655-2c5de9baef7d' User entered 'None (0)'	System	05 Sep 2020 02:19:06
	System	05 Sep 2020 02:19:06

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:44:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-04T21:18:47', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'e8cfae82-2ea3-4a25-a655-2c5de9baef7d' User entered 'None (0)'	System	05 Sep 2020 02:19:06
	System	05 Sep 2020 02:19:06

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:44:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-04T21:18:50', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'e8cfae82-2ea3-4a25-a655-2c5de9baef7d' User entered 'None (0)'	System	05 Sep 2020 02:19:06
	System	05 Sep 2020 02:19:06

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:44:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-04T21:18:52', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'e8cfae82-2ea3-4a25-a655-2c5de9baef7d' User entered 'None (0)'	System	05 Sep 2020 02:19:06
	System	05 Sep 2020 02:19:06

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:44:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-04T21:18:54', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'e8cfae82-2ea3-4a25-a655-2c5de9baef7d' User entered 'None (0)'	System	05 Sep 2020 02:19:06
	System	05 Sep 2020 02:19:06

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-04T21:18:59', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'e8cfae82-2ea3-4a25-a655-2c5de9baef7d' User entered 'No (N)'	System	05 Sep 2020 02:19:06
	System	05 Sep 2020 02:19:06

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:44:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-04T21:19:02', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'e8cfae82-2ea3-4a25-a655-2c5de9baef7d' User entered '04 Sep 2020 21:19'	System	05 Sep 2020 02:19:06
	System	05 Sep 2020 02:19:06

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	03 Sep 2020 19:08:07
User entered 'Day 3'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:44:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-05T16:14:31', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '0627b7ba-8fc9-4c19-88d0-c9813b160e47' User entered 'None (0)'	System	05 Sep 2020 21:14:51
	System	05 Sep 2020 21:14:51

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:44:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-05T16:14:33', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '0627b7ba-8fc9-4c19-88d0-c9813b160e47' User entered 'None (0)'	System	05 Sep 2020 21:14:51
	System	05 Sep 2020 21:14:51

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:44:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-05T16:14:35', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '0627b7ba-8fc9-4c19-88d0-c9813b160e47' User entered 'None (0)'	System	05 Sep 2020 21:14:51
	System	05 Sep 2020 21:14:51

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:44:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-05T16:14:37', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '0627b7ba-8fc9-4c19-88d0-c9813b160e47' User entered 'None (0)'	System	05 Sep 2020 21:14:51
	System	05 Sep 2020 21:14:51

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:44:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-05T16:14:39', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '0627b7ba-8fc9-4c19-88d0-c9813b160e47' User entered 'None (0)'	System	05 Sep 2020 21:14:51
	System	05 Sep 2020 21:14:51

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:44:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-05T16:14:41', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '0627b7ba-8fc9-4c19-88d0-c9813b160e47' User entered 'None (0)'	System	05 Sep 2020 21:14:51
	System	05 Sep 2020 21:14:51

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-05T16:14:44', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '0627b7ba-8fc9-4c19-88d0-c9813b160e47' User entered 'No (N)'	System	05 Sep 2020 21:14:51
	System	05 Sep 2020 21:14:51

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:44:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-05T16:14:49', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '0627b7ba-8fc9-4c19-88d0-c9813b160e47' User entered '05 Sep 2020 16:14'	System	05 Sep 2020 21:14:51
	System	05 Sep 2020 21:14:51

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	03 Sep 2020 19:08:07
User entered 'Day 4'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:44:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-06T19:58:46', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'b81286c2-c077-45b9-9038-7528c262498d' User entered 'None (0)'	System	07 Sep 2020 00:59:12
	System	07 Sep 2020 00:59:12

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:44:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-06T19:58:47', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'b81286c2-c077-45b9-9038-7528c262498d' User entered 'None (0)'	System	07 Sep 2020 00:59:12
	System	07 Sep 2020 00:59:12

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:44:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-06T19:58:50', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'b81286c2-c077-45b9-9038-7528c262498d' User entered 'None (0)'	System	07 Sep 2020 00:59:12
	System	07 Sep 2020 00:59:12

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:44:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-06T19:58:53', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'b81286c2-c077-45b9-9038-7528c262498d' User entered 'None (0)'	System	07 Sep 2020 00:59:12
	System	07 Sep 2020 00:59:12

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:44:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-06T19:58:56', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'b81286c2-c077-45b9-9038-7528c262498d' User entered 'None (0)'	System	07 Sep 2020 00:59:12
	System	07 Sep 2020 00:59:12

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:44:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-06T19:58:59', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'b81286c2-c077-45b9-9038-7528c262498d' User entered 'None (0)'	System	07 Sep 2020 00:59:12
	System	07 Sep 2020 00:59:12

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-06T19:59:04', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'b81286c2-c077-45b9-9038-7528c262498d' User entered 'No (N)'	System	07 Sep 2020 00:59:12
	System	07 Sep 2020 00:59:12

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:44:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-06T19:59:07', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'b81286c2-c077-45b9-9038-7528c262498d' User entered '06 Sep 2020 19:59'	System	07 Sep 2020 00:59:12
	System	07 Sep 2020 00:59:12

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	03 Sep 2020 19:08:07
User entered 'Day 5'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:44:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-07T15:56:39', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'd74db32b-39b8-4ebe-b18e-3694396e668a' User entered 'None (0)'	System	07 Sep 2020 20:57:02
	System	07 Sep 2020 20:57:02

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:44:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-07T15:56:41', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'd74db32b-39b8-4ebe-b18e-3694396e668a' User entered 'None (0)'	System	07 Sep 2020 20:57:02
	System	07 Sep 2020 20:57:02

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:44:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-07T15:56:43', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'd74db32b-39b8-4ebe-b18e-3694396e668a' User entered 'None (0)'	System	07 Sep 2020 20:57:02
	System	07 Sep 2020 20:57:02

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:44:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-07T15:56:47', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'd74db32b-39b8-4ebe-b18e-3694396e668a' User entered 'None (0)'	System	07 Sep 2020 20:57:02
	System	07 Sep 2020 20:57:02

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:44:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-07T15:56:49', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'd74db32b-39b8-4ebe-b18e-3694396e668a' User entered 'None (0)'	System	07 Sep 2020 20:57:02
	System	07 Sep 2020 20:57:02

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:44:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-07T15:56:51', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'd74db32b-39b8-4ebe-b18e-3694396e668a' User entered 'None (0)'	System	07 Sep 2020 20:57:02
	System	07 Sep 2020 20:57:02

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-07T15:56:54', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'd74db32b-39b8-4ebe-b18e-3694396e668a' User entered 'No (N)'	System	07 Sep 2020 20:57:02
	System	07 Sep 2020 20:57:02

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:44:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-07T15:57:00', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'd74db32b-39b8-4ebe-b18e-3694396e668a' User entered '07 Sep 2020 15:57'	System	07 Sep 2020 20:57:02
	System	07 Sep 2020 20:57:02

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	03 Sep 2020 19:08:07
User entered 'Day 6'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:44:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-08T21:41:47', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'e81f7b0e-ca92-4aa0-8bd1-ce8eda02eeac' User entered 'None (0)'	System	09 Sep 2020 02:42:08
	System	09 Sep 2020 02:42:08

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:44:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-08T21:41:49', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'e81f7b0e-ca92-4aa0-8bd1-ce8eda02eeac' User entered 'None (0)'	System	09 Sep 2020 02:42:08
	System	09 Sep 2020 02:42:08

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:44:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-08T21:41:52', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'e81f7b0e-ca92-4aa0-8bd1-ce8eda02eeac' User entered 'None (0)'	System	09 Sep 2020 02:42:08
	System	09 Sep 2020 02:42:08

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:44:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-08T21:41:54', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'e81f7b0e-ca92-4aa0-8bd1-ce8eda02eeac' User entered 'None (0)'	System	09 Sep 2020 02:42:08
	System	09 Sep 2020 02:42:08

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:44:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-08T21:41:56', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'e81f7b0e-ca92-4aa0-8bd1-ce8eda02eeac' User entered 'None (0)'	System	09 Sep 2020 02:42:08
	System	09 Sep 2020 02:42:08

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:44:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-08T21:41:58', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'e81f7b0e-ca92-4aa0-8bd1-ce8eda02eeac' User entered 'None (0)'	System	09 Sep 2020 02:42:08
	System	09 Sep 2020 02:42:08

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-08T21:42:02', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'e81f7b0e-ca92-4aa0-8bd1-ce8eda02eeac' User entered 'No (N)'	System	09 Sep 2020 02:42:08
	System	09 Sep 2020 02:42:08

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:44:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-08T21:42:05', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'e81f7b0e-ca92-4aa0-8bd1-ce8eda02eeac' User entered '08 Sep 2020 21:42'	System	09 Sep 2020 02:42:08
	System	09 Sep 2020 02:42:08

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	03 Sep 2020 19:08:07
User entered 'Day 7'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:44:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-09T21:48:20', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'dc36a285-705e-4e74-93b2-d64a50372874' User entered 'None (0)'	System	10 Sep 2020 02:48:43
	System	10 Sep 2020 02:48:43

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:44:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-09T21:48:22', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'dc36a285-705e-4e74-93b2-d64a50372874' User entered 'None (0)'	System	10 Sep 2020 02:48:43
	System	10 Sep 2020 02:48:43

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:44:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-09T21:48:24', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'dc36a285-705e-4e74-93b2-d64a50372874' User entered 'None (0)'	System	10 Sep 2020 02:48:43
	System	10 Sep 2020 02:48:43

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:44:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-09T21:48:27', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'dc36a285-705e-4e74-93b2-d64a50372874' User entered 'None (0)'	System	10 Sep 2020 02:48:43
	System	10 Sep 2020 02:48:43

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:44:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-09T21:48:30', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'dc36a285-705e-4e74-93b2-d64a50372874' User entered 'None (0)'	System	10 Sep 2020 02:48:43
	System	10 Sep 2020 02:48:43

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:44:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-09T21:48:33', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'dc36a285-705e-4e74-93b2-d64a50372874' User entered 'None (0)'	System	10 Sep 2020 02:48:43
	System	10 Sep 2020 02:48:43

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:44:45

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 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-09T21:48:37', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'dc36a285-705e-4e74-93b2-d64a50372874' User entered 'No (N)'	System	10 Sep 2020 02:48:43
	System	10 Sep 2020 02:48:43

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:44:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-09-09T21:48:40', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'dc36a285-705e-4e74-93b2-d64a50372874' User entered '09 Sep 2020 21:48'	System	10 Sep 2020 02:48:43
	System	10 Sep 2020 02:48:43

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 19:08:07

US3452203

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 19:08:07

US3452203

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Chalimar Rojo (b) (4) (b) (4)	11 Sep 2020 16:12:18

US3452203

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '10 Sep 2020'	(b) (4) Chalimar Rojo (b) (4) (b) (4)	11 Sep 2020 16:12:18

US3452203

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Contact Made (CONTACT MADE)'	Chalimar Rojo (b) (4)	11 Sep 2020 16:12:18

US3452203

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered empty.	(b) (4) Chalimar Rojo (b) (4) (b) (4)	11 Sep 2020 16:12:18

US3452203

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Chalimar Rojo (b) (4) (b) (4)	11 Sep 2020 16:12:23

US3452203

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered '1'	System	11 Sep 2020 16:12:23

US3452203

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Chalimar Rojo (b) (4) (b) (4)	18 Sep 2020 14:31:22

US3452203

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '18 Sep 2020'	(b) (4) Chalimar Rojo (b) (4) (b) (4)	18 Sep 2020 14:31:22

US3452203

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Chalimar Rojo (b) (4)	18 Sep 2020 14:31:22
	(b) (4)	

US3452203

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered empty.	(b) (4) Chalimar Rojo (b) (4) (b) (4)	18 Sep 2020 14:31:22

US3452203

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Chalimar Rojo (b) (4) (b) (4)	18 Sep 2020 14:31:31

US3452203

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered '1'	System	18 Sep 2020 14:31:31

US3452203

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Chalimar Rojo (b) (4) (b) (4)	24 Sep 2020 18:12:41

US3452203

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '24 Sep 2020'	(b) (4) Chalimar Rojo (b) (4) (b) (4)	24 Sep 2020 18:12:41

US3452203

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Chalimar Rojo (b) (4)	24 Sep 2020 18:12:41
	(b) (4)	

US3452203

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered empty.	(b) (4) Chalimar Rojo (b) (4) (b) (4)	24 Sep 2020 18:12:41

US3452203

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Chalimar Rojo (b) (4) (b) (4)	24 Sep 2020 18:12:47

US3452203

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered '1'	System	24 Sep 2020 18:12:47

US3452203

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	06 Oct 2020 20:52:02

US3452203

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:45

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '06 Oct 2020'	(b) (4) Kim Calloway (b) (4)	06 Oct 2020 20:52:02

US3452203

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:45

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Clinic (Clinic)'	Kim Calloway (b) (4)	06 Oct 2020 20:52:02

US3452203

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered 'VISIT3'	System	06 Oct 2020 20:52:02

US3452203

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'No (N)'	(b) (4) Kim Calloway (b) (4)	06 Oct 2020 20:52:08

US3452203

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered empty.	(b) (4) Kim Calloway (b) (4)	06 Oct 2020 20:52:08

US3452203

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered empty.	(b) (4) Kim Calloway (b) (4)	06 Oct 2020 20:52:08

US3452203

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered empty.	System	06 Oct 2020 20:52:08

US3452203

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered empty.	(b) (4) Kim Calloway (b) (4)	06 Oct 2020 20:52:08

US3452203

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered empty.	(b) (4) Kim Calloway (b) (4)	06 Oct 2020 20:52:08

US3452203

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered empty.	(b) (4) Kim Calloway (b) (4)	06 Oct 2020 20:52:08
	(b) (4)	

US3452203

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered empty.	(b) (4) Kim Calloway (b) (4)	06 Oct 2020 20:52:08

US3452203

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered empty.	System	06 Oct 2020 20:52:08

US3452203

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered empty.	(b) (4) Kim Calloway (b) (4)	06 Oct 2020 20:52:08

US3452203

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered empty.	System	06 Oct 2020 20:52:08

US3452203

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered empty.	(b) (4) Kim Calloway (b) (4)	06 Oct 2020 20:52:08

US3452203

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered empty.	System	06 Oct 2020 20:52:08

US3452203

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered empty.	(b) (4) Kim Calloway (b) (4)	06 Oct 2020 20:52:08

US3452203

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered empty.	System	06 Oct 2020 20:52:08

US3452203

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01

US3452203

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01

US3452203

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:44:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	06 Oct 2020 20:52:17

US3452203

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:44:45

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '06 Oct 2020'	(b) (4) Kim Calloway (b) (4)	06 Oct 2020 20:52:17

US3452203

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:44:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	06 Oct 2020 20:52:30

US3452203

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:44:45

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '06 Oct 2020'	(b) (4) Kim Calloway (b) (4)	06 Oct 2020 20:52:30
	(b) (4)	

US3452203

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:44:45

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered '13:40'	(b) (4) Kim Calloway (b) (4) (b) (4)	06 Oct 2020 20:52:30

US3452203

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:44:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered '06 Oct 2020 13:40'	System	06 Oct 2020 20:52:30

US3452203

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:05:31
User entered 'Yes (Y)'	(b) (4) Chalimar Rojo (b) (4)	29 Oct 2020 17:23:22
	(b) (4)	

US3452203

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered '1'	System	29 Oct 2020 17:23:22

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	04 Aug 2020 20:04:25
User entered 'Day 64'	System	04 Aug 2020 20:04:25

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-10-05T18:59:57', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '654d2c27-9c60-4fa9-a269-060258b5803f' User entered 'No (N)'	System	06 Oct 2020 00:00:24
	System	06 Oct 2020 00:00:24

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-10-05T19:00:03', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '654d2c27-9c60-4fa9-a269-060258b5803f'	System	06 Oct 2020 00:00:24
User entered 'No (N)'	System	06 Oct 2020 00:00:24

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-10-05T19:00:20', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '654d2c27-9c60-4fa9-a269-060258b5803f' User entered '05 Oct 2020 19:00:20'	System	06 Oct 2020 00:00:24
	System	06 Oct 2020 00:00:24

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	04 Aug 2020 20:04:25
User entered '04 Oct 2020 00:01'	System	04 Aug 2020 20:04:25

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	04 Aug 2020 20:04:25
User entered '08 Oct 2020 23:59'	System	04 Aug 2020 20:04:25

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	04 Aug 2020 20:04:25
User entered 'Day 71'	System	04 Aug 2020 20:04:25

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-10-12T08:58:31', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '7f465c37-7c94-4977-8d62-8dd592ea6d94'	System	12 Oct 2020 13:58:56
User entered 'No (N)'	System	12 Oct 2020 13:58:56

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-10-12T08:58:39', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '7f465c37-7c94-4977-8d62-8dd592ea6d94'	System	12 Oct 2020 13:58:56
User entered 'No (N)'	System	12 Oct 2020 13:58:56

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-10-12T08:58:50', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '7f465c37-7c94-4977-8d62-8dd592ea6d94' User entered '12 Oct 2020 08:58:50'	System	12 Oct 2020 13:58:56
	System	12 Oct 2020 13:58:56

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	04 Aug 2020 20:04:25
User entered '11 Oct 2020 00:01'	System	04 Aug 2020 20:04:25

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	04 Aug 2020 20:04:25
User entered '15 Oct 2020 23:59'	System	04 Aug 2020 20:04:25

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	04 Aug 2020 20:04:25
User entered 'Day 78'	System	04 Aug 2020 20:04:25

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-10-22T12:23:40', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '066c6b89-c4e1-4ff0-8372-ef485b9e39d9'	System	16 Nov 2020 15:30:04
User entered 'No (N)'	System	16 Nov 2020 15:30:04

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-10-22T12:23:44', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '066c6b89-c4e1-4ff0-8372-ef485b9e39d9'	System	16 Nov 2020 15:30:04
User entered 'No (N)'	System	16 Nov 2020 15:30:04

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-10-22T12:23:49', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '066c6b89-c4e1-4ff0-8372-ef485b9e39d9' User entered '22 Oct 2020 12:23:49'	System	16 Nov 2020 15:30:04
	System	16 Nov 2020 15:30:04

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	04 Aug 2020 20:04:25
User entered '18 Oct 2020 00:01'	System	04 Aug 2020 20:04:25

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	04 Aug 2020 20:04:25
User entered '22 Oct 2020 23:59'	System	04 Aug 2020 20:04:25

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	04 Aug 2020 20:04:25
User entered 'Day 92'	System	04 Aug 2020 20:04:25

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-11-02T08:22:37', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'd3b22052-a70a-4072-bd07-8fa15f3bbf18'	System	16 Nov 2020 15:30:04
User entered 'No (N)'	System	16 Nov 2020 15:30:04

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-11-02T08:22:43', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'd3b22052-a70a-4072-bd07-8fa15f3bbf18'	System	16 Nov 2020 15:30:04
User entered 'No (N)'	System	16 Nov 2020 15:30:04

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-11-02T08:22:48', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'd3b22052-a70a-4072-bd07-8fa15f3bbf18' User entered '02 Nov 2020 08:22:48'	System	16 Nov 2020 15:30:04
	System	16 Nov 2020 15:30:04

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	04 Aug 2020 20:04:25
User entered '01 Nov 2020 00:01'	System	04 Aug 2020 20:04:25

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	04 Aug 2020 20:04:25
User entered '05 Nov 2020 23:59'	System	04 Aug 2020 20:04:25

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:21:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:47:58
Data entry locked.	System	04 Aug 2020 20:04:25
User entered 'Day 99'	System	04 Aug 2020 20:04:25

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:21:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:47:58

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:21:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:47:58

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:21:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:47:58

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:21:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:47:58

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:21:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:47:58

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:21:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:47:58

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:21:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:47:58

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:21:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:47:58

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:21:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:47:58

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:21:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:47:58

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:21:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:47:58

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:21:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:47:58

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:21:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:47:58

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:21:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:47:58

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:21:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:47:58

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:21:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:47:58

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:21:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:47:58

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:21:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:47:58

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:21:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:47:58

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:21:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:47:58

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:21:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:47:58

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:21:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:47:58

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:21:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:47:58

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:21:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:47:58

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:21:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:47:58

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:21:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:47:58
Data entry locked.	System	04 Aug 2020 20:04:25
User entered '08 Nov 2020 00:01'	System	04 Aug 2020 20:04:25

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:21:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:47:58
Data entry locked.	System	04 Aug 2020 20:04:25
User entered '12 Nov 2020 23:59'	System	04 Aug 2020 20:04:25

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	04 Aug 2020 20:04:25
User entered 'Day 106'	System	04 Aug 2020 20:04:25

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-11-15T07:01:04', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '7c13a68a-208f-42b3-add8-3e19940e79f4'	System	16 Nov 2020 15:30:06
User entered 'No (N)'	System	16 Nov 2020 15:30:06

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-11-15T07:01:08', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '7c13a68a-208f-42b3-add8-3e19940e79f4'	System	16 Nov 2020 15:30:06
User entered 'No (N)'	System	16 Nov 2020 15:30:06

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-11-15T07:01:13', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '7c13a68a-208f-42b3-add8-3e19940e79f4' User entered '15 Nov 2020 07:01:13'	System	16 Nov 2020 15:30:06
	System	16 Nov 2020 15:30:06

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	04 Aug 2020 20:04:25
User entered '15 Nov 2020 00:01'	System	04 Aug 2020 20:04:25

US3452203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:06:41
Data entry locked.	System	04 Aug 2020 20:04:25
User entered '19 Nov 2020 23:59'	System	04 Aug 2020 20:04:25

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-11-19T09:54:52', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '98a78949-3939-47dc-b212-db6201c3ed63'	System	19 Nov 2020 15:56:40
User entered 'Yes (Y)'	System	19 Nov 2020 15:56:40

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Have you been exposed to someone with 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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-11-19T09:54:59', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '98a78949-3939-47dc-b212-db6201c3ed63'	System	19 Nov 2020 15:56:40
User entered 'Yes (Y)'	System	19 Nov 2020 15:56:40

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-11-19T09:55:05', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '98a78949-3939-47dc-b212-db6201c3ed63'	System	19 Nov 2020 15:56:40
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Nov 2020 15:56:40

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-11-19T09:55:14', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '98a78949-3939-47dc-b212-db6201c3ed63'	System	19 Nov 2020 15:56:40
User entered 'Yes (Y)'	System	19 Nov 2020 15:56:40

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-11-19T09:55:52', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '98a78949-3939-47dc-b212-db6201c3ed63'	System	19 Nov 2020 15:56:40
User entered '1'	System	19 Nov 2020 15:56:40

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-11-19T09:55:52', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '98a78949-3939-47dc-b212-db6201c3ed63'	System	19 Nov 2020 15:56:40
User entered '0'	System	19 Nov 2020 15:56:40

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-11-19T09:55:52', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '98a78949-3939-47dc-b212-db6201c3ed63'	System	19 Nov 2020 15:56:40
User entered '1'	System	19 Nov 2020 15:56:40

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-11-19T09:55:52', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '98a78949-3939-47dc-b212-db6201c3ed63' User entered '0'	System	19 Nov 2020 15:56:40
	System	19 Nov 2020 15:56:40

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-11-19T09:55:52', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '98a78949-3939-47dc-b212-db6201c3ed63'	System	19 Nov 2020 15:56:40
User entered '0'	System	19 Nov 2020 15:56:40

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-11-19T09:55:52', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '98a78949-3939-47dc-b212-db6201c3ed63'	System	19 Nov 2020 15:56:40
User entered '0'	System	19 Nov 2020 15:56:40

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-11-19T09:55:52', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '98a78949-3939-47dc-b212-db6201c3ed63'	System	19 Nov 2020 15:56:40
User entered '0'	System	19 Nov 2020 15:56:40

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-11-19T09:55:52', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '98a78949-3939-47dc-b212-db6201c3ed63'	System	19 Nov 2020 15:56:40
User entered '1'	System	19 Nov 2020 15:56:40

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-11-19T09:55:52', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '98a78949-3939-47dc-b212-db6201c3ed63'	System	19 Nov 2020 15:56:40
User entered '0'	System	19 Nov 2020 15:56:40

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-11-19T09:55:52', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '98a78949-3939-47dc-b212-db6201c3ed63' User entered '0'	System	19 Nov 2020 15:56:40
	System	19 Nov 2020 15:56:40

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-11-19T09:55:52', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '98a78949-3939-47dc-b212-db6201c3ed63' User entered '0'	System	19 Nov 2020 15:56:40
	System	19 Nov 2020 15:56:40

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-11-19T09:55:52', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '98a78949-3939-47dc-b212-db6201c3ed63' User entered '0'	System	19 Nov 2020 15:56:40
	System	19 Nov 2020 15:56:40

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-11-19T09:55:52', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '98a78949-3939-47dc-b212-db6201c3ed63' User entered '0'	System	19 Nov 2020 15:56:40
	System	19 Nov 2020 15:56:40

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-11-19T09:55:52', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '98a78949-3939-47dc-b212-db6201c3ed63'	System	19 Nov 2020 15:56:40
User entered '0'	System	19 Nov 2020 15:56:40

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-11-19T09:55:52', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '98a78949-3939-47dc-b212-db6201c3ed63'	System	19 Nov 2020 15:56:40
User entered '0'	System	19 Nov 2020 15:56:40

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-11-19T09:55:52', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '98a78949-3939-47dc-b212-db6201c3ed63'	System	19 Nov 2020 15:56:40
User entered '0'	System	19 Nov 2020 15:56:40

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-11-19T09:55:52', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '98a78949-3939-47dc-b212-db6201c3ed63'	System	19 Nov 2020 15:56:40
User entered '0'	System	19 Nov 2020 15:56:40

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-11-19T09:55:55', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '98a78949-3939-47dc-b212-db6201c3ed63'	System	19 Nov 2020 15:56:40
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Nov 2020 15:56:40

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-11-19T09:56:04', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '98a78949-3939-47dc-b212-db6201c3ed63'	System	19 Nov 2020 15:56:40
User entered 'Yes (Y)'	System	19 Nov 2020 15:56:40

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-11-19T09:56:07', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '98a78949-3939-47dc-b212-db6201c3ed63'	System	19 Nov 2020 15:56:40
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Nov 2020 15:56:40

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-11-19T09:56:27', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '98a78949-3939-47dc-b212-db6201c3ed63' User entered '19 Nov 2020 09:56:27'	System	19 Nov 2020 15:56:40
	System	19 Nov 2020 15:56:40

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-11-27T10:51:32', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'd425b0da-04f7-4bd7-ad7f-ce27e9c6151a' User entered 'No (N)'	System	27 Nov 2020 16:51:52
	System	27 Nov 2020 16:51:52

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Have you been exposed to someone with 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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-11-27T10:51:43', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'd425b0da-04f7-4bd7-ad7f-ce27e9c6151a' User entered 'No (N)'	System	27 Nov 2020 16:51:52
	System	27 Nov 2020 16:51:52

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-11-27T10:51:47', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'd425b0da-04f7-4bd7-ad7f-ce27e9c6151a' User entered '27 Nov 2020 10:51:47'	System	27 Nov 2020 16:51:52
	System	27 Nov 2020 16:51:52

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-12-03T15:59:49', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '03976021-5b97-4923-bd99-10f0309bd3ec'	System	14 Dec 2020 20:46:33
User entered 'No (N)'	System	14 Dec 2020 20:46:33

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Have you been exposed to someone with 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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-12-03T15:59:54', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '03976021-5b97-4923-bd99-10f0309bd3ec'	System	14 Dec 2020 20:46:33
User entered 'No (N)'	System	14 Dec 2020 20:46:33

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-12-03T15:59:58', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '03976021-5b97-4923-bd99-10f0309bd3ec' User entered '03 Dec 2020 15:59:58'	System	14 Dec 2020 20:46:33
	System	14 Dec 2020 20:46:33

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-12-10T07:46:36', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'e20beaf3-8204-42d8-8866-d4bd0b964e4f' User entered 'No (N)'	System	14 Dec 2020 20:46:34
	System	14 Dec 2020 20:46:34

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Have you been exposed to someone with 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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-12-10T07:46:40', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'e20beaf3-8204-42d8-8866-d4bd0b964e4f' User entered 'No (N)'	System	14 Dec 2020 20:46:34
	System	14 Dec 2020 20:46:34

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-12-10T07:46:44', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'e20beaf3-8204-42d8-8866-d4bd0b964e4f' User entered '10 Dec 2020 07:46:44'	System	14 Dec 2020 20:46:34
	System	14 Dec 2020 20:46:34

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-12-17T18:40:35', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '752b74ce-5825-4267-81fb-cfa530bb5e9e'	System	18 Dec 2020 00:40:48
User entered 'No (N)'	System	18 Dec 2020 00:40:48

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Have you been exposed to someone with 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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-12-17T18:40:39', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '752b74ce-5825-4267-81fb-cfa530bb5e9e'	System	18 Dec 2020 00:40:48
User entered 'No (N)'	System	18 Dec 2020 00:40:48

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-12-17T18:40:45', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '752b74ce-5825-4267-81fb-cfa530bb5e9e' User entered '17 Dec 2020 18:40:45'	System	18 Dec 2020 00:40:48
	System	18 Dec 2020 00:40:48

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-12-27T08:06:46', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '37e35817-5d95-48f4-bae0-0869ebb9e4e6'	System	27 Dec 2020 14:06:56
User entered 'No (N)'	System	27 Dec 2020 14:06:56

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Have you been exposed to someone with 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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-12-27T08:06:49', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '37e35817-5d95-48f4-bae0-0869ebb9e4e6' User entered 'No (N)'	System	27 Dec 2020 14:06:56
	System	27 Dec 2020 14:06:56

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-12-27T08:06:54', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '37e35817-5d95-48f4-bae0-0869ebb9e4e6' User entered '27 Dec 2020 08:06:54'	System	27 Dec 2020 14:06:56
	System	27 Dec 2020 14:06:56

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-12-31T11:52:48', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '7ee349ae-02f6-49e8-947a-f9681f799516'	System	31 Dec 2020 17:53:02
User entered 'No (N)'	System	31 Dec 2020 17:53:02

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Have you been exposed to someone with 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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-12-31T11:52:52', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '7ee349ae-02f6-49e8-947a-f9681f799516'	System	31 Dec 2020 17:53:02
User entered 'No (N)'	System	31 Dec 2020 17:53:02

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2020-12-31T11:52:56', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '7ee349ae-02f6-49e8-947a-f9681f799516' User entered '31 Dec 2020 11:52:56'	System	31 Dec 2020 17:53:02
	System	31 Dec 2020 17:53:02

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-01-07T12:16:55', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '17940a7e-fb22-4fad-8b3d-902fcf0a76f6'	System	07 Jan 2021 18:17:13
User entered 'No (N)'	System	07 Jan 2021 18:17:13

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Have you been exposed to someone with 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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-01-07T12:17:00', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '17940a7e-fb22-4fad-8b3d-902fcf0a76f6'	System	07 Jan 2021 18:17:13
User entered 'No (N)'	System	07 Jan 2021 18:17:13

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-01-07T12:17:10', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '17940a7e-fb22-4fad-8b3d-902fcf0a76f6' User entered '07 Jan 2021 12:17:10'	System	07 Jan 2021 18:17:13
	System	07 Jan 2021 18:17:13

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-01-15T23:39:24', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '4f787dda-46cb-44c6-b045-0cc95b972a1c' User entered 'No (N)'	System	16 Jan 2021 05:42:18
	System	16 Jan 2021 05:42:18

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Have you been exposed to someone with 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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-01-15T23:39:29', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '4f787dda-46cb-44c6-b045-0cc95b972a1c' User entered 'No (N)'	System	16 Jan 2021 05:42:18
	System	16 Jan 2021 05:42:18

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-01-15T23:39:34', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '4f787dda-46cb-44c6-b045-0cc95b972a1c' User entered '15 Jan 2021 23:39:34'	System	16 Jan 2021 05:42:18
	System	16 Jan 2021 05:42:18

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-01-21T08:33:22', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '08aa35b0-3ea0-41d4-a3b1-2cda98779d02'	System	21 Jan 2021 14:33:34
User entered 'No (N)'	System	21 Jan 2021 14:33:34

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Have you been exposed to someone with 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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-01-21T08:33:27', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '08aa35b0-3ea0-41d4-a3b1-2cda98779d02'	System	21 Jan 2021 14:33:34
User entered 'No (N)'	System	21 Jan 2021 14:33:34

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-01-21T08:33:32', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '08aa35b0-3ea0-41d4-a3b1-2cda98779d02' User entered '21 Jan 2021 08:33:32'	System	21 Jan 2021 14:33:34
	System	21 Jan 2021 14:33:34

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-01-28T08:52:40', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '1b08985b-ec1c-4567-852a-863a9b46e199'	System	28 Jan 2021 14:52:52
User entered 'No (N)'	System	28 Jan 2021 14:52:52

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Have you been exposed to someone with 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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-01-28T08:52:43', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '1b08985b-ec1c-4567-852a-863a9b46e199'	System	28 Jan 2021 14:52:52
User entered 'No (N)'	System	28 Jan 2021 14:52:52

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-01-28T08:52:48', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '1b08985b-ec1c-4567-852a-863a9b46e199'	System	28 Jan 2021 14:52:52
User entered '28 Jan 2021 08:52:48'	System	28 Jan 2021 14:52:52

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-02-07T19:52:09', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'f10ae519-b43b-4bda-90c0-5dff898be6d1'	System	08 Feb 2021 01:52:22
User entered 'No (N)'	System	08 Feb 2021 01:52:22

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Have you been exposed to someone with 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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-02-07T19:52:13', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'f10ae519-b43b-4bda-90c0-5dff898be6d1'	System	08 Feb 2021 01:52:22
User entered 'No (N)'	System	08 Feb 2021 01:52:22

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-02-07T19:52:19', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'f10ae519-b43b-4bda-90c0-5dff898be6d1' User entered '07 Feb 2021 19:52:19'	System	08 Feb 2021 01:52:22

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-02-12T12:57:10', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'df1d4b2a-204d-48c5-9d2d-bad5c9a42685'	System	12 Feb 2021 18:57:22
User entered 'No (N)'	System	12 Feb 2021 18:57:22

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Have you been exposed to someone with 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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-02-12T12:57:14', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'df1d4b2a-204d-48c5-9d2d-bad5c9a42685'	System	12 Feb 2021 18:57:22
User entered 'No (N)'	System	12 Feb 2021 18:57:22

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-02-12T12:57:18', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'df1d4b2a-204d-48c5-9d2d-bad5c9a42685'	System	12 Feb 2021 18:57:22
User entered '12 Feb 2021 12:57:18'	System	12 Feb 2021 18:57:22

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-02-19T08:45:37', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '802adb59-8851-4fe6-a086-299600f4705a' User entered 'No (N)'	System	22 Feb 2021 19:11:54
	System	22 Feb 2021 19:11:54

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Have you been exposed to someone with 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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-02-19T08:45:42', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '802adb59-8851-4fe6-a086-299600f4705a'	System	22 Feb 2021 19:11:54
User entered 'No (N)'	System	22 Feb 2021 19:11:54

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-02-19T08:45:46', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '802adb59-8851-4fe6-a086-299600f4705a' User entered '19 Feb 2021 08:45:46'	System	22 Feb 2021 19:11:54
	System	22 Feb 2021 19:11:54

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-02-27T09:53:31-06:00', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'a7d2d46b-b7e6-4403-ab42-3af3a7df060f'	System	27 Feb 2021 15:53:43
User entered 'No (N)'	System	27 Feb 2021 15:53:43

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Have you been exposed to someone with 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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-02-27T09:53:34-06:00', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'a7d2d46b-b7e6-4403-ab42-3af3a7df060f' User entered 'No (N)'	System	27 Feb 2021 15:53:43
	System	27 Feb 2021 15:53:43

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-02-27T09:53:40-06:00', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'a7d2d46b-b7e6-4403-ab42-3af3a7df060f' User entered '27 Feb 2021 15:53:40'	System	27 Feb 2021 15:53:43
	System	27 Feb 2021 15:53:43

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-03-04T12:19:28-06:00', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'e19b520a-6c7f-4b13-959a-822430291387'	System	04 Mar 2021 18:19:46
User entered 'No (N)'	System	04 Mar 2021 18:19:46

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Have you been exposed to someone with 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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-03-04T12:19:34-06:00', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'e19b520a-6c7f-4b13-959a-822430291387'	System	04 Mar 2021 18:19:46
User entered 'No (N)'	System	04 Mar 2021 18:19:46

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-03-04T12:19:44-06:00', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'e19b520a-6c7f-4b13-959a-822430291387'	System	04 Mar 2021 18:19:46
User entered '04 Mar 2021 12:19:44'	System	04 Mar 2021 18:19:46

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-03-13T15:23:41-06:00', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'e5bc4297-f9de-47e9-ac0b-6fa9285fad99'	System	14 Mar 2021 12:13:54
User entered 'Yes (Y)'	System	14 Mar 2021 12:13:54

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Have you been exposed to someone with 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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-03-13T15:23:45-06:00', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'e5bc4297-f9de-47e9-ac0b-6fa9285fad99'	System	14 Mar 2021 12:13:54
User entered 'No (N)'	System	14 Mar 2021 12:13:54

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-03-13T15:23:51-06:00', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'e5bc4297-f9de-47e9-ac0b-6fa9285fad99'	System	14 Mar 2021 12:13:54
User entered 'No (N)'	System	14 Mar 2021 12:13:54

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-03-13T15:24:00-06:00', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'e5bc4297-f9de-47e9-ac0b-6fa9285fad99'	System	14 Mar 2021 12:13:54
User entered 'Yes (Y)'	System	14 Mar 2021 12:13:54

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-03-14T07:13:09-05:00', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'e5bc4297-f9de-47e9-ac0b-6fa9285fad99'	System	14 Mar 2021 12:13:54
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Mar 2021 12:13:54

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-03-14T07:13:43-05:00', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'e5bc4297-f9de-47e9-ac0b-6fa9285fad99' User entered '14 Mar 2021 07:13:43'	System	14 Mar 2021 12:13:54
	System	14 Mar 2021 12:13:54

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-03-18T10:27:11-05:00', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'd3b6c160-7c0e-4f3c-8d10-c6b2707a18f4'	System	18 Mar 2021 15:27:21
User entered 'No (N)'	System	18 Mar 2021 15:27:21

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Have you been exposed to someone with 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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-03-18T10:27:14-05:00', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'd3b6c160-7c0e-4f3c-8d10-c6b2707a18f4'	System	18 Mar 2021 15:27:21
User entered 'No (N)'	System	18 Mar 2021 15:27:21

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-03-18T10:27:18-05:00', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'd3b6c160-7c0e-4f3c-8d10-c6b2707a18f4'	System	18 Mar 2021 15:27:21
User entered '18 Mar 2021 10:27:18'	System	18 Mar 2021 15:27:21

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-03-25T08:19:18-05:00', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '704a20d8-10af-453b-8efa-ec4d4def640e'	System	25 Mar 2021 13:19:46
User entered 'No (N)'	System	25 Mar 2021 13:19:46

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Have you been exposed to someone with 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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-03-25T08:19:23-05:00', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '704a20d8-10af-453b-8efa-ec4d4def640e'	System	25 Mar 2021 13:19:46
User entered 'No (N)'	System	25 Mar 2021 13:19:46

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-03-25T08:19:40-05:00', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '704a20d8-10af-453b-8efa-ec4d4def640e'	System	25 Mar 2021 13:19:46
User entered '25 Mar 2021 08:19:40'	System	25 Mar 2021 13:19:46

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-04-01T04:24:49-05:00', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '461115f8-2fc9-4663-9190-d7061ceabcf9'	System	01 Apr 2021 09:25:00
User entered 'No (N)'	System	01 Apr 2021 09:25:00

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Have you been exposed to someone with 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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-04-01T04:24:52-05:00', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '461115f8-2fc9-4663-9190-d7061ceabcf9'	System	01 Apr 2021 09:25:00
User entered 'No (N)'	System	01 Apr 2021 09:25:00

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-04-01T04:24:57-05:00', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '461115f8-2fc9-4663-9190-d7061ceabcf9'	System	01 Apr 2021 09:25:00
User entered '01 Apr 2021 04:24:57'	System	01 Apr 2021 09:25:00

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-04-08T07:58:53-05:00', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '5fa96d81-d286-4f3f-82b7-5172f09beac1'	System	08 Apr 2021 12:59:06
User entered 'No (N)'	System	08 Apr 2021 12:59:06

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Have you been exposed to someone with 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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-04-08T07:58:57-05:00', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '5fa96d81-d286-4f3f-82b7-5172f09beac1'	System	08 Apr 2021 12:59:06
User entered 'No (N)'	System	08 Apr 2021 12:59:06

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-04-08T07:59:01-05:00', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '5fa96d81-d286-4f3f-82b7-5172f09beac1'	System	08 Apr 2021 12:59:06
User entered '08 Apr 2021 07:59:01'	System	08 Apr 2021 12:59:06

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-04-15T08:30:06-05:00', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '688aed95-7421-45b4-b70f-05e01b09fc7e'	System	15 Apr 2021 13:30:23
User entered 'No (N)'	System	15 Apr 2021 13:30:23

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Have you been exposed to someone with 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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-04-15T08:30:11-05:00', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '688aed95-7421-45b4-b70f-05e01b09fc7e' User entered 'No (N)'	System	15 Apr 2021 13:30:23
	System	15 Apr 2021 13:30:23

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-04-15T08:30:19-05:00', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '688aed95-7421-45b4-b70f-05e01b09fc7e' User entered '15 Apr 2021 08:30:19'	System	15 Apr 2021 13:30:23
	System	15 Apr 2021 13:30:23

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-04-22T09:02:36-05:00', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'd74f6df7-dd90-4a99-a1c6-c40751266873'	System	22 Apr 2021 14:02:47
User entered 'No (N)'	System	22 Apr 2021 14:02:47

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Have you been exposed to someone with 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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-04-22T09:02:40-05:00', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'd74f6df7-dd90-4a99-a1c6-c40751266873'	System	22 Apr 2021 14:02:47
User entered 'No (N)'	System	22 Apr 2021 14:02:47

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-04-22T09:02:45-05:00', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'd74f6df7-dd90-4a99-a1c6-c40751266873'	System	22 Apr 2021 14:02:47
User entered '22 Apr 2021 09:02:45'	System	22 Apr 2021 14:02:47

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-05-02T20:44:13-05:00', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '19b93b76-da55-4237-ac7d-9da17d79c37a'	System	03 May 2021 01:44:26
User entered 'No (N)'	System	03 May 2021 01:44:26

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

Have you been exposed to someone with 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 (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-05-02T20:44:18-05:00', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '19b93b76-da55-4237-ac7d-9da17d79c37a'	System	03 May 2021 01:44:26
User entered 'No (N)'	System	03 May 2021 01:44:26

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-05-02T20:44:23-05:00', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: '19b93b76-da55-4237-ac7d-9da17d79c37a'	System	03 May 2021 01:44:26
User entered '02 May 2021 20:44:23'	System	03 May 2021 01:44:26

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 12:47:58

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US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 12:47:58

US3452203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:58
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 12:47:58

US3452203

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:44:45

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)	26 Apr 2021 12:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-02-27T09:53:52-06:00', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'e935a288-aaa4-4d3e-9e8c-9c928fd329b7'	System	27 Feb 2021 15:54:08
User entered 'No (N)'	System	27 Feb 2021 15:54:08

US3452203

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:44:45

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1C5029E-4217-4292-8C1B-E40FFE7CC343)', Time: '2021-02-27T09:54:02-06:00', User OID: 'PatientReportedOutcome (US3452203)', ODM File OID: 'e935a288-aaa4-4d3e-9e8c-9c928fd329b7'	System	27 Feb 2021 15:54:08
User entered '27 Feb 2021 15:54:02'	System	27 Feb 2021 15:54:08

US3452203

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Yes (Y)'	(b) (4) Chalimar Rojo (b) (4) (b) (4)	29 Oct 2020 17:23:32

US3452203

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered '29 Oct 2020'	(b) (4) Chalimar Rojo (b) (4) (b) (4)	29 Oct 2020 17:23:32

US3452203

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Chalimar Rojo (b) (4)	29 Oct 2020 17:23:32

US3452203

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered empty.	(b) (4) Chalimar Rojo (b) (4) (b) (4)	29 Oct 2020 17:23:32

US3452203

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Yes (Y)'	(b) (4) Chalimar Rojo (b) (4) (b) (4)	29 Oct 2020 17:23:37

US3452203

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:01
User entered '1'	System	29 Oct 2020 17:23:37

US3452203

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:39:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Yes (Y)'	Chalimar Rojo (b) (4)	03 Dec 2020 21:31:38

US3452203

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:39:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered '3 Dec 2020'	(b) (4) Chalimar Rojo (b) (4) (b) (4)	03 Dec 2020 21:31:38

US3452203

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:39:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Contact Made (CONTACT MADE)'	Chalimar Rojo (b) (4)	03 Dec 2020 21:31:38

US3452203

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:39:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered empty.	(b) (4) Chalimar Rojo (b) (4) (b) (4)	03 Dec 2020 21:31:38

US3452203

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:39:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Yes (Y)'	Chalimar Rojo (b) (4)	30 Dec 2020 20:02:30

US3452203

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:39:45
User entered '1'	System	30 Dec 2020 20:02:30

US3452203

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:39:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Yes (Y)'	Chalimar Rojo (b) (4)	30 Dec 2020 20:02:42

US3452203

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:39:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered '30 Dec 2020'	(b) (4) Chalimar Rojo (b) (4) (b) (4)	30 Dec 2020 20:02:42

US3452203

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:39:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Contact Made (CONTACT MADE)'	Chalimar Rojo (b) (4)	30 Dec 2020 20:02:42

US3452203

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:39:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered empty.	(b) (4) Chalimar Rojo (b) (4) (b) (4)	30 Dec 2020 20:02:42

US3452203

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:39:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Yes (Y)'	Chalimar Rojo (b) (4)	01 Feb 2021 19:30:49

US3452203

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:39:45
User entered '1'	System	01 Feb 2021 19:30:49

US3452203

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:39:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Yes (Y)'	Chalimar Rojo (b) (4)	01 Feb 2021 19:31:00

US3452203

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:39:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered '31 Jan 2021'	Chalimar Rojo (b) (4)	01 Feb 2021 19:31:00

US3452203

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:39:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Contact Made (CONTACT MADE)'	Chalimar Rojo (b) (4)	01 Feb 2021 19:31:00

US3452203

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:39:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered empty.	Chalimar Rojo (b) (4)	01 Feb 2021 19:31:00

US3452203

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:39:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Yes (Y)'	Destiny Heinzig-Cartwright (b) (4)	08 Feb 2021 15:51:47

US3452203

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:39:45
User entered '1'	System	08 Feb 2021 15:51:47

US3452203

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:38:31
User entered 'Yes (Y)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	04 Mar 2021 22:53:24

US3452203

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:45

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:31
User entered '4 Mar 2021'	(b) (4)	04 Mar 2021 22:53:24
	Destiny	
	Heinzig-Cartwright (b) (4)	
	(b) (4)	

US3452203

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:45

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:31
User entered 'Home (Home)'	(b) (4)	04 Mar 2021 22:53:24
	Destiny	
	Heinzig-Cartwright (b) (4)	
	(b) (4)	

US3452203

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered 'VISIT4'	System	04 Mar 2021 22:53:24

US3452203

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:31
User entered 'No (N)'	(b) (4) Chalimar Rojo (b) (4)	30 Mar 2021 17:08:50
	(b) (4)	

US3452203

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:31
User entered empty.	(b) (4) Chalimar Rojo (b) (4) (b) (4)	30 Mar 2021 17:08:50

US3452203

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:31
User entered empty.	(b) (4) Chalimar Rojo (b) (4) (b) (4)	30 Mar 2021 17:08:50

US3452203

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered empty.	System	30 Mar 2021 17:08:50

US3452203

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:31
User entered empty.	(b) (4) Chalimar Rojo (b) (4) (b) (4)	30 Mar 2021 17:08:50

US3452203

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:31
User entered empty.	(b) (4) Chalimar Rojo (b) (4) (b) (4)	30 Mar 2021 17:08:50

US3452203

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:31
User entered empty.	(b) (4) Chalimar Rojo (b) (4) (b) (4)	30 Mar 2021 17:08:50

US3452203

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:38:31
User entered empty.	Chalimar Rojo (b) (4) (b) (4)	30 Mar 2021 17:08:50

US3452203

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered empty.	System	30 Mar 2021 17:08:50

US3452203

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:31
User entered empty.	(b) (4) Chalimar Rojo (b) (4)	30 Mar 2021 17:08:50
	(b) (4)	

US3452203

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered empty.	System	30 Mar 2021 17:08:50

US3452203

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:31
User entered empty.	(b) (4) Chalimar Rojo (b) (4)	30 Mar 2021 17:08:50
	(b) (4)	

US3452203

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered empty.	System	30 Mar 2021 17:08:50

US3452203

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:31
User entered empty.	(b) (4) Chalimar Rojo (b) (4) (b) (4)	30 Mar 2021 17:08:50

US3452203

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered empty.	System	30 Mar 2021 17:08:50

US3452203

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56

US3452203

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56

US3452203

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:44:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:31
User entered 'Yes (Y)'	(b) (4)	04 Mar 2021 22:53:33
	Destiny	
	Heinzig-Cartwright (b) (4)	
	(b) (4)	

US3452203

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:44:45

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:31
User entered '4 Mar 2021'	(b) (4)	
	Destiny	04 Mar 2021 22:53:33
	Heinzig-Cartwright (b) (4)	
	(b) (4)	

US3452203

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:44:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:38:31
User entered 'Yes (Y)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	04 Mar 2021 22:53:48

US3452203

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:44:45

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:31
User entered '4 Mar 2021'	(b) (4)	04 Mar 2021 22:53:48
	Destiny	
	Heinzig-Cartwright (b) (4)	
	(b) (4)	

US3452203

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:44:45

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:31
User entered '15:57'	(b) (4)	04 Mar 2021 22:53:48
	Destiny	
	Heinzig-Cartwright (b) (4)	
	(b) (4)	

US3452203

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:44:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered '4 Mar 2021 15:57'	System	04 Mar 2021 22:53:48

US3452203

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:38:31
User entered 'Yes (Y)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	04 Mar 2021 22:53:10

US3452203

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:01:56
User entered '1'	System	04 Mar 2021 22:53:10

US3452203

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
	(b) (4)	
User entered 'Yes (Y)'	Chalimar Rojo (b) (4)	01 Apr 2021 15:18:32
	(b) (4)	

US3452203

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
	(b) (4)	
User entered '1 Apr 2021'	Chalimar Rojo (b) (4)	01 Apr 2021 15:18:32
	(b) (4)	

US3452203

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Chalimar Rojo (b) (4)	01 Apr 2021 15:18:32
	(b) (4)	

US3452203

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
	(b) (4)	
User entered empty.	Chalimar Rojo (b) (4)	01 Apr 2021 15:18:32
	(b) (4)	

US3452203

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
	(b) (4)	
User entered 'Yes (Y)'	Chalimar Rojo (b) (4)	01 Apr 2021 15:20:28
	(b) (4)	

US3452203

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:45

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 15:20:28

US3452203

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	30 Apr 2021 18:38:56
	(b) (4)	
User entered 'Yes (Y)'	Chalimar Rojo (b) (4)	30 Apr 2021 15:17:04
	(b) (4)	

US3452203

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	30 Apr 2021 18:38:56
	(b) (4)	
User entered '30 Apr 2021'	Chalimar Rojo (b) (4)	30 Apr 2021 15:17:04
	(b) (4)	

US3452203

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	30 Apr 2021 18:38:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Chalimar Rojo (b) (4)	30 Apr 2021 15:17:04
	(b) (4)	

US3452203

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	30 Apr 2021 18:38:56
	(b) (4)	
User entered empty.	Chalimar Rojo (b) (4)	30 Apr 2021 15:17:04
	(b) (4)	

US3452203

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	30 Apr 2021 18:38:56
	(b) (4)	
User entered 'Yes (Y)'	Chalimar Rojo (b) (4)	30 Apr 2021 15:16:53
	(b) (4)	

US3452203

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:45

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 15:16:53

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:44:45

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:12
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User closed query 'Please reconcile and enter severity log. Please note symptom log shows subject experienced O2 <= 93% beginning on 18Nov2020 - ongoing with lowest value of 91%. This must be added to severity page.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:03:30
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:44:14
User closed query 'Please reconcile and enter diagnostic page' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 17:44:10
Query 'Please reconcile and enter severity log. Please note symptom log shows subject experienced O2 <= 93% beginning on 18Nov2020 - ongoing with lowest value of 91%. This must be added to severity page.' answered with 'updated' (Site from CRA).	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 14:23:05
Query 'Please reconcile and enter diagnostic page' answered with 'date of contact is correct' (Site from CRA).	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 14:23:01
User opened query 'Please reconcile and enter severity log. Please note symptom log shows subject experienced O2 <= 93% beginning on 18Nov2020 - ongoing with lowest value of 91%. This must be added to severity page.' (Site from CRA).	(b) (4), (b) (6)	21 Nov 2020 17:29:51
Query 'Please reconcile and enter severity page. Please note that O2 <=93% present on symptom log and must be recorded on severity log beginning on 18Nov2020 with a lowest value thus far of 91%' canceled (Site from CRA).	(b) (4), (b) (6)	21 Nov 2020 17:28:53
User opened query 'Please reconcile and enter severity page. Please note that O2 <=93% present on symptom log and must be recorded on severity log beginning on 18Nov2020 with a lowest value thus far of 91%' (Site from CRA).	(b) (4), (b) (6)	21 Nov 2020 17:28:47
User opened query 'Please reconcile and enter diagnostic page' (Site from CRA).	(b) (4), (b) (6)	21 Nov 2020 17:27:49
User entered '17 Nov 2020'	Kim Calloway (b) (4) (b) (4)	18 Nov 2020 14:18:29

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Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:44:45

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:12
User closed query 'Per GCL Lab Reconciliation: Swab: Re-query: Per response, since an additional swab was collected and in EDC, Unscheduled swab can be recorded only under COVID-19 Assessment visit- COVID diagnostic form. Please review and initiate a COVID-19 Assessment visit and record the swab under COVID Diagnostic form. Please confirm the correct visit to update PPD central labs, Also amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	30 Apr 2021 06:26:12
Query 'Per GCL Lab Reconciliation: Swab: Re-query: Per response, since an additional swab was collected and in EDC, Unscheduled swab can be recorded only under COVID-19 Assessment visit- COVID diagnostic form. Please review and initiate a COVID-19 Assessment visit and record the swab under COVID Diagnostic form. Please confirm the correct visit to update PPD central labs, Also amend EDC or Preclarus as appropriate. Thank you.' answered with 'In COVID_19 assessment page, are all other pages "inactivated"' (Site from DM).	Chalimar Rojo (b) (4) (b) (4)	29 Apr 2021 21:14:15
User opened query 'Per GCL Lab Reconciliation: Swab: Re-query: Per response, since an additional swab was collected and in EDC, Unscheduled swab can be recorded only under COVID-19 Assessment visit- COVID diagnostic form. Please review and initiate a COVID-19 Assessment visit and record the swab under COVID Diagnostic form. Please confirm the correct visit to update PPD central labs, Also amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 08:22:16

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Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:44:45

[Time of Contact](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 18-JAN-2021 is reported under Unscheduled Visit in PPD portal; however, swab sample for 18-JAN-2021 is missing in EDC. Kindly consider updating swab data by initiating separate Covid -19 Assessment eCRF for swab sample if collected on 18-JAN-2021 and updating swab data in the COVID Diagnostic Test eCRF, as there is no provision to capture swab data on unscheduled eCRF, else clarify.' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 08:22:16
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 18-JAN-2021 is reported under Unscheduled Visit in PPD portal; however, swab sample for 18-JAN-2021 is missing in EDC. Kindly consider updating swab data by initiating separate Covid -19 Assessment eCRF for swab sample if collected on 18-JAN-2021 and updating swab data in the COVID Diagnostic Test eCRF, as there is no provision to capture swab data on unscheduled eCRF, else clarify.' answered with 'No EDC page available to add swab' (Site from DM).	Chalimar Rojo (b) (4)	26 Apr 2021 21:07:51
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 18-JAN-2021 is reported under Unscheduled Visit in PPD portal; however, swab sample for 18-JAN-2021 is missing in EDC. Kindly consider updating swab data by initiating separate Covid -19 Assessment eCRF for swab sample if collected on 18-JAN-2021 and updating swab data in the COVID Diagnostic Test eCRF, as there is no provision to capture swab data on unscheduled eCRF, else clarify.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 20:24:27
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:14
User entered '14:00'	Kim Calloway (b) (4)	18 Nov 2020 14:18:29

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:44:45

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:12
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 18-JAN-2021 is reported under Unscheduled Visit in PPD portal; however, swab sample for 18-JAN-2021 is missing in EDC. Kindly consider updating swab data by initiating separate Covid -19 Assessment eCRF for swab sample if collected on 18-JAN-2021 and updating swab data in the COVID Diagnostic Test eCRF, as there is no provision to capture swab data on unscheduled eCRF, else clarify. ' canceled (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 20:24:30
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 18-JAN-2021 is reported under Unscheduled Visit in PPD portal; however, swab sample for 18-JAN-2021 is missing in EDC. Kindly consider updating swab data by initiating separate Covid -19 Assessment eCRF for swab sample if collected on 18-JAN-2021 and updating swab data in the COVID Diagnostic Test eCRF, as there is no provision to capture swab data on unscheduled eCRF, else clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 11:22:15
User entered '17 Nov 2020 14:00'	System	18 Nov 2020 14:18:29

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Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:44:45

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:12
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 23-FEB-2021 is reported under Unscheduled Visit in PPD portal; however, swab sample for 23-FEB-2021 is missing in EDC. Kindly consider updating swab data by initiating separate Covid -19 Assessment eCRF for swab sample if collected on 23-FEB-2021 and updating swab data in the COVID Diagnostic Test eCRF, as there is no provision to capture swab data on unscheduled eCRF, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:29:33
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 23-FEB-2021 is reported under Unscheduled Visit in PPD portal; however, swab sample for 23-FEB-2021 is missing in EDC. Kindly consider updating swab data by initiating separate Covid -19 Assessment eCRF for swab sample if collected on 23-FEB-2021 and updating swab data in the COVID Diagnostic Test eCRF, as there is no provision to capture swab data on unscheduled eCRF, else clarify.' answered with 'no place to add in EDC' (Site from DM).	Chalimar Rojo (b) (4) (b) (4)	25 Mar 2021 21:37:47
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 23-FEB-2021 is reported under Unscheduled Visit in PPD portal; however, swab sample for 23-FEB-2021 is missing in EDC. Kindly consider updating swab data by initiating separate Covid -19 Assessment eCRF for swab sample if collected on 23-FEB-2021 and updating swab data in the COVID Diagnostic Test eCRF, as there is no provision to capture swab data on unscheduled eCRF, else clarify.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 05:48:07
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:44:14
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Kim Calloway (b) (4) (b) (4)	18 Nov 2020 14:18:29

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:44:45

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:12
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:14
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	18 Nov 2020 14:18:29

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:44:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User closed query 'Per ETRTR, Illness visit occurred on 17 Nov 2020. Day 1 visit is expected to be the first day when patient started experiencing symptoms. Please confirm if date entered is correct or update if needed.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:38:59
Query 'Per ETRTR, Illness visit occurred on 17 Nov 2020. Day 1 visit is expected to be the first day when patient started experiencing symptoms. Please confirm if date entered is correct or update if needed.'	Chalimar Rojo (b) (4) (b) (4)	11 Dec 2020 18:24:43
answered with 'DAY 1 IS 11/17/20' (Site from CRA). User opened query 'Per ETRTR, Illness visit occurred on 17 Nov 2020. Day 1 visit is expected to be the first day when patient started experiencing symptoms. Please confirm if date entered is correct or update if needed.' (Site from CRA).	(b) (4), (b) (6)	09 Dec 2020 16:36:46
User entered 'Day 1 (Day 1)'	Kim Calloway (b) (4) (b) (4)	18 Nov 2020 14:22:13

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:44:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered '17 Nov 2020'	Kim Calloway (b) (4) (b) (4)	18 Nov 2020 14:22:13

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:44:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered '0'	Kim Calloway (b) (4) (b) (4)	18 Nov 2020 14:22:13

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:44:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User closed query 'Per ETRTR, Please enter data. If not done, please ensure a PD is recorded.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:39:08
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:39:01
Query 'Per ETRTR, Please enter data. If not done, please ensure a PD is recorded.' answered with 'UPDATED' (Site from CRA).	Chalimar Rojo (b) (4) (b) (4)	11 Dec 2020 18:25:48
User entered '93' reason for change: Data Entry Error	Chalimar Rojo (b) (4) (b) (4)	11 Dec 2020 18:25:43
DataPoint Un-verified.	Chalimar Rojo (b) (4) (b) (4)	11 Dec 2020 18:24:35
User entered missing code ND - Not Done; reason for change Data Entry Error	Chalimar Rojo (b) (4) (b) (4)	11 Dec 2020 18:24:35
User opened query 'Per ETRTR, Please enter data. If not done, please ensure a PD is recorded.' (Site from CRA).	(b) (4), (b) (6)	09 Dec 2020 16:48:53
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered empty.	Kim Calloway (b) (4) (b) (4)	18 Nov 2020 14:22:13

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:44:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User entered '%'	System	11 Dec 2020 18:24:35
User entered empty.	System	18 Nov 2020 14:22:13

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:44:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered '98.0' F	Kim Calloway (b) (4) (b) (4)	18 Nov 2020 14:22:13

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:44:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Kim Calloway (b) (4) (b) (4)	18 Nov 2020 14:22:13

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:44:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'Mild (Mild)'	Kim Calloway (b) (4) (b) (4)	18 Nov 2020 14:22:13

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:44:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'Mild (Mild)'	Kim Calloway (b) (4) (b) (4)	18 Nov 2020 14:22:13

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:44:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Kim Calloway (b) (4) (b) (4)	18 Nov 2020 14:22:13

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:44:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Kim Calloway (b) (4) (b) (4)	18 Nov 2020 14:22:13

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:44:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Kim Calloway (b) (4) (b) (4)	18 Nov 2020 14:22:13

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:44:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Kim Calloway (b) (4) (b) (4)	18 Nov 2020 14:22:13

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:44:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Kim Calloway (b) (4) (b) (4)	18 Nov 2020 14:22:13

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:44:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Kim Calloway (b) (4) (b) (4)	18 Nov 2020 14:22:13

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:44:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Kim Calloway (b) (4) (b) (4)	18 Nov 2020 14:22:13

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:44:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Kim Calloway (b) (4) (b) (4)	18 Nov 2020 14:22:13

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:44:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'Mild (Mild)'	Kim Calloway (b) (4) (b) (4)	18 Nov 2020 14:22:13

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:44:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Kim Calloway (b) (4) (b) (4)	18 Nov 2020 14:22:13

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:44:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Kim Calloway (b) (4) (b) (4)	18 Nov 2020 14:22:13

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:44:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Kim Calloway (b) (4) (b) (4)	18 Nov 2020 14:22:13

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:44:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Kim Calloway (b) (4) (b) (4)	18 Nov 2020 14:22:13

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:44:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Day 2 (Day 2)'	(b) (4) Chalimar Rojo (b) (4)	18 Nov 2020 20:36:56
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:44:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered '18 Nov 2020'	Chalimar Rojo (b) (4) (b) (4)	18 Nov 2020 20:36:56

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:44:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered '0'	Chalimar Rojo (b) (4) (b) (4)	18 Nov 2020 20:36:56

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:44:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered '92'	Chalimar Rojo (b) (4) (b) (4)	18 Nov 2020 20:36:56

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:44:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User entered '%'	System	18 Nov 2020 20:36:56

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:44:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered '98.9' F	Chalimar Rojo (b) (4) (b) (4)	18 Nov 2020 20:36:56

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:44:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	18 Nov 2020 20:36:56

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:44:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'Mild (Mild)'	Chalimar Rojo (b) (4) (b) (4)	18 Nov 2020 20:36:56

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:44:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	18 Nov 2020 20:36:56

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:44:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	18 Nov 2020 20:36:56

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:44:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	18 Nov 2020 20:36:56

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:44:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	18 Nov 2020 20:36:56

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:44:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	18 Nov 2020 20:36:56

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:44:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	18 Nov 2020 20:36:56

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:44:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	18 Nov 2020 20:36:56

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:44:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	18 Nov 2020 20:36:56

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:44:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	18 Nov 2020 20:36:56

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:44:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'Mild (Mild)'	Chalimar Rojo (b) (4) (b) (4)	18 Nov 2020 20:36:56

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:44:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	18 Nov 2020 20:36:56

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:44:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	18 Nov 2020 20:36:56

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:44:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	18 Nov 2020 20:36:56

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:44:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	18 Nov 2020 20:36:56

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:44:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Day 3 (Day 3)'	(b) (4) Chalimar Rojo (b) (4)	20 Nov 2020 18:22:14
	(b) (4)	

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:44:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered '19 Nov 2020'	Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:44:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered '0'	Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:44:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered '91'	Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:44:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User entered '%'	System	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:44:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered '98.2' F	Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:44:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:44:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'Mild (Mild)'	Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:44:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:44:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'Mild (Mild)'	Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:44:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:44:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:44:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:44:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:44:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:44:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:44:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:44:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'Mild (Mild)'	Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:44:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:44:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:44:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:44:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:44:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Day 4 (Day 4)'	(b) (4) Chalimar Rojo (b) (4)	20 Nov 2020 18:22:14
	(b) (4)	

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:44:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered '20 Nov 2020'	Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:44:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered '0'	Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:44:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered '91'	Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:44:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User entered '%'	System	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:44:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered '99.0' F	Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:44:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:44:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'Mild (Mild)'	Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:44:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:44:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'Mild (Mild)'	Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:44:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:44:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:44:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:44:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:44:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:44:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:44:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:44:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'Mild (Mild)'	Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:44:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:44:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:44:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:44:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:44:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User closed query 'Please add symptom day #' (Site from CRA).	(b) (4) (b) (4), (b) (6)	07 Dec 2020 22:03:26
Query 'Please add symptom day #' answered with 'updated' (Site from CRA).	Chalimar Rojo (b) (4)	30 Nov 2020 22:03:24
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	(b) (4)	30 Nov 2020 22:03:13
User opened query 'Please add symptom day #' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 03:33:43
User entered empty.	Chalimar Rojo (b) (4)	20 Nov 2020 18:22:14
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:44:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User closed query 'Please reconcile and complete log line and add 22Nov2020 symptoms' (Site from CRA).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:33:45
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:44:46
Query 'Please reconcile and complete log line and add 22Nov2020 symptoms' answered with 'updated' (Site from CRA).	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 15:34:47
User opened query 'Please reconcile and complete log line and add 22Nov2020 symptoms' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 15:27:47
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 14:23:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Nov 2020 14:23:19
User entered '21 Nov 2020' reason for change: Data Entry Error	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 14:23:19
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 18:22:14
User entered empty.	Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:44:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered '0'	Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:44:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered '93' reason for change: Data Entry Error	Chalimar Rojo (b) (4)	23 Nov 2020 15:34:42
User entered empty.	(b) (4) Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:44:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User entered '%'	System	23 Nov 2020 15:34:42
User entered empty.	System	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:44:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered '97.7' F reason for change: Data Entry Error	Chalimar Rojo (b) (4)	23 Nov 2020 15:34:42
User entered empty.	(b) (4) Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:44:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)' reason for change: Data Entry Error	Chalimar Rojo (b) (4)	23 Nov 2020 15:34:42
User entered empty.	(b) (4) Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:44:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)' reason for change: Data Entry Error	Chalimar Rojo (b) (4)	23 Nov 2020 15:34:42
User entered empty.	(b) (4) Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:44:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)' reason for change: Data Entry Error	Chalimar Rojo (b) (4)	23 Nov 2020 15:34:42
User entered empty.	(b) (4) Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:44:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)' reason for change: Data Entry Error	Chalimar Rojo (b) (4)	23 Nov 2020 15:34:42
User entered empty.	(b) (4) Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:44:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)' reason for change: Data Entry Error	Chalimar Rojo (b) (4)	23 Nov 2020 15:34:42
User entered empty.	(b) (4) Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:44:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)' reason for change: Data Entry Error	Chalimar Rojo (b) (4)	23 Nov 2020 15:34:42
User entered empty.	(b) (4) Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:44:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)' reason for change: Data Entry Error	Chalimar Rojo (b) (4)	23 Nov 2020 15:34:42
User entered empty.	(b) (4) Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:44:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)' reason for change: Data Entry Error	Chalimar Rojo (b) (4)	23 Nov 2020 15:34:42
User entered empty.	(b) (4) Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:44:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)' reason for change: Data Entry Error	Chalimar Rojo (b) (4)	23 Nov 2020 15:34:42
User entered empty.	(b) (4) Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:44:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)' reason for change: Data Entry Error	Chalimar Rojo (b) (4)	23 Nov 2020 15:34:42
User entered empty.	(b) (4) Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:44:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)' reason for change: Data Entry Error	Chalimar Rojo (b) (4)	23 Nov 2020 15:34:42
User entered empty.	(b) (4) Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:44:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	Chalimar Rojo (b) (4)	23 Nov 2020 15:34:42
User entered empty.	(b) (4) Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:44:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)' reason for change: Data Entry Error	Chalimar Rojo (b) (4)	23 Nov 2020 15:34:42
User entered empty.	(b) (4) Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:44:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)' reason for change: Data Entry Error	Chalimar Rojo (b) (4)	23 Nov 2020 15:34:42
User entered empty.	(b) (4) Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:44:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	Chalimar Rojo (b) (4)	23 Nov 2020 15:34:42
User entered empty.	(b) (4) Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:44:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)' reason for change: Data Entry Error	Chalimar Rojo (b) (4)	23 Nov 2020 15:34:42
User entered empty.	(b) (4) Chalimar Rojo (b) (4) (b) (4)	20 Nov 2020 18:22:14

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:44:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Day 6 (Day 6)'	(b) (4) Chalimar Rojo (b) (4)	23 Nov 2020 15:35:28
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:44:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered '22 Nov 2020'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 15:35:28

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:44:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered '0'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 15:35:28

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:44:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered '93'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 15:35:28

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:44:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User entered '%'	System	23 Nov 2020 15:35:28

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:44:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered '97.8' F	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 15:35:28

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:44:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 15:35:28

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:44:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 15:35:28

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:44:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 15:35:28

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:44:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'Mild (Mild)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 15:35:28

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:44:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 15:35:28

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:44:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 15:35:28

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:44:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 15:35:28

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:44:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 15:35:28

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:44:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 15:35:28

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:44:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 15:35:28

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:44:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 15:35:28

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:44:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'Mild (Mild)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 15:35:28

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:44:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 15:35:28

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:44:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 15:35:28

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:44:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'Mild (Mild)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 15:35:28

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:44:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 15:35:28

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:44:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Day 7 (Day 7)'	(b) (4) Chalimar Rojo (b) (4)	23 Nov 2020 15:35:56
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:44:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered '23 Nov 2020'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 15:35:56

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:44:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered '0'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 15:35:56

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:44:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered '93'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 15:35:56

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:44:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User entered '%'	System	23 Nov 2020 15:35:56

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:44:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered '98.3' F	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 15:35:56

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:44:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 15:35:56

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:44:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 15:35:56

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:44:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 15:35:56

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:44:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'Mild (Mild)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 15:35:56

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:44:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 15:35:56

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:44:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 15:35:56

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:44:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 15:35:56

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:44:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 15:35:56

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:44:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 15:35:56

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:44:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 15:35:56

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:44:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 15:35:56

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:44:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'Mild (Mild)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 15:35:56

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:44:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 15:35:56

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:44:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 15:35:56

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:44:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'Mild (Mild)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 15:35:56

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:44:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:46
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 15:35:56

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:44:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Day 8 (Day 8)'	(b) (4) Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:04:08

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:44:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered '24 Nov 2020'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:04:08

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:44:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered '0'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:04:08

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:44:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered '93'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:04:08

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:44:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User entered '%'	System	30 Nov 2020 22:04:08

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:44:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered '98.4' F	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:04:08

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:44:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:04:08

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:44:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:04:08

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:44:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:04:08

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:44:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'Mild (Mild)' reason for change: Data Entry Error	Chalimar Rojo (b) (4)	30 Nov 2020 22:04:24
User entered 'None (None)'	(b) (4) Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:04:08

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:44:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:04:08

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:44:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:04:08

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:44:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:04:08

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:44:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:04:08

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:44:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:04:08

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:44:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:04:08

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:44:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:04:08

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:44:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:04:08

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:44:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:04:08

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:44:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:04:08

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:44:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:04:08

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:44:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:04:08

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:44:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Day 9 (Day 9)'	(b) (4) Chalimar Rojo (b) (4)	30 Nov 2020 22:04:52
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:44:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered '25 Nov 2020'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:04:52

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:44:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered '0'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:04:52

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:44:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered '93'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:04:52

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:44:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User entered '%'	System	30 Nov 2020 22:04:52

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:44:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered '97.7' F	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:04:52

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:44:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:04:52

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:44:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:04:52

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:44:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:04:52

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:44:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:04:52

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:44:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:04:52

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:44:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:04:52

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:44:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:04:52

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:44:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:04:52

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:44:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:04:52

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:44:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:04:52

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:44:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:04:52

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:44:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:04:52

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:44:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:04:52

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:44:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:04:52

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:44:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:04:52

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:44:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:04:52

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:44:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Day 10 (Day 10)'	(b) (4) Chalimar Rojo (b) (4)	30 Nov 2020 22:05:13
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:44:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered '26 Nov 2020'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:05:13

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:44:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered '0'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:05:13

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:44:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered '93'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:05:13

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:44:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User entered '%'	System	30 Nov 2020 22:05:13

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:44:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered '97.4' F	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:05:13

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:44:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:05:13

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:44:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:05:13

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:44:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:05:13

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:44:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:05:13

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:44:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:05:13

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:44:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:05:13

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:44:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:05:13

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:44:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:05:13

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:44:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:05:13

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:44:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:05:13

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:44:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:05:13

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:44:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:05:13

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:44:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:05:13

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:44:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:05:13

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:44:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:05:13

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:44:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:05:13

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:44:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Day 11 (Day 11)'	(b) (4) Chalimar Rojo (b) (4)	30 Nov 2020 22:05:38
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:44:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered '27 Nov 2020'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:05:38

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:44:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered '0'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:05:38

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:44:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered '93'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:05:38

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:44:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User entered '%'	System	30 Nov 2020 22:05:38

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:44:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered '97.9' F	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:05:38

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:44:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:05:38

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:44:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:05:38

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:44:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:05:38

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:44:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:05:38

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:44:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:05:38

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:44:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:05:38

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:44:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:05:38

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:44:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:05:38

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:44:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:05:38

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:44:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:05:38

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:44:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:05:38

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:44:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:05:38

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:44:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:05:38

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:44:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:05:38

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:44:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:05:38

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:44:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:05:38

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:44:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User closed query 'Per CDM: Per sponsor review, please verify data and add entry for Symptom Day 12 (28Nov2020) to Symptom Log. If Not Done, please check Not Done for the applicable Symptom Day and Date.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:15:10
User closed query 'Per CDM: Per sponsor review, 'Symptom Days' are out of sequence starting on 29Nov2020. Please review data and consider updating to 'Day 13' on this form. Then update the rest of 'Symptom Days' to follow in sequence with this update, or please clarify' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 16:15:08
Query 'Per CDM: Per sponsor review, please verify data and add entry for Symptom Day 12 (28Nov2020) to Symptom Log. If Not Done, please check Not Done for the applicable Symptom Day and Date.' answered with 'date updated per source' (Site from DM).	Chalimar Rojo (b) (4) (b) (4)	15 Mar 2021 20:23:12
Query 'Per CDM: Per sponsor review, 'Symptom Days' are out of sequence starting on 29Nov2020. Please review data and consider updating to 'Day 13' on this form. Then update the rest of 'Symptom Days' to follow in sequence with this update, or please clarify' answered with 'date updated per source' (Site from DM).	Chalimar Rojo (b) (4) (b) (4)	15 Mar 2021 20:23:05
User opened query 'Per CDM: Per sponsor review, please verify data and add entry for Symptom Day 12 (28Nov2020) to Symptom Log. If Not Done, please check Not Done for the applicable Symptom Day and Date.' (Site from DM).	(b) (4), (b) (6)	14 Mar 2021 21:41:01
User opened query 'Per CDM: Per sponsor review, 'Symptom Days' are out of sequence starting on 29Nov2020. Please review data and consider updating to 'Day 13' on this form. Then update the rest of 'Symptom Days' to follow in sequence with this update, or please clarify' (Site from DM).	(b) (4), (b) (6)	14 Mar 2021 21:40:28

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:44:45

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 12 (Day 12)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:08

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:44:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:14:16
DataPoint Un-verified.	Chalimar Rojo (b) (4)	15 Mar 2021 20:22:50
User entered '28 Nov 2020' reason for change: Data Entry Error	(b) (4) Chalimar Rojo (b) (4)	15 Mar 2021 20:22:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered '29 Nov 2020'	Chalimar Rojo (b) (4)	30 Nov 2020 22:06:08
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:44:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered '0'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:08

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:44:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered '93'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:08

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:44:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User entered '%'	System	30 Nov 2020 22:06:08

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:44:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered '97.4' F	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:08

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:44:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:08

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:44:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:08

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:44:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:08

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:44:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:08

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:44:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:08

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:44:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:08

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:44:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:08

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:44:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:08

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:44:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:08

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:44:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:08

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:44:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:08

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:44:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:08

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:44:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:08

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:44:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:08

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:44:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:08

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:44:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:08

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:44:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Day 13 (Day 13)'	(b) (4) Chalimar Rojo (b) (4)	30 Nov 2020 22:06:31
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:44:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered '29 Nov 2020'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:31

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:44:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered '0'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:31

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:44:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered '93'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:31

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:44:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User entered '%'	System	30 Nov 2020 22:06:31

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:44:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered '97.7' F	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:31

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:44:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:31

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:44:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:31

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:44:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:31

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:44:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:31

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:44:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:31

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:44:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:31

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:44:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:31

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:44:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:31

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:44:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:31

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:44:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:31

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:44:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:31

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:44:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:31

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:44:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:31

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:44:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:31

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:44:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:31

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:44:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:31

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:44:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Day 14 (Day 14)'	(b) (4) Chalimar Rojo (b) (4)	30 Nov 2020 22:06:58
	(b) (4)	

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:44:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered '30 Nov 2020'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:58

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:44:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered '0'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:58

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:44:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 21:17:05
DataPoint Un-verified.	Chalimar Rojo (b) (4)	09 Apr 2021 14:51:12
User entered '96' reason for change: Data Entry Error	(b) (4) Chalimar Rojo (b) (4)	09 Apr 2021 14:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered '93'	Chalimar Rojo (b) (4)	30 Nov 2020 22:06:58
	(b) (4)	

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:44:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User entered '%'	System	30 Nov 2020 22:06:58

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:44:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered '97.4' F	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:58

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:44:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:58

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:44:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:58

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:44:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:58

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:44:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:58

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:44:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:58

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:44:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:58

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:44:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:58

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:44:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:58

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:44:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:58

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:44:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:58

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:44:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:58

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:44:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:58

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:44:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:58

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:44:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:58

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:44:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:58

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:44:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:12
User entered 'None (None)'	Chalimar Rojo (b) (4) (b) (4)	30 Nov 2020 22:06:58

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:44:45

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:54
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:56
User entered '17 Nov 2020'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 14:23:48

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:44:45

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:54
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:56
User entered 'Yes (Y)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 14:23:48

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:44:45

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:54
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 06:40:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:44:56
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 'updated' (Site from System).	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 14:23:55
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	23 Nov 2020 14:23:48
User entered 'Yes (Y)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 14:23:48

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Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:44:45

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:54
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:56
User entered '17 Nov 2020'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 14:23:48

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Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:44:45

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:54
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:56
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 14:23:48

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Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:44:45

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:54
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:56
User entered empty.	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 14:23:48

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Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:44:45

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:54
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:56
User entered 'No (N)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 14:23:48

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:44:45

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:54
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:56
User entered empty.	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 14:23:48

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:44:45

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:54
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:44:56
User entered empty.	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 14:23:48

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:44:45

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:54
User entered '1'	System	23 Nov 2020 14:23:48

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:44:45

Did the subject have Respiratory Rates \geq 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:26:09
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:49:21
User entered 'No (N)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 14:25:07

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:44:45

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:26:09
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:49:21
User entered empty.	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 14:25:07

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:44:45

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:26:09
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:49:21
User entered empty.	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 14:25:07

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:44:45

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:26:09
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:49:21
User entered empty.	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 14:25:07

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:44:45

[Did the subject have Heart Rate \$\geq\$ 125 beats per minute](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:26:09
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:49:21
User entered 'No (N)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 14:25:07

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:44:45

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:26:09
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:49:21
User entered empty.	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 14:25:07

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:44:45

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:26:09
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:49:21
User entered empty.	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 14:25:07

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:44:45

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:26:09
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:49:21
User entered empty.	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 14:25:07

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:44:45

Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:26:09
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:49:21
User entered 'Yes (Y)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 14:25:07

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:44:45

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:26:09
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:49:21
User entered '17 Nov 2020'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 14:25:07

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:44:45

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:26:09
User closed query 'Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level? Is marked YES but end date is missing. Please review and reconcile. Else, clarify. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	29 Apr 2021 11:11:19
DataPoint Verified.	Carl Griffin (b) (4) (b) (4) (b) (4), (b) (6)	16 Apr 2021 03:38:06
Query 'Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level? Is marked YES but end date is missing. Please review and reconcile. Else, clarify. ' answered with 'updated' (Site from DM).	Chalimar Rojo (b) (4) (b) (4)	14 Apr 2021 21:16:28
DataPoint Un-verified.	Chalimar Rojo (b) (4) (b) (4)	09 Apr 2021 14:50:48
User entered '30 Nov 2020' reason for change: Data Entry Error	Chalimar Rojo (b) (4) (b) (4)	09 Apr 2021 14:50:37
User opened query 'Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level? Is marked YES but end date is missing. Please review and reconcile. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 23:23:13
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:49:21
User entered empty.	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 14:25:07

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:26:09
User signature succeeded.	Carl Griffin (b) (4)	29 Apr 2021 17:43:21
User closed query 'Per CDM : Please note Day 3(19Nov20) has oxygen saturation of 91%, Kindly check and update or else clarify. Thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Apr 2021 11:11:22
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:56:24
Query 'Per CDM : Please note Day 3(19Nov20) has oxygen saturation of 91%, Kindly check and update or else clarify. Thanks ' answered with 'updated per source' (Site from DM).	Chalimar Rojo (b) (4) (b) (4)	22 Apr 2021 18:30:41
DataPoint Un-verified.	Chalimar Rojo (b) (4) (b) (4)	22 Apr 2021 18:30:30
Signature has been broken.	Chalimar Rojo (b) (4) (b) (4)	22 Apr 2021 18:30:30
User entered '91' reason for change: Data Entry Error	Chalimar Rojo (b) (4) (b) (4)	22 Apr 2021 18:30:30
User opened query 'Per CDM : Please note Day 3(19Nov20) has oxygen saturation of 91%, Kindly check and update or else clarify. Thanks ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 10:11:09
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:49:21
User entered '93'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 14:25:07

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:26:09
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:49:21
User entered 'No (N)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 14:25:07

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:26:09
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:49:21
User entered empty.	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 14:25:07

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:26:09
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:49:21
User entered empty.	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 14:25:07

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:26:09
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:49:21
User entered empty.	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 14:25:07

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[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:26:09
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:49:21
User entered 'No (N)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 14:25:07

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:26:09
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:49:21
User entered empty.	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 14:25:07

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:26:09
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:49:21
User entered 'No (N)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 14:25:07

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[High-Flow Oxygen?](#)

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:26:09
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:49:21
User entered 'No (N)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 14:25:07

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:26:09
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:49:21
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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:26:09
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:49:21
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[Mechanical Ventilation?](#)

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User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:49:21
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[ECMO?](#)

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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:26:09
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:49:21
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[Evidence of Shock Requires](#)

[Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:26:09
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
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[Acute Renal Dysfunction?](#)

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:26:09
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[Hepatic Dysfunction?](#)

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[Neurologic Dysfunction?](#)

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:26:09
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[Clinical Evidence](#)

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:26:09
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[Date of Assessment](#)

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[Radiographical Evidence](#)

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[Admission to an intensive care unit due to SARS-CoV-2](#)

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:26:09
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User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:49:21
User entered empty.	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 14:25:07

US3452203

Folder: Covid-19 Assessment 17 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:44:45

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:26:16
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:59:07
User closed query 'Please clarify if this should be no since this is 1 case & no other new COVID cases have been reported for subjects.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 20:59:04
Query 'Please clarify if this should be no since this is 1 case & no other new COVID cases have been reported for subjects.' answered with 'updated' (Site from CRA).	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 20:44:33
DataPoint Un-verified.	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 20:44:28
User entered 'No (N)' reason for change: Data Entry Error	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 20:44:28
User opened query 'Please clarify if this should be no since this is 1 case & no other new COVID cases have been reported for subjects.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 20:07:32
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:49:31
User entered 'Yes (Y)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 14:25:17

US3452203

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:44:45

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 19:05:16

US3452203

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:44:45

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:46
User entered 'Yes (Y)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 19:05:16

US3452203

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:44:45

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User closed query 'Per GCL Lab Reconciliation: Saliva: Requery1: Please confirm when the samples are shipped, kindly keep the query open till then .Thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 07:29:07
Query 'Per GCL Lab Reconciliation: Saliva: Requery1: Please confirm when the samples are shipped, kindly keep the query open till then .Thanks ' answered with 'samples being shipped today, 12/14/2020' (Site from DM).	Chalimar Rojo (b) (4) (b) (4)	14 Dec 2020 16:16:39
User opened query 'Per GCL Lab Reconciliation: Saliva: Requery1: Please confirm when the samples are shipped, kindly keep the query open till then .Thanks ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 08:07:45
Query 'Per GCL Lab Reconciliation: Saliva: Requery1: Please confirm when the samples are shipped, kindly keep the query open.Thanks' canceled (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 08:07:16
User opened query 'Per GCL Lab Reconciliation: Saliva: Requery1: Please confirm when the samples are shipped, kindly keep the query open.Thanks' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 08:06:47
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19,21,23,25NOV2020 is recorded under Illness Visit Day 3 ,5,7,9in 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)	14 Dec 2020 08:06:47
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19,21,23,25NOV2020 is recorded under Illness Visit Day 3 ,5,7,9in 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 'SAMPLES PENDING SHIPMENT' (Site from DM).	Chalimar Rojo (b) (4) (b) (4)	11 Dec 2020 18:36:48

US3452203

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:44:45

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19,21,23,25NOV2020 is recorded under Illness Visit Day 3 ,5,7,9in 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). DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 07:30:33
	(b) (4), (b) (6)	03 Dec 2020 18:46:46
User entered '19 Nov 2020'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 19:05:16

US3452203

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:44:45

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	23 Nov 2020 19:05:16

US3452203

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:44:45

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:46
User entered 'Yes (Y)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 19:05:16

US3452203

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:44:45

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:46
User entered '21 Nov 2020'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 19:05:16

US3452203

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:44:45

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	23 Nov 2020 19:05:16

US3452203

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:44:45

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:46
User entered 'Yes (Y)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 19:05:16

US3452203

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:44:45

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:46
User entered '23 Nov 2020'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 19:05:16

US3452203

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:44:45

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	23 Nov 2020 19:05:16

US3452203

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:44:45

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4)	03 Dec 2020 18:46:46
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Nov 2020 22:07:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Nov 2020 22:07:23
User entered 'Yes (Y)' reason for change: Data Entry Error	Chalimar Rojo (b) (4)	30 Nov 2020 22:07:23
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 19:05:16
User entered empty.	Chalimar Rojo (b) (4)	23 Nov 2020 19:05:16
	(b) (4)	

US3452203

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:44:45

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 18:46:46
User entered '25 Nov 2020' reason for change: Data Entry Error	Chalimar Rojo (b) (4)	30 Nov 2020 22:07:23
User entered empty.	(b) (4)	
	Chalimar Rojo (b) (4)	23 Nov 2020 19:05:16
	(b) (4)	

US3452203

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:44:45

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 19:05:16

US3452203

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:44:45

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4)	03 Dec 2020 18:46:46
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Nov 2020 22:07:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Nov 2020 22:07:23
User entered 'Yes (Y)' reason for change: Data Entry Error	Chalimar Rojo (b) (4)	30 Nov 2020 22:07:23
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 19:05:16
User entered empty.	Chalimar Rojo (b) (4)	23 Nov 2020 19:05:16
	(b) (4)	

US3452203

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:44:45

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:46:46
User entered '30 Nov 2020' reason for change: Data Entry Error	Chalimar Rojo (b) (4)	30 Nov 2020 22:07:23
User entered empty.	(b) (4) Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 19:05:16

US3452203

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:44:45

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 19:05:16

US3452203

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:44:45

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4)	15 Dec 2020 16:49:17
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Dec 2020 18:26:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Dec 2020 18:26:18
DataPoint Un-verified.	Chalimar Rojo (b) (4)	11 Dec 2020 18:26:18
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Chalimar Rojo (b) (4)	11 Dec 2020 18:26:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 18:46:46
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 19:05:16
User entered empty.	Chalimar Rojo (b) (4)	23 Nov 2020 19:05:16
	(b) (4)	

US3452203

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:44:45

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4)	15 Dec 2020 16:49:17
DataPoint Un-verified.	(b) (4), (b) (6)	
DataPoint Un-verified.	Chalimar Rojo (b) (4)	11 Dec 2020 18:26:18
User entered '07 Dec 2020' reason for change: Data Entry Error	(b) (4)	11 Dec 2020 18:26:18
DataPoint Verified.	Chalimar Rojo (b) (4)	03 Dec 2020 18:46:46
User entered empty.	(b) (4), (b) (6)	
	Chalimar Rojo (b) (4)	23 Nov 2020 19:05:16
	(b) (4)	

US3452203

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:44:45

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 19:05:16

US3452203

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:44:45

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4)	15 Dec 2020 16:49:17
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Dec 2020 18:26:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Dec 2020 18:26:18
DataPoint Un-verified.	Chalimar Rojo (b) (4)	11 Dec 2020 18:26:18
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Chalimar Rojo (b) (4)	11 Dec 2020 18:26:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 18:46:46
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 19:05:16
User entered empty.	Chalimar Rojo (b) (4)	23 Nov 2020 19:05:16
	(b) (4)	

US3452203

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:44:45

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4)	15 Dec 2020 16:49:17
DataPoint Un-verified.	(b) (4), (b) (6)	
DataPoint Un-verified.	Chalimar Rojo (b) (4)	11 Dec 2020 18:26:18
User entered '11 Dec 2020' reason for change: Data Entry Error	(b) (4)	11 Dec 2020 18:26:18
DataPoint Verified.	Chalimar Rojo (b) (4)	03 Dec 2020 18:46:46
User entered empty.	(b) (4), (b) (6)	
	Chalimar Rojo (b) (4)	23 Nov 2020 19:05:16
	(b) (4)	

US3452203

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User closed query 'Please reconcile and enter saliva log' (Site from CRA).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:34:00
Query 'Please reconcile and enter saliva log' answered with 'UPDATED' (Site from CRA).	Chalimar Rojo (b) (4)	23 Nov 2020 21:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:49:50
User opened query 'Please reconcile and enter saliva log' (Site from CRA).	(b) (4), (b) (6)	21 Nov 2020 17:26:18
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	18 Nov 2020 14:13:56

US3452203

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:45

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:49:50
User entered '17 Nov 2020'	Kim Calloway (b) (4) (b) (4)	18 Nov 2020 14:13:56

US3452203

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:45

[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 16:41:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:49:50
User entered 'Clinic (Clinic)'	Kim Calloway (b) (4) (b) (4)	18 Nov 2020 14:13:56

US3452203

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:24
User entered 'SICKD1'	System	18 Nov 2020 14:13:56

US3452203

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:49:59
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	18 Nov 2020 14:15:01

US3452203

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:49:59
User entered '17 Nov 2020'	Kim Calloway (b) (4) (b) (4)	18 Nov 2020 14:15:01

US3452203

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:49:59
User entered '14:27'	Kim Calloway (b) (4) (b) (4)	18 Nov 2020 14:15:01

US3452203

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:24
User entered '17 Nov 2020 14:27'	System	18 Nov 2020 14:15:01

US3452203

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:49:59
User entered '61.0' in	Kim Calloway (b) (4)	18 Nov 2020 14:15:01
DataPoint set to visible.	(b) (4) System	18 Nov 2020 14:13:56

US3452203

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:49:59
User entered '198.0' lb	Kim Calloway (b) (4)	18 Nov 2020 14:15:01
DataPoint set to visible.	(b) (4) System	18 Nov 2020 14:13:56

US3452203

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:49:59
User entered '98.0' F	Kim Calloway (b) (4) (b) (4)	18 Nov 2020 14:15:01

US3452203

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:49:59
User entered 'Oral (Oral)'	Kim Calloway (b) (4) (b) (4)	18 Nov 2020 14:15:01

US3452203

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:49:59
User entered empty.	Kim Calloway (b) (4) (b) (4)	18 Nov 2020 14:15:01

US3452203

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:49:59
User entered '86'	Kim Calloway (b) (4) (b) (4)	18 Nov 2020 14:15:01

US3452203

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:24
User entered 'bpm'	System	18 Nov 2020 14:15:01

US3452203

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:49:59
User entered '20'	Kim Calloway (b) (4) (b) (4)	18 Nov 2020 14:15:01

US3452203

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:24
User entered 'breaths/min'	System	18 Nov 2020 14:15:01

US3452203

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:49:59
User entered '130'	Kim Calloway (b) (4) (b) (4)	18 Nov 2020 14:15:01

US3452203

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:24
User entered 'mmHg'	System	18 Nov 2020 14:15:01

US3452203

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:49:59
User entered '65'	Kim Calloway (b) (4) (b) (4)	18 Nov 2020 14:15:01

US3452203

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:24
User entered 'mmHg'	System	18 Nov 2020 14:15:01

US3452203

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:24

US3452203

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:24

US3452203

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:44:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:50:09
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	18 Nov 2020 14:15:14

US3452203

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:44:45

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:50:09
User entered '17 Nov 2020'	Kim Calloway (b) (4) (b) (4)	18 Nov 2020 14:15:14

US3452203

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:44:45

[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 16:41:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:50:16
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	18 Nov 2020 14:16:19

US3452203

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:44:45

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:50:16
User entered '17 Nov 2020'	Kim Calloway (b) (4) (b) (4)	18 Nov 2020 14:16:19

US3452203

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:32
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:48:41
User entered 'Yes (Y)'	Chalimar Rojo (b) (4) (b) (4)	14 Dec 2020 16:07:24

US3452203

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:45

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:32
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:48:41
User entered '11 Dec 2020'	Chalimar Rojo (b) (4) (b) (4)	14 Dec 2020 16:07:24

US3452203

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:45

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:32
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:48:41
User entered 'Clinic (Clinic)'	Chalimar Rojo (b) (4) (b) (4)	14 Dec 2020 16:07:24

US3452203

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:32
User entered 'SICKD28'	System	14 Dec 2020 16:07:24

US3452203

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:48:48
User entered 'Yes (Y)'	Chalimar Rojo (b) (4) (b) (4)	14 Dec 2020 16:08:12

US3452203

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:48:48
User entered '11 Dec 2020'	Chalimar Rojo (b) (4) (b) (4)	14 Dec 2020 16:08:12

US3452203

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:48:48
User entered '11:01'	Chalimar Rojo (b) (4) (b) (4)	14 Dec 2020 16:08:12

US3452203

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:24
User entered '11 Dec 2020 11:01'	System	14 Dec 2020 16:08:12

US3452203

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:48:48
User entered '61.7' in	Chalimar Rojo (b) (4)	14 Dec 2020 16:08:12
DataPoint set to visible.	(b) (4) System	14 Dec 2020 16:07:24

US3452203

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:48:48
User entered '198.2' lb	Chalimar Rojo (b) (4)	14 Dec 2020 16:08:12
DataPoint set to visible.	(b) (4) System	14 Dec 2020 16:07:24

US3452203

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:48:48
User entered '98.4' F	Chalimar Rojo (b) (4) (b) (4)	14 Dec 2020 16:08:12

US3452203

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:48:48
User entered 'Oral (Oral)'	Chalimar Rojo (b) (4) (b) (4)	14 Dec 2020 16:08:12

US3452203

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:48:48
User entered empty.	Chalimar Rojo (b) (4) (b) (4)	14 Dec 2020 16:08:12

US3452203

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:48:48
User entered '73'	Chalimar Rojo (b) (4) (b) (4)	14 Dec 2020 16:08:12

US3452203

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:24
User entered 'bpm'	System	14 Dec 2020 16:08:12

US3452203

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:48:48
User entered '20'	Chalimar Rojo (b) (4) (b) (4)	14 Dec 2020 16:08:12

US3452203

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:24
User entered 'breaths/min'	System	14 Dec 2020 16:08:12

US3452203

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:48:48
User entered '138'	Chalimar Rojo (b) (4) (b) (4)	14 Dec 2020 16:08:12

US3452203

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:24
User entered 'mmHg'	System	14 Dec 2020 16:08:12

US3452203

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:48:48
User entered '77'	Chalimar Rojo (b) (4) (b) (4)	14 Dec 2020 16:08:12

US3452203

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:24
User entered 'mmHg'	System	14 Dec 2020 16:08:12

US3452203

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:24

US3452203

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:44:45

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:24

US3452203

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:44:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:36
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:48:59
User entered 'Yes (Y)'	Chalimar Rojo (b) (4) (b) (4)	14 Dec 2020 16:08:21

US3452203

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:44:45

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:36
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:48:59
User entered '11 Dec 2020'	Chalimar Rojo (b) (4) (b) (4)	14 Dec 2020 16:08:21

US3452203

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:44:45

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:39
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:49:07
User entered 'Yes (Y)'	Chalimar Rojo (b) (4) (b) (4)	14 Dec 2020 16:08:32

US3452203

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:44:45

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:39
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:49:07
User entered '11 Dec 2020'	Chalimar Rojo (b) (4) (b) (4)	14 Dec 2020 16:08:32

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 20:43:06

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:45

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered '09 Mar 2021'	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 20:43:06

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:45

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Clinic (Clinic)'	(b) (4) Kim Calloway (b) (4) (b) (4)	09 Mar 2021 20:43:06

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User entered 'UNBLND_DECIDE'	System	09 Mar 2021 20:43:06

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:44:45

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered '09 Mar 2021'	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 20:43:42

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:44:45

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered '0'	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 20:43:42

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:44:45

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 20:43:42

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:44:45

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Amendment 6 or later (Amendment 6 or later)'	Kim Calloway (b) (4)	09 Mar 2021 20:43:42

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:44:45

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered '09 Mar 2021'	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 20:43:42

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:44:45

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Placebo (Placebo)'	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 20:43:42

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:44:45

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Placebo (Placebo)'	(b) (4) Kim Calloway (b) (4) (b) (4)	09 Mar 2021 20:43:42

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:44:45

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Placebo (Placebo)'	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 20:43:42

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:44:45

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 20:43:42

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:44:45

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User entered '1'	System	09 Mar 2021 20:43:42

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:44:45

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User entered '1'	System	09 Mar 2021 20:43:42

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:44:45

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered missing code ND - Not Done.	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 20:44:49

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:44:45

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered missing code ND - Not Done.	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 20:44:49

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:44:45

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User entered empty.	System	09 Mar 2021 20:44:49
DataPoint set to visible.	System	09 Mar 2021 20:43:42

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:44:45

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered missing code ND - Not Done.	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 20:44:49

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:44:45

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered missing code ND - Not Done.	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 20:44:49

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:44:45

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User entered empty.	System	09 Mar 2021 20:44:49
DataPoint set to visible.	System	09 Mar 2021 20:43:42

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User accepted default value 'Pre-Dose (PREDOSE)'	Kim Calloway (b) (4) (b) (4)	09 Mar 2021 20:44:49

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 20:44:49

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered '09 Mar 2021'	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 20:44:49

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered '13:45'	(b) (4) Kim Calloway (b) (4) (b) (4)	09 Mar 2021 20:44:49

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User entered '09 Mar 2021 13:45'	System	09 Mar 2021 20:44:49

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered '97.4' F	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 20:44:49

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Oral (Oral)'	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 20:44:49

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered empty.	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 20:44:49

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered '60'	(b) (4) Kim Calloway (b) (4) (b) (4)	09 Mar 2021 20:44:49

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User entered 'bpm'	System	09 Mar 2021 20:44:49

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered '16'	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 20:44:49

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User entered 'breaths/min'	System	09 Mar 2021 20:44:49

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered '144'	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 20:44:49

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User entered 'mmHg'	System	09 Mar 2021 20:44:49

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered '80'	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 20:44:49

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User entered 'mmHg'	System	09 Mar 2021 20:44:49

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:44:45

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered missing code ND - Not Done.	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 20:44:49

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:44:45

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered missing code ND - Not Done.	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 20:44:49

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:44:45

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User entered empty.	System	09 Mar 2021 20:44:49
DataPoint set to visible.	System	09 Mar 2021 20:43:42

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User accepted default value 'Post-Dose (POSTDOSE)'	Kim Calloway (b) (4) (b) (4)	09 Mar 2021 21:43:55

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 21:43:55

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered '09 Mar 2021'	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 21:43:55

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered '14:55'	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 21:43:55

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User entered '09 Mar 2021 14:55'	System	09 Mar 2021 21:43:55

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered '98.7' F	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 21:43:55

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Oral (Oral)'	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 21:43:55

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered empty.	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 21:43:55

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered '59'	(b) (4) Kim Calloway (b) (4) (b) (4)	09 Mar 2021 21:43:55

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User entered 'bpm'	System	09 Mar 2021 21:43:55

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered '14'	(b) (4) Kim Calloway (b) (4) (b) (4)	09 Mar 2021 21:43:55

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User entered 'breaths/min'	System	09 Mar 2021 21:43:55

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered '131'	(b) (4) Kim Calloway (b) (4) (b) (4)	09 Mar 2021 21:43:55

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User entered 'mmHg'	System	09 Mar 2021 21:43:55

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered '77'	(b) (4) Kim Calloway (b) (4) (b) (4)	09 Mar 2021 21:43:55

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User entered 'mmHg'	System	09 Mar 2021 21:43:55

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:44:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 20:45:03

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:44:45

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered '09 Mar 2021'	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 20:45:03

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:45

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 20:45:32

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:45

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered empty.	(b) (4) Kim Calloway (b) (4) (b) (4)	09 Mar 2021 20:45:32

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:45

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)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered empty.	Kim Calloway (b) (4)	09 Mar 2021 20:45:32

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:45

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User entered 'mRNA-1273'	System	09 Mar 2021 20:45:32
DataPoint set to visible.	System	09 Mar 2021 20:43:42

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:45

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered '09 Mar 2021'	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 20:45:32

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:45

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered '14:24'	(b) (4) Kim Calloway (b) (4) (b) (4)	09 Mar 2021 20:45:32

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:45

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User entered '09 Mar 2021 14:24'	System	09 Mar 2021 20:45:32

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:45

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Kim Calloway (b) (4) (b) (4)	09 Mar 2021 20:45:32

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:45

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User entered 'ONCE'	System	09 Mar 2021 20:45:32

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:45

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User entered 'INTRAMUSCULAR'	System	09 Mar 2021 20:45:32

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:44:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 20:45:47

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:44:45

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered '09 Mar 2021'	(b) (4) Kim Calloway (b) (4) (b) (4)	09 Mar 2021 20:45:47

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:44:45

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered '13:49'	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 20:45:47

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:44:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User entered '09 Mar 2021 13:49'	System	09 Mar 2021 20:45:47

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:44:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 20:45:58

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:44:45

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered '09 Mar 2021'	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 20:45:58

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:44:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered '13:47'	(b) (4) Kim Calloway (b) (4) (b) (4)	09 Mar 2021 20:45:58

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:44:45

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User entered '09 Mar 2021 13:47'	System	09 Mar 2021 20:45:58

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4) (b) (4)	09 Mar 2021 20:46:02

US3452203

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:56
User entered '1'	System	09 Mar 2021 20:46:02

US3452203

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:43
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:31
User entered 'Yes (Y)'	(b) (4) Chalimar Rojo (b) (4) (b) (4)	16 Mar 2021 15:03:55

US3452203

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:43
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:31
User closed query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	16 Mar 2021 15:04:52
Query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	16 Mar 2021 15:04:52
User closed query 'The 'Date of Contact or Contact Attempt' is before the 'Date of updated Informed Consent'. Please review and reconcile.' (Site from System).	System	16 Mar 2021 15:04:52
User entered '16 Mar 2021' reason for change: Data Entry Error	Chalimar Rojo (b) (4)	16 Mar 2021 15:04:52
User opened query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	16 Mar 2021 15:03:55
User opened query 'The 'Date of Contact or Contact Attempt' is before the 'Date of updated Informed Consent'. Please review and reconcile.' (Site from System).	System	16 Mar 2021 15:03:55
User entered '01 Mar 2021'	Chalimar Rojo (b) (4)	16 Mar 2021 15:03:55

US3452203

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:43
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Chalimar Rojo (b) (4)	16 Mar 2021 15:03:55

US3452203

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:44:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:43
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:31
User entered empty.	(b) (4) Chalimar Rojo (b) (4) (b) (4)	16 Mar 2021 15:03:55

US3452203

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:43
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:31
User entered 'Yes (Y)'	(b) (4) Chalimar Rojo (b) (4) (b) (4)	16 Mar 2021 15:06:20

US3452203

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:43
User entered '1'	System	16 Mar 2021 15:06:20

US3452203

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:45

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:43
User entered '1'	System	16 Mar 2021 15:06:20
DataPoint set to visible.	System	16 Mar 2021 15:06:20

US3452203

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
	(b) (4)	
User entered 'Yes (Y)'	Kim Calloway (b) (4)	09 Apr 2021 12:03:27
	(b) (4)	

US3452203

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:45

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
	(b) (4)	
User entered '08 Apr 2021'	Kim Calloway (b) (4)	09 Apr 2021 12:03:27
	(b) (4)	

US3452203

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:45

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
	(b) (4)	
User entered 'Clinic (Clinic)'	Kim Calloway (b) (4)	09 Apr 2021 12:03:27
	(b) (4)	

US3452203

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:44:45

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD29'	System	09 Apr 2021 12:03:27

US3452203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Kim Calloway (b) (4) (b) (4)	09 Apr 2021 12:04:07

US3452203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
	(b) (4)	
User entered 'Yes (Y)'	Kim Calloway (b) (4)	09 Apr 2021 12:04:07
	(b) (4)	

US3452203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
	(b) (4)	
User entered '08 Apr 2021'	Kim Calloway (b) (4)	09 Apr 2021 12:04:07
	(b) (4)	

US3452203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
	(b) (4)	
User entered '13:35'	Kim Calloway (b) (4)	09 Apr 2021 12:04:07
	(b) (4)	

US3452203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '08 Apr 2021 13:35'	System	09 Apr 2021 12:04:07

US3452203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
	(b) (4)	
User entered '97.9' F	Kim Calloway (b) (4)	09 Apr 2021 12:04:07
	(b) (4)	

US3452203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
	(b) (4)	
User entered 'Oral (Oral)'	Kim Calloway (b) (4)	09 Apr 2021 12:04:07
	(b) (4)	

US3452203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
	(b) (4)	
User entered empty.	Kim Calloway (b) (4)	09 Apr 2021 12:04:07
	(b) (4)	

US3452203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
	(b) (4)	
User entered '67'	Kim Calloway (b) (4)	09 Apr 2021 12:04:07
	(b) (4)	

US3452203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	09 Apr 2021 12:04:07

US3452203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
	(b) (4)	
User entered '14'	Kim Calloway (b) (4)	09 Apr 2021 12:04:07
	(b) (4)	

US3452203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	09 Apr 2021 12:04:07

US3452203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
	(b) (4)	
User entered '140'	Kim Calloway (b) (4)	09 Apr 2021 12:04:07
	(b) (4)	

US3452203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Apr 2021 12:04:07

US3452203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
	(b) (4)	
User entered '66'	Kim Calloway (b) (4)	09 Apr 2021 12:04:07
	(b) (4)	

US3452203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:44:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Apr 2021 12:04:07

US3452203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Kim Calloway (b) (4) (b) (4)	09 Apr 2021 12:04:56

US3452203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
	(b) (4)	
User entered 'Yes (Y)'	Kim Calloway (b) (4)	09 Apr 2021 12:04:56
	(b) (4)	

US3452203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
	(b) (4)	
User entered '08 Apr 2021'	Kim Calloway (b) (4)	09 Apr 2021 12:04:56
	(b) (4)	

US3452203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
	(b) (4)	
User entered '14:24'	Kim Calloway (b) (4)	09 Apr 2021 12:04:56
	(b) (4)	

US3452203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '08 Apr 2021 14:24'	System	09 Apr 2021 12:04:56

US3452203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
	(b) (4)	
User entered '98.1' F	Kim Calloway (b) (4)	09 Apr 2021 12:04:56
	(b) (4)	

US3452203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
	(b) (4)	
User entered 'Oral (Oral)'	Kim Calloway (b) (4)	09 Apr 2021 12:04:56
	(b) (4)	

US3452203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
	(b) (4)	
User entered empty.	Kim Calloway (b) (4)	09 Apr 2021 12:04:56
	(b) (4)	

US3452203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
	(b) (4)	
User entered '58'	Kim Calloway (b) (4)	09 Apr 2021 12:04:56
	(b) (4)	

US3452203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	09 Apr 2021 12:04:56

US3452203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
	(b) (4)	
User entered '16'	Kim Calloway (b) (4)	09 Apr 2021 12:04:56
	(b) (4)	

US3452203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	09 Apr 2021 12:04:56

US3452203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
	(b) (4)	
User entered '132'	Kim Calloway (b) (4)	09 Apr 2021 12:04:56
	(b) (4)	

US3452203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Apr 2021 12:04:56

US3452203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
	(b) (4)	
User entered '68'	Kim Calloway (b) (4)	09 Apr 2021 12:04:56
	(b) (4)	

US3452203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:44:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Apr 2021 12:04:56

US3452203

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:44:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
	(b) (4)	
User entered 'Yes (Y)'	Kim Calloway (b) (4)	09 Apr 2021 12:05:39
	(b) (4)	

US3452203

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:44:45

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
	(b) (4)	
User entered '08 Apr 2021'	Kim Calloway (b) (4)	09 Apr 2021 12:05:39
	(b) (4)	

US3452203

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:45

[Was study treatment given?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
	(b) (4)	
User entered 'Yes (Y)'	Kim Calloway (b) (4)	09 Apr 2021 12:05:52
	(b) (4)	

US3452203

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:45

[If No, reason not given](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
	(b) (4)	
User entered empty.	Kim Calloway (b) (4)	09 Apr 2021 12:05:52
	(b) (4)	

US3452203

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:45

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
	(b) (4)	
User entered empty.	Kim Calloway (b) (4)	09 Apr 2021 12:05:52
	(b) (4)	

US3452203

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:45

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
User entered 'mRNA-1273'	System	09 Apr 2021 12:05:52
DataPoint set to visible.	System	16 Mar 2021 15:06:20

US3452203

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:45

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
	(b) (4)	
User entered '08 Apr 2021'	Kim Calloway (b) (4)	09 Apr 2021 12:05:52
	(b) (4)	

US3452203

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:45

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
	(b) (4)	
User entered '13:53'	Kim Calloway (b) (4)	09 Apr 2021 12:05:52
	(b) (4)	

US3452203

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:45

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '08 Apr 2021 13:53'	System	09 Apr 2021 12:05:52

US3452203

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:45

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Kim Calloway (b) (4)	09 Apr 2021 12:05:52
	(b) (4)	

US3452203

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:45

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	09 Apr 2021 12:05:52

US3452203

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:44:45

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	09 Apr 2021 12:05:52

US3452203

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
	(b) (4)	
User entered 'Yes (Y)'	Kim Calloway (b) (4)	09 Apr 2021 12:05:56
	(b) (4)	

US3452203

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:44:45

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 12:05:56

US3452203

Folder: **Unscheduled 18 Jan 2021**

Form: **Unscheduled Visit Assessment**

Generated On: **11 Aug 2021 22:44:45**

[Visit Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:31
User entered '18 Jan 2021'	(b) (4) Chalimar Rojo (b) (4)	23 Feb 2021 18:58:23
	(b) (4)	

US3452203

Folder: **Unscheduled 18 Jan 2021**

Form: **Unscheduled Visit Assessment**

Generated On: **11 Aug 2021 22:44:45**

[Physical Exam](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:31
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Chalimar Rojo (b) (4)	23 Feb 2021 18:58:55
	(b) (4)	
User closed query 'Procedure(s) performed is missing. Please check at least one procedure from the options provided.' (Site from System).	System	23 Feb 2021 18:58:48
User entered '1' reason for change: Data Entry Error	Chalimar Rojo (b) (4)	23 Feb 2021 18:58:48
	(b) (4)	
User opened query 'Procedure(s) performed is missing. Please check at least one procedure from the options provided.' (Site from System).	System	23 Feb 2021 18:58:23
User entered '0'	Chalimar Rojo (b) (4)	23 Feb 2021 18:58:23
	(b) (4)	

US3452203

Folder: **Unscheduled 18 Jan 2021**

Form: **Unscheduled Visit Assessment**

Generated On: **11 Aug 2021 22:44:45**

[Vital Signs](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:31
	(b) (4)	
User entered '0'	Chalimar Rojo (b) (4)	23 Feb 2021 18:58:23
	(b) (4)	

US3452203

Folder: **Unscheduled 18 Jan 2021**

Form: **Unscheduled Visit Assessment**

Generated On: **11 Aug 2021 22:44:45**

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Query ' PER CDM: Immunogenicity marked as 'ASSESSED', however form is blank. Please review form and update else clarify' answered with 'UNSCHEDULED VISIT WAS FOR NASAL SWAB ONLY. THERE IN NO OPTION FOR ONLY NASAL SWAB SO PHYSICAL EXAM WAS SELECTED TO CLOSE THE QUERY' (Site from DM).	Chalimar Rojo (b) (4) (b) (4)	03 May 2021 14:52:22
User opened query ' PER CDM: Immunogenicity marked as 'ASSESSED', however form is blank. Please review form and update else clarify' (Site from DM).	(b) (4), (b) (6)	30 Apr 2021 18:08:37
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:38:31
User entered '1' reason for change: Data Entry Error	Chalimar Rojo (b) (4) (b) (4)	23 Feb 2021 18:58:55
User entered '0'	Chalimar Rojo (b) (4) (b) (4)	23 Feb 2021 18:58:23

US3452203

Folder: **Unscheduled 18 Jan 2021**

Form: **Unscheduled Visit Assessment**

Generated On: **11 Aug 2021 22:44:45**

[Pregnancy Test](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:31
User entered '0'	(b) (4) Chalimar Rojo (b) (4)	23 Feb 2021 18:58:23
	(b) (4)	

US3452203

Folder: **Unscheduled 23 Feb 2021**

Form: **Unscheduled Visit Assessment**

Generated On: **11 Aug 2021 22:44:45**

[Visit Date](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 23FEB2021 is recorded under Unscheduled visit in PPD Central lab, however the same collection date is recorded in Covid-19 Assessments and corresponding visit details not updated in EDC. Please reconcile the data and amend EDC or Preclarus as appropriate. Thank you.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	26 Apr 2021 10:22:58
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 23FEB2021 is recorded under Unscheduled visit in PPD Central lab, however the same collection date is recorded in Covid-19 Assessments and corresponding visit details not updated in EDC. Please reconcile the data and amend EDC or Preclarus as appropriate. Thank you.' answered with 'cc' (Site from DM).	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:38:31
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 23FEB2021 is recorded under Unscheduled visit in PPD Central lab, however the same collection date is recorded in Covid-19 Assessments and corresponding visit details not updated in EDC. Please reconcile the data and amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).	Chalimar Rojo (b) (4) (b) (4)	15 Apr 2021 15:55:39
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 23-FEB-2021 is reported under Illness Visit Day 1 in PPD portal; however, corresponding swab sample is missing in EDC for 23-FEB-2021. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating separate Covid -19 Assessment eCRF for the corresponding date and updating swab data in the Covid Diagnostic Test eCRF as there is no provision to capture Unscheduled sample in Unscheduled eCRF, else clarify. ' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 10:32:15
	(b) (4), (b) (6)	16 Mar 2021 10:27:53

US3452203

Folder: **Unscheduled 23 Feb 2021**

Form: **Unscheduled Visit Assessment**

Generated On: **11 Aug 2021 22:44:45**

[Visit Date](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 23-FEB-2021 is reported under Illness Visit Day 1 in PPD portal; however, corresponding swab sample is missing in EDC for 23-FEB-2021. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating separate Covid -19 Assessment eCRF for the corresponding date and updating swab data in the Covid Diagnostic Test eCRF as there is no provision to capture Unscheduled sample in Unscheduled eCRF, else clarify. ' answered with 'Swab for date 02/23/21 is an unscheduled nasal swab NOT illness visit' (Site from DM).	Chalimar Rojo (b) (4) (b) (4)	15 Mar 2021 19:47:22
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 23-FEB-2021 is reported under Illness Visit Day 1 in PPD portal; however, corresponding swab sample is missing in EDC for 23-FEB-2021. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating separate Covid -19 Assessment eCRF for the corresponding date and updating swab data in the Covid Diagnostic Test eCRF as there is no provision to capture Unscheduled sample in Unscheduled eCRF, else clarify. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 10:23:23
User entered '23 Feb 2021'	Chalimar Rojo (b) (4) (b) (4)	23 Feb 2021 18:59:59

US3452203

Folder: **Unscheduled 23 Feb 2021**

Form: **Unscheduled Visit Assessment**

Generated On: **11 Aug 2021 22:44:45**

[Physical Exam](#)

Audit	User	Time (GMT)
Query 'PER CDM: Physical Exam marked as 'ASSESSED', however form is blank. Please review form and update else clarify. ' answered with 'UNSCHEDULED VISIT WAS FOR NASAL SWAB ONLY. THERE IN NO OPTION FOR ONLY NASAL SWAB SO PHYSICAL EXAM WAS SELECTED TO CLOSE THE QUERY' (Site from DM).	Chalimar Rojo (b) (4) (b) (4)	03 May 2021 14:48:46
User opened query 'PER CDM: Physical Exam marked as 'ASSESSED', however form is blank. Please review form and update else clarify. ' (Site from DM).	(b) (4), (b) (6)	30 Apr 2021 18:07:52
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:38:31
User closed query 'Procedure(s) performed is missing. Please check at least one procedure from the options provided.' (Site from System).	System	08 Mar 2021 01:56:23
User entered '1' reason for change: Data Entry Error	Chalimar Rojo (b) (4) (b) (4)	08 Mar 2021 01:56:23
User opened query 'Procedure(s) performed is missing. Please check at least one procedure from the options provided.' (Site from System).	System	23 Feb 2021 18:59:59
User entered '0'	Chalimar Rojo (b) (4) (b) (4)	23 Feb 2021 18:59:59

US3452203

Folder: **Unscheduled 23 Feb 2021**

Form: **Unscheduled Visit Assessment**

Generated On: **11 Aug 2021 22:44:45**

[Vital Signs](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:31
	(b) (4)	
User entered '0'	Chalimar Rojo (b) (4)	23 Feb 2021 18:59:59
	(b) (4)	

US3452203

Folder: **Unscheduled 23 Feb 2021**

Form: **Unscheduled Visit Assessment**

Generated On: **11 Aug 2021 22:44:45**

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:31
	(b) (4)	
User entered '0'	Chalimar Rojo (b) (4)	23 Feb 2021 18:59:59
	(b) (4)	

US3452203

Folder: **Unscheduled 23 Feb 2021**

Form: **Unscheduled Visit Assessment**

Generated On: **11 Aug 2021 22:44:45**

[Pregnancy Test](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:31
	(b) (4)	
User entered '0'	Chalimar Rojo (b) (4)	23 Feb 2021 18:59:59
	(b) (4)	

US3452203

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:44:45

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:01:43
User closed query 'Per DM CLR: Per Day 222 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 13:48:32
Query 'Per DM CLR: Per Day 222 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'cc' (Site from DM).	Chalimar Rojo (b) (4) (b) (4)	31 Mar 2021 20:58:25
User opened query 'Per DM CLR: Per Day 222 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 12:46:30
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	13 Mar 2021 17:15:42
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 17:17:21
User entered 'Yes (Y)'	April Green (b) (4) (b) (4)	20 Nov 2020 21:56:34

US3452203

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:45

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:15:42
DataPoint Verified.	(b) (4)	03 Dec 2020 18:53:09
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 17:11:02
User entered 'USA-US208-2020-mRNA-1273-P301000010'	System	01 Dec 2020 17:10:56
User entered 'New'	(b) (4), (b) (6)	01 Dec 2020 17:10:56

US3452203

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:45

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:15:42
DataPoint Verified.	(b) (4)	23 Nov 2020 20:59:56
	(b) (4), (b) (6)	
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)	20 Nov 2020 21:59:03
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Nov 2020 21:59:03
	(b) (4)	
Data point term sent to Coder	System	20 Nov 2020 21:58:32
User entered 'COVID 19'	April Green (b) (4)	20 Nov 2020 21:58:15
	(b) (4)	

US3452203

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:59:56
User closed query 'Please reconcile as per protocol an illness visit = MAAE' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 15:28:02
Query 'Please reconcile as per protocol an illness visit = MAAE' answered with 'updated' (Site from CRA).	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 14:27:22
User entered 'Yes (Y)' reason for change: Data Entry Error	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 14:27:16
User opened query 'Please reconcile as per protocol an illness visit = MAAE' (Site from CRA).	(b) (4), (b) (6)	21 Nov 2020 17:26:48
User entered 'No (N)'	April Green (b) (4) (b) (4)	20 Nov 2020 21:58:15

US3452203

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:59:56
User entered 'No (N)'	April Green (b) (4) (b) (4)	20 Nov 2020 21:58:15

US3452203

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:59:56
User closed query 'Please reconcile as positive illness results received' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 15:28:04
Query 'Please reconcile as positive illness results received' answered with 'updated' (Site from CRA).	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 14:27:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 14:27:16
User opened query 'Please reconcile as positive illness results received' (Site from CRA).	(b) (4), (b) (6)	21 Nov 2020 17:27:00
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 21:58:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 21:58:33
User entered 'No (N)' reason for change: Data Entry Error	April Green (b) (4) (b) (4)	20 Nov 2020 21:58:33
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 21:58:15
User entered empty.	April Green (b) (4) (b) (4)	20 Nov 2020 21:58:15

US3452203

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:59:56
User entered '17 Nov 2020'	April Green (b) (4) (b) (4)	20 Nov 2020 21:58:15

US3452203

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:45

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:59:56
User entered empty.	April Green (b) (4) (b) (4)	20 Nov 2020 21:58:15

US3452203

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 21:58:15

US3452203

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:41:58
DataPoint Un-verified.	Chalimar Rojo (b) (4) (b) (4)	11 Dec 2020 18:20:12
User entered 'No (N)' reason for change: Data Entry Error	Chalimar Rojo (b) (4) (b) (4)	11 Dec 2020 18:20:12
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:59:56
User entered 'Yes (Y)'	April Green (b) (4) (b) (4)	20 Nov 2020 21:58:15

US3452203

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:15:42
DataPoint Verified.	(b) (4)	15 Dec 2020 16:41:58
	(b) (4), (b) (6)	
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 15:31:27
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	14 Dec 2020 05:11:44
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'date added' (Site from System).	Chalimar Rojo (b) (4)	11 Dec 2020 18:20:35
	(b) (4)	
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).	Chalimar Rojo (b) (4)	11 Dec 2020 18:20:22
	(b) (4)	
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	11 Dec 2020 18:20:12
DataPoint Un-verified.	Chalimar Rojo (b) (4)	11 Dec 2020 18:20:12
	(b) (4)	
User entered '25 Nov 2020' reason for change: Data Entry Error	Chalimar Rojo (b) (4)	11 Dec 2020 18:20:12
	(b) (4)	
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 17:17:16
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:59:56
	(b) (4)	
User entered empty.	April Green (b) (4)	20 Nov 2020 21:58:15
	(b) (4)	

US3452203

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:45

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:59:56
User entered empty.	April Green (b) (4) (b) (4)	20 Nov 2020 21:58:15

US3452203

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 21:58:15

US3452203

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:45

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:15:42
DataPoint Verified.	(b) (4)	23 Nov 2020 20:59:56
	(b) (4), (b) (6)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Chalimar Rojo (b) (4)	23 Nov 2020 15:26:37
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	April Green (b) (4)	20 Nov 2020 21:58:15
	(b) (4)	

US3452203

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:59:56
User entered 'No (N)'	April Green (b) (4) (b) (4)	20 Nov 2020 21:58:15

US3452203

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:45

Death

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:59:56
User entered '0'	April Green (b) (4) (b) (4)	20 Nov 2020 21:58:15

US3452203

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:59:56
User entered '0'	April Green (b) (4) (b) (4)	20 Nov 2020 21:58:15

US3452203

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:59:56
User entered '0'	April Green (b) (4) (b) (4)	20 Nov 2020 21:58:15

US3452203

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:59:56
User entered empty.	April Green (b) (4) (b) (4)	20 Nov 2020 21:58:15

US3452203

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:45

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:59:56
User entered empty.	April Green (b) (4) (b) (4)	20 Nov 2020 21:58:15

US3452203

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:59:56
User entered empty.	April Green (b) (4) (b) (4)	20 Nov 2020 21:58:15

US3452203

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:59:56
User entered empty.	April Green (b) (4) (b) (4)	20 Nov 2020 21:58:15

US3452203

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:59:56
User entered '0'	April Green (b) (4) (b) (4)	20 Nov 2020 21:58:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:59:56
User entered '0'	April Green (b) (4) (b) (4)	20 Nov 2020 21:58:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:59:56
User entered '0'	April Green (b) (4) (b) (4)	20 Nov 2020 21:58:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:59:56
User entered 'Not Related (NOT RELATED)'	April Green (b) (4) (b) (4)	20 Nov 2020 21:58:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:59:56
User entered 'Not Related (NOT RELATED)'	April Green (b) (4) (b) (4)	20 Nov 2020 21:58:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:45

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:59:56
User entered 'Not Applicable (NOT APPLICABLE)'	April Green (b) (4) (b) (4)	20 Nov 2020 21:58:15

US3452203

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:45

None

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:15:42
DataPoint Verified.	(b) (4)	23 Nov 2020 20:59:56
	(b) (4), (b) (6)	
User entered '0' reason for change: Data Entry Error	Chalimar Rojo (b) (4)	23 Nov 2020 14:27:16
	(b) (4)	
User entered '1'	April Green (b) (4)	20 Nov 2020 21:58:15
	(b) (4)	

US3452203

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:15:42
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Dec 2020 05:12:50
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'cm added' (Site from DM).	Chalimar Rojo (b) (4) (b) (4)	11 Dec 2020 18:20:53
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 06:33:19
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:59:56
User entered '1' reason for change: Data Entry Error	Chalimar Rojo (b) (4) (b) (4)	23 Nov 2020 14:27:16
User entered '0'	April Green (b) (4) (b) (4)	20 Nov 2020 21:58:15

US3452203

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:59:56
User entered '0'	April Green (b) (4) (b) (4)	20 Nov 2020 21:58:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:45

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:15:42
DataPoint Verified.	(b) (4)	15 Dec 2020 16:41:58
	(b) (4), (b) (6)	
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)	14 Dec 2020 15:31:34
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).	Chalimar Rojo (b) (4)	11 Dec 2020 18:21:07
DataPoint Un-verified.	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Chalimar Rojo (b) (4)	11 Dec 2020 18:21:01
Data Entry Error	(b) (4)	
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)	08 Dec 2020 17:17:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:59:56
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 21:58:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 21:58:33
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	April Green (b) (4)	20 Nov 2020 21:58:33
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 21:58:15
User entered empty.	April Green (b) (4)	20 Nov 2020 21:58:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:45

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:59:56
User entered empty.	April Green (b) (4) (b) (4)	20 Nov 2020 21:58:15

US3452203

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:45

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:15:42
DataPoint Verified.	(b) (4)	15 Dec 2020 16:41:58
	(b) (4), (b) (6)	
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 15:31:48
User closed query 'PV query: The subject has medical history of hypocholesterolemia and ezetimibe is prescribed. Does the subject have hypocholesterolemia or hypercholesterolemia?' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 15:31:43
Query 'PV query: The subject has medical history of hypocholesterolemia and ezetimibe is prescribed. Does the subject have hypocholesterolemia or hypercholesterolemia?' answered with 'HYPERCHOLESTEROLEMIA' (Site from Safety).	Chalimar Rojo (b) (4)	11 Dec 2020 18:22:09
	(b) (4)	
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'updated' (Site from Safety).	Chalimar Rojo (b) (4)	11 Dec 2020 18:21:58
	(b) (4)	
DataPoint Un-verified.	Chalimar Rojo (b) (4)	11 Dec 2020 18:21:53
	(b) (4)	
User entered 'SUBJECT CAME TO SITE WITH SYMPTOMS OF COVID. ILLNESS VISIT WAS CONDUCTED. SUBJECT IS COVID POSITIVE. SUBJECT COMPLETING CONVALESCENT ILLNESS VISITS. CM started and added to EDC.' reason for change: Data Entry Error	Chalimar Rojo (b) (4)	11 Dec 2020 18:21:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:45

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV query: The subject has medical history of hypocholesterolemia and ezetimibe is prescribed. Does the subject have hypocholesterolemia or hypercholesterolemia?' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 17:27:38
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 17:18:09
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:59:56
User entered 'Subject came to site with symptoms of COVID. Illness visit was conducted. SUBJECT IS COVID POSITIVE. Subject completing convalescent illness visits.' reason for change: Data Entry Error	Chalimar Rojo (b) (4)	23 Nov 2020 14:27:16
User entered 'SUBJECT COVID POSITIVE'	April Green (b) (4)	20 Nov 2020 21:58:15

US3452203

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:45

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	20 Nov 2020 21:58:15

US3452203

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:44:45

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	23 Nov 2020 14:27:16
User entered '0'	System	20 Nov 2020 21:58:15

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:44:45

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:01:43
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:42:17
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:43:34

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:44:45

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4)	23 Nov 2020 21:00:26
	(b) (4), (b) (6)	
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: THYROID, PRODUCTSYNONYM: ARMOUR THYROID - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Oct 2020 20:24:25
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Oct 2020 20:24:25
	(b) (4)	
Data point term sent to Coder	System	19 Oct 2020 20:22:59
Coding entries removed.	Kim Calloway (b) (4)	19 Oct 2020 20:22:23
	(b) (4)	
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: THYROID, PRODUCTSYNONYM: ARMOUR THYROID - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Aug 2020 03:57:19
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Aug 2020 03:57:19
	(b) (4)	
Data point term sent to Coder	System	20 Aug 2020 16:45:11
User entered 'ARMOUR THYROID'	Kim Calloway (b) (4)	20 Aug 2020 16:44:23
	(b) (4)	

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:44:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:44:23

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:44:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'HYPOTHYROIDISM' reason for change: Data Entry Error	Kim Calloway (b) (4) (b) (4)	19 Oct 2020 20:22:23
User entered 'HYPORTHYROIDISM'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:44:23

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:44:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered '30'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:44:23

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:44:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'mg (mg)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:44:23

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:44:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:44:23

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:44:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'once daily (QD)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:44:23

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:44:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:44:23

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:44:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'Oral (ORAL)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:44:23

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:44:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:44:23

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:44:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4)	23 Nov 2020 21:00:26
	(b) (4), (b) (6)	
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 02:03:52
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 16:44:23
User entered 'UN UNK 2016'	Kim Calloway (b) (4)	20 Aug 2020 16:44:23
	(b) (4)	

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:44:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered '0'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:44:23

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:44:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:44:23

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:44:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:44:23

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:44:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:44:23

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:44:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 16:44:23

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:44:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 16:44:23

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:44:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 16:44:23

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:44:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 16:45:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 16:45:33
Data point term sent to Coder	System	20 Aug 2020 16:45:11
User entered 'LEVOTHYROXINE'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:45:11

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:44:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:45:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:44:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'HYPOTHYROIDISM'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:45:11

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:44:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered '100'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:45:11

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:44:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User closed query 'Per CDM: MCG is equivalent to UG. Since UG is an option in the drop down, please consider updating Dose Unit to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 19:28:18
Query 'Per CDM: MCG is equivalent to UG. Since UG is an option in the drop down, please consider updating Dose Unit to the available equivalent rather than Other. Thank you.' answered with '.' (Site from DM).	Kim Calloway (b) (4) (b) (4)	17 Sep 2020 22:23:09
User entered 'ug (ug)' reason for change: Per Query Resolution	Kim Calloway (b) (4) (b) (4)	17 Sep 2020 22:23:05
User opened query 'Per CDM: MCG is equivalent to UG. Since UG is an option in the drop down, please consider updating Dose Unit to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 15:23:57
User entered 'Other (OTHER)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:45:11

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:44:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty; reason for change Data Entry Error	Kim Calloway (b) (4) (b) (4)	17 Sep 2020 22:23:05
User entered 'MCG'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:45:11

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:44:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'once daily (QD)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:45:11

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:44:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:45:11

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:44:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'Oral (ORAL)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:45:11

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:44:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:45:11

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:44:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 02:03:52
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 16:45:11
User entered 'UN UNK 1970'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:45:11

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:44:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered '0'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:45:11

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:44:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:45:11

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:44:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:45:11

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:44:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:45:11

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:44:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 16:45:11

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:44:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 16:45:11

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:44:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 16:45:11

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:44:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: ALDOSTERONE ANTAGONISTS, PRODUCT: SPIRONOLACTONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 09:43:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 09:43:13
Data point term sent to Coder	System	20 Aug 2020 16:47:17
User entered 'SPIRONOLACTONE'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:46:17

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:44:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:46:17

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:44:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 14:51:36
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with '! (Site from DM).	Kim Calloway (b) (4) (b) (4)	06 Oct 2020 20:53:47
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 08:58:01
User entered 'HIGH BLOOD PRESSURE'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:46:17

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:44:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered '50'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:46:17

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:44:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'mg (mg)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:46:17

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:44:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:46:17

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:44:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'once daily (QD)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:46:17

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:44:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:46:17

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:44:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'Oral (ORAL)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:46:17

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:44:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:46:17

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:44:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 02:03:52
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 16:46:17
User entered 'UN UNK 2016'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:46:17

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:44:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered '0'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:46:17

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:44:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:46:17

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:44:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:46:17

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:44:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:46:17

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:44:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 16:46:17

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:44:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 16:46:17

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:44:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 16:46:17

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:44:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 16:48:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 16:48:25
Data point term sent to Coder	System	20 Aug 2020 16:47:18
User entered 'PANTOPRAZOLE'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:47:00

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:44:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:47:00

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:44:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'GERD'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:47:00

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:44:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered '40'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:47:00

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:44:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'mg (mg)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:47:00

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:44:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:47:00

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:44:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'once daily (QD)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:47:00

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:44:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:47:00

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:44:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'Oral (ORAL)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:47:00

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:44:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:47:00

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:44:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4)	23 Nov 2020 21:00:26
	(b) (4), (b) (6)	
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 02:03:52
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 16:47:00
User entered 'UN UNK 2016'	Kim Calloway (b) (4)	20 Aug 2020 16:47:00
	(b) (4)	

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:44:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered '0'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:47:00

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:44:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:47:00

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:44:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:47:00

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:44:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:47:00

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:44:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 16:47:00

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:44:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 16:47:00

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:44:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 16:47:00

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:44:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
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: DICLOFENAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 12:38:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 12:38:14
Data point term sent to Coder User entered 'DICLOFENIC'	System Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:48:22 20 Aug 2020 16:47:45

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:44:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:47:45

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:44:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'OSTEOARTHRITIS'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:47:45

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:44:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered '25'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:47:45

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:44:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'mg (mg)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:47:45

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:44:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:47:45

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:44:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'twice daily (BID)' reason for change: Data Entry Error	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:48:49
User entered 'once daily (QD)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:47:45

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:44:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:47:45

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:44:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'Oral (ORAL)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:47:45

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:44:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:47:45

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:44:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 02:03:52
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 16:47:45
User entered 'UN UNK 2018'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:47:45

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:44:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered '0'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:47:45

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:44:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:47:45

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:44:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:47:45

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:44:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:47:45

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:44:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	20 Aug 2020 16:48:49
User entered '1'	System	20 Aug 2020 16:47:45

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:44:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 16:47:45

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:44:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 16:47:45

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:44:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTI-PARKINSON DRUGS, ATC: DOPAMINERGIC AGENTS, ATC: DOPAMINE AGONISTS, PRODUCT: ROPINIROLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 10:15:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 10:15:17
Data point term sent to Coder	System	20 Aug 2020 16:49:25
User entered 'RAPINIROLE'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:48:35

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:44:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:48:35

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:44:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'RLS'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:48:35

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:44:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 16:00:09
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'UPDATED' (Site from DM).	Chalimar Rojo (b) (4) (b) (4)	09 Oct 2020 14:41:14
User entered '.25' reason for change: Data Entry Error	Chalimar Rojo (b) (4) (b) (4)	09 Oct 2020 14:41:09
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 08:48:43
User entered '25'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:48:35

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:44:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'mg (mg)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:48:35

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:44:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:48:35

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:44:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'twice daily (BID)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:48:35

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:44:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:48:35

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:44:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'Oral (ORAL)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:48:35

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:44:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:48:35

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:44:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 02:03:52
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 16:48:35
User entered 'UN UNK 2015'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:48:35

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:44:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered '0'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:48:35

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:44:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:48:35

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:44:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:48:35

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:44:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:48:35

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:44:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	20 Aug 2020 16:48:35

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:44:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 16:48:35

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:44:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 16:48:35

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:44:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 21:00:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Aug 2020 17:00:36
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Aug 2020 17:00:36
	(b) (4)	
Data point term sent to Coder	System	20 Aug 2020 16:58:50
User entered 'TRAMADOL'	Kim Calloway (b) (4)	20 Aug 2020 16:57:56
	(b) (4)	

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:44:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:57:56

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:44:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'OSTEOARTHRITIS'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:57:56

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:44:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered '100'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:57:56

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:44:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'mg (mg)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:57:56

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:44:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:57:56

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:44:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'once daily (QD)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:57:56

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:44:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:57:56

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:44:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'Oral (ORAL)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:57:56

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:44:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:57:56

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:44:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 02:03:52
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 16:57:56
User entered 'UN UNK 2017'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:57:56

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:44:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered '0'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:57:56

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:44:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:57:56

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:44:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:57:56

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:44:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 16:57:56

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:44:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 16:57:56

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:44:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 16:57:56

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:44:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 16:57:56

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:44:45

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 08:36:23
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 Oct 2020 08:36:23
Data point term sent to Coder Coding entries removed.	System Chalimar Rojo (b) (4) (b) (4)	23 Oct 2020 16:19:32 23 Oct 2020 16:19:20
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 17:05:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 17:05:26
Data point term sent to Coder User entered 'GABAPENTIN'	System Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:04:00 20 Aug 2020 17:03:35

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:44:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:03:35

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:44:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User closed query 'Per DM CLR: Please update the indication and clarify the type and location of the NEUROPATHY (i.e. sensory or motor; Bilateral, left, Right; Arm or legs). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 01:58:03
Query 'Per DM CLR: Please update the indication and clarify the type and location of the NEUROPATHY (i.e. sensory or motor; Bilateral, left, Right; Arm or legs). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'updated' (Site from DM).	Chalimar Rojo (b) (4) (b) (4)	23 Oct 2020 16:19:24
User entered 'sensory NEUROPATHY of bilateral extremities' reason for change: Data Entry Error	Chalimar Rojo (b) (4) (b) (4)	23 Oct 2020 16:19:20
User opened query 'Per DM CLR: Please update the indication and clarify the type and location of the NEUROPATHY (i.e. sensory or motor; Bilateral, left, Right; Arm or legs). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 18:32:57
User entered 'NEUROPATHY'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:03:35

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:44:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered '100'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:03:35

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:44:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'mg (mg)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:03:35

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:44:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:03:35

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:44:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'twice daily (BID)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:03:35

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:44:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:03:35

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:44:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'Oral (ORAL)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:03:35

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:44:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:03:35

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:44:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4)	23 Nov 2020 21:00:26
	(b) (4), (b) (6)	
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 02:03:52
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 17:03:35
User entered 'UN UNK 2017'	Kim Calloway (b) (4)	20 Aug 2020 17:03:35
	(b) (4)	

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:44:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered '0'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:03:35

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:44:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:03:35

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:44:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:03:35

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:44:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:03:35

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:44:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	20 Aug 2020 17:03:35

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:44:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 17:03:35

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:44:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 17:03:35

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:44:45

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE, PRODUCTSYNONYM: CLARITIN [LORATADINE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 12:41:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 12:41:51
Data point term sent to Coder Coding entries removed.	System Kim Calloway (b) (4) (b) (4)	22 Oct 2020 12:40:44 22 Oct 2020 12:39:57
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE, PRODUCTSYNONYM: CLARITIN [LORATADINE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 16:14:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 16:14:35
Data point term sent to Coder Coding entries removed.	System Kim Calloway (b) (4) (b) (4)	24 Aug 2020 16:14:12 24 Aug 2020 16:14:08

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:44:45

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE, PRODUCTSYNONYM: CLARITIN [LORATADINE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Aug 2020 17:16:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Aug 2020 17:16:19
Data point term sent to Coder	System	20 Aug 2020 17:15:33
User entered 'CLARITIN'	Kim Calloway (b) (4)	20 Aug 2020 17:14:59

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:44:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:14:59

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:44:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of ALLERGIES. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 08:18:33
Query 'Per DM CLR: Please update the indication to reflect the location and type of ALLERGIES. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with '.' (Site from DM).	Kim Calloway (b) (4) (b) (4)	22 Oct 2020 12:40:02
User entered 'SEASONAL ALLERGIES' reason for change: Data Entry Error	Kim Calloway (b) (4) (b) (4)	22 Oct 2020 12:39:57
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of ALLERGIES. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 18:03:43
User entered 'ALLERGIES'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:14:59

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:44:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered '10'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:14:59

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:44:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'mg (mg)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:14:59

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:44:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:14:59

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:44:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'once daily (QD)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:14:59

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:44:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:14:59

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:44:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4)	23 Nov 2020 21:00:26
	(b) (4), (b) (6)	
User closed query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	System	24 Aug 2020 16:14:08
User opened query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	System	20 Aug 2020 17:14:59
User entered 'Oral (ORAL)'	Kim Calloway (b) (4)	20 Aug 2020 17:14:59
	(b) (4)	

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:44:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty; reason for change Data Entry Error	Kim Calloway (b) (4) (b) (4)	24 Aug 2020 16:14:08
User entered '	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:14:59

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:44:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4)	23 Nov 2020 21:00:26
	(b) (4), (b) (6)	
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 02:03:52
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 17:14:59
User entered 'UN UNK 2015'	Kim Calloway (b) (4)	20 Aug 2020 17:14:59
	(b) (4)	

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:44:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered '0'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:14:59

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:44:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:14:59

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:44:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:14:59

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:44:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:14:59

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:44:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 17:14:59

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:44:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 17:14:59

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:44:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 17:14:59

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:44:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: EZETIMIBE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 17:17:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 17:17:26
Data point term sent to Coder	System	20 Aug 2020 17:16:33
User entered 'EZETIMIBE'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:15:50

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:44:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:15:50

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:44:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'HIGH CHOLESTEROL'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:15:50

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:44:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered '10'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:15:50

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:44:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'mg (mg)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:15:50

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:44:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:15:50

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:44:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'once daily (QD)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:15:50

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:44:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:15:50

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:44:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'Oral (ORAL)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:15:50

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:44:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:15:50

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:44:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4)	23 Nov 2020 21:00:26
	(b) (4), (b) (6)	
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 02:03:52
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 17:15:50
User entered 'UN UNK 2015'	Kim Calloway (b) (4)	20 Aug 2020 17:15:50
	(b) (4)	

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:44:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered '0'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:15:50

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:44:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:15:50

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:44:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:15:50

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:44:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:15:50

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:44:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 17:15:50

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:44:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 17:15:50

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:44:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 17:15:50

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:44:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	24 Nov 2020 06:08:51
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 Nov 2020 06:08:51
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:00:26
Data point term sent to Coder Coding entries removed.	System Kim Calloway (b) (4)	22 Oct 2020 12:38:43 22 Oct 2020 12:38:20
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 17:50:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 17:50:51
Data point term sent to Coder	System	27 Aug 2020 15:40:04
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	27 Aug 2020 15:39:39

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:44:45

[Name of Medication](#)

Audit	User	Time (GMT)
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 'SPELLING IS CORRECT AND INGREDIENTS HAVE BEEN ADDED' (Site from System).	Kim Calloway (b) (4)	27 Aug 2020 15:39:39
User entered 'GOLDEN REVIVE (TUMERIC, BROMELAIN, BOSWELLIA, QUERCETIN, MAGNESIUM, PIPERINE)' reason for change: Data Entry Error	Kim Calloway (b) (4)	27 Aug 2020 15:39:31
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)	26 Aug 2020 06:01:34
Data point term sent to Coder	System	20 Aug 2020 17:16:35
User entered 'GOLDEN REVIVE'	Kim Calloway (b) (4)	20 Aug 2020 17:16:32

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:44:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:16:32

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:44:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of JOINT INFLAMMATION. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 01:33:03
Query 'Per DM CLR: Please update the indication to reflect the location and type of JOINT INFLAMMATION. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'OA IS ALREADY IN MH' (Site from DM).	Kim Calloway (b) (4) (b) (4)	22 Oct 2020 12:38:35
User entered 'JOINT INFLAMMATION ALL JOINTS DUE TO OA' reason for change: Data Entry Error	Kim Calloway (b) (4) (b) (4)	22 Oct 2020 12:38:20
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of JOINT INFLAMMATION. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 18:33:32
User entered 'JOINT INFLAMMATION'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:16:32

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:44:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered '2'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:16:32

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:44:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'capsule (CAPSULE)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:16:32

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:44:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:16:32

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:44:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'once daily (QD)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:16:32

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:44:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:16:32

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:44:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'Oral (ORAL)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:16:32

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:44:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:16:32

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:44:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 02:03:52
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 17:16:32
User entered 'UN Apr 2020'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:16:32

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:44:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered '0'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:16:32

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:44:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:16:32

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:44:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:16:32

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:44:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:16:32

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:44:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 17:16:32

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:44:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 17:16:32

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:44:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 17:16:32

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:44:45

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
User closed query 'Per ETRTR, According to AE covid 19, subject received concomitant medication but no concomitant medication is entered for COVID 19. Please reconcile.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:42:59
Query 'Per ETRTR, According to AE covid 19, subject received concomitant medication but no concomitant medication is entered for COVID 19. Please reconcile.' answered with 'EDC UPDATED' (Site from CRA).	Chalimar Rojo (b) (4) (b) (4)	11 Dec 2020 18:22:41
User opened query 'Per ETRTR, According to AE covid 19, subject received concomitant medication but no concomitant medication is entered for COVID 19. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	09 Dec 2020 16:55:07
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:00:26
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STERIODS FOR TOPICAL USE, PRODUCT: DICLOFENAC SODIUM - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 12:38:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 12:38:13
Data point term sent to Coder	System	20 Aug 2020 17:18:39
User entered 'DICLOFENAC SODIUM'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:17:40

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:44:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:17:40

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:44:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
Query 'Per DM CLR: Please update the indication to reflect the location and type of OA/JOINT INFLAMMATION. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 18:28:39
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of OA/JOINT INFLAMMATION. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 18:25:36
User entered 'OA/JOINT INFLAMMATION'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:17:40

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:44:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered '1'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:17:40

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:44:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'Other (OTHER)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:17:40

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:44:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'APPLICATION'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:17:40

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:44:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'as needed (PRN)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:17:40

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:44:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:17:40

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:44:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'Topical (TOPICAL)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:17:40

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:44:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:17:40

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:44:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
User closed query 'Per DM CLR: Con Med DICLOFENAC SODIUM was added/changed on UN AUG 2020. Please clarify if there was WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:23:52
Query 'Per DM CLR: Con Med DICLOFENAC SODIUM was added/changed on UN AUG 2020. Please clarify if there was WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' answered with 'updated to match source' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'UN Apr 2020' reason for change: Data Entry Error	Chalimar Rojo (b) (4) (b) (4)	06 Nov 2020 17:14:48
User opened query 'Per DM CLR: Con Med DICLOFENAC SODIUM was added/changed on UN AUG 2020. Please clarify if there was WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' (Site from DM). User entered 'UN Aug 2020'	Chalimar Rojo (b) (4) (b) (4)	06 Nov 2020 17:14:38
	(b) (4), (b) (6)	30 Oct 2020 14:31:53
	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:17:40

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:44:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered '0'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:17:40

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:44:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:17:40

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:44:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered empty.	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:17:40

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:44:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:00:26
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	20 Aug 2020 17:17:40

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:44:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 17:17:40

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:44:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 17:17:40

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:44:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 17:17:40

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:44:45

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:09:37
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Feb 2021 07:33:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Feb 2021 07:33:08
Data point term sent to Coder Coding entries removed.	System Chalimar Rojo (b) (4)	10 Feb 2021 19:08:21 10 Feb 2021 19:07:20
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	26 Jan 2021 11:00:13
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 11:00:13
Data point term sent to Coder Coding entries removed.	System Kim Calloway (b) (4)	25 Jan 2021 16:50:07 25 Jan 2021 16:49:49
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Dec 2020 20:37:58

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:44:45

[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. DataPoint Verified.	Coder Import (b) (4) (b) (4)	16 Dec 2020 20:37:58
	(b) (4), (b) (6)	15 Dec 2020 16:42:34
Data point term sent to Coder	System	11 Dec 2020 18:24:08
User entered 'PREDNISON'	Chalimar Rojo (b) (4) (b) (4)	11 Dec 2020 18:23:58

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:44:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:09:37
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:42:34
User entered 'No (N)'	Chalimar Rojo (b) (4) (b) (4)	11 Dec 2020 18:23:58

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:44:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:09:37
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
User closed query 'Per DM CLR: After reviewing the indication of SOB, please note that there is no AE matching this Con Med indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 07:26:55
User closed query 'Per DM CLR: Please review the indication of SOB as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 07:26:39
Query 'Per DM CLR: After reviewing the indication of SOB, please note that there is no AE matching this Con Med indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	Chalimar Rojo (b) (4) (b) (4)	10 Feb 2021 19:07:37
Query 'Per DM CLR: Please review the indication of SOB as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	Chalimar Rojo (b) (4) (b) (4)	10 Feb 2021 19:07:31
User entered 'SOB CAUSED BY COVID 19' reason for change: Data Entry Error DataPoint Un-verified.	Chalimar Rojo (b) (4) (b) (4)	10 Feb 2021 19:07:20
User entered 'COUGH CAUSED BY COVID 19' reason for change: Data Entry Error	Kim Calloway (b) (4) (b) (4)	25 Jan 2021 16:49:49
User opened query 'Per DM CLR: After reviewing the indication of SOB, please note that there is no AE matching this Con Med indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	Kim Calloway (b) (4) (b) (4), (b) (6)	25 Jan 2021 16:49:49
User opened query 'Per DM CLR: After reviewing the indication of SOB, please note that there is no AE matching this Con Med indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 11:25:19

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:44:45

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review the indication of SOB as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 11:25:07
	(b) (4), (b) (6)	15 Dec 2020 16:42:34
User entered 'SOB/COUGH CAUSED BY COVID 19'	Chalimar Rojo (b) (4)	11 Dec 2020 18:23:58
	(b) (4)	

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:44:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:09:37
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:42:34
User entered '20'	Chalimar Rojo (b) (4) (b) (4)	11 Dec 2020 18:23:58

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:44:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:09:37
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:42:34
User entered 'mg (mg)'	Chalimar Rojo (b) (4) (b) (4)	11 Dec 2020 18:23:58

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:44:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:09:37
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:42:34
User entered empty.	Chalimar Rojo (b) (4) (b) (4)	11 Dec 2020 18:23:58

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:44:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:09:37
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:42:34
User entered 'once daily (QD)'	Chalimar Rojo (b) (4) (b) (4)	11 Dec 2020 18:23:58

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:44:45

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:09:37
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:42:34
User entered empty.	Chalimar Rojo (b) (4) (b) (4)	11 Dec 2020 18:23:58

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:44:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:09:37
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:42:34
User entered 'Oral (ORAL)'	Chalimar Rojo (b) (4) (b) (4)	11 Dec 2020 18:23:58

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:44:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:09:37
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:42:34
User entered empty.	Chalimar Rojo (b) (4) (b) (4)	11 Dec 2020 18:23:58

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:44:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:09:37
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:42:34
User entered '17 Nov 2020'	Chalimar Rojo (b) (4) (b) (4)	11 Dec 2020 18:23:58

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:44:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:09:37
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:42:34
User entered '0'	Chalimar Rojo (b) (4) (b) (4)	11 Dec 2020 18:23:58

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:44:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:09:37
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:42:34
User entered 'No (N)'	Chalimar Rojo (b) (4) (b) (4)	11 Dec 2020 18:23:58

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:44:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:09:37
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:42:34
User entered '24 Nov 2020'	Chalimar Rojo (b) (4) (b) (4)	11 Dec 2020 18:23:58

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:44:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:09:37
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:11:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:42:34
User entered 'No (N)'	Chalimar Rojo (b) (4) (b) (4)	11 Dec 2020 18:23:58

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:44:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:09:37
User entered '1'	System	11 Dec 2020 18:23:58

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:44:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:09:37
User entered '1'	System	11 Dec 2020 18:23:58

US3452203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:44:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:09:37
User entered '804 (804)'	System	11 Dec 2020 18:23:58

US3452203

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:44:45

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
	(b) (4)	
User entered 'No (N)'	Destiny	05 Feb 2021 17:02:57
	Heinzig-Cartwright (b) (4)	
	(b) (4)	

US3452203

Folder: SAE USA-US208-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:44:45

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:51:55
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 17:11:19
User entered 'USA-US208-2020-MRNA-1273-P301000010'	System	01 Dec 2020 17:10:56

US3452203

Folder: SAE USA-US208-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:44:45

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4)	03 Dec 2020 18:51:55
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 17:11:19
User entered 'No (N)'	System	01 Dec 2020 17:10:56

US3452203

Folder: SAE USA-US208-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:44:45

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:51:55
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 17:11:19
User entered 'No (N)'	System	01 Dec 2020 17:10:56

US3452203

Folder: SAE USA-US208-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:44:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:51:55
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 17:11:19
User entered 'No (N)'	System	01 Dec 2020 17:10:56

US3452203

Folder: SAE USA-US208-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:44:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:51:55
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 17:11:19
User entered 'No (N)'	System	01 Dec 2020 17:10:56

US3452203

Folder: SAE USA-US208-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:44:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4)	03 Dec 2020 18:51:55
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 17:11:19
User entered 'No (N)'	System	01 Dec 2020 17:10:56

US3452203

Folder: SAE USA-US208-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:44:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:51:55
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 17:11:19
User entered 'No (N)'	System	01 Dec 2020 17:10:56

US3452203

Folder: SAE USA-US208-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:44:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4)	03 Dec 2020 18:51:55
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 17:11:19
User entered 'No (N)'	System	01 Dec 2020 17:10:56

US3452203

Folder: SAE USA-US208-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:44:45

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 15:32:10
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 18:51:55
User entered 'US'	System	01 Dec 2020 17:11:27

US3452203

Folder: SAE USA-US208-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:44:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	14 Dec 2020 15:32:31
User entered '1'	System	01 Dec 2020 17:11:27

US3452203

Folder: SAE USA-US208-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:44:45

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 18:51:55
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 17:11:19
User entered		
'USA-US208-2020-MRNA-1273-P301000010'	System	01 Dec 2020 17:10:56

US3452203

Folder: SAE USA-US208-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:44:45

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 18:51:55
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 17:11:19
User entered 'No (N)'	System	01 Dec 2020 17:10:56

US3452203

Folder: SAE USA-US208-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:44:45

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 18:51:55
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 17:11:19
User entered 'No (N)'	System	01 Dec 2020 17:10:56

US3452203

Folder: SAE USA-US208-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:44:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 18:51:55
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 17:11:19
User entered 'No (N)'	System	01 Dec 2020 17:10:56

US3452203

Folder: SAE USA-US208-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:44:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4)	03 Dec 2020 18:51:55
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 17:11:19
User entered 'No (N)'	System	01 Dec 2020 17:10:56

US3452203

Folder: SAE USA-US208-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:44:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4)	03 Dec 2020 18:51:55
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 17:11:19
User entered 'No (N)'	System	01 Dec 2020 17:10:56

US3452203

Folder: SAE USA-US208-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:44:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:51:55
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 17:11:19
User entered 'No (N)'	System	01 Dec 2020 17:10:56

US3452203

Folder: SAE USA-US208-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:44:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4)	03 Dec 2020 18:51:55
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 17:11:19
User entered 'No (N)'	System	01 Dec 2020 17:10:56

US3452203

Folder: SAE USA-US208-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:44:45

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 15:32:10
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 18:51:55
User entered 'US'	System	01 Dec 2020 17:11:27

US3452203

Folder: SAE USA-US208-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:44:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	14 Dec 2020 15:32:31
User entered '1'	System	01 Dec 2020 17:11:27

US3452203

Folder: SAE USA-US208-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:44:45

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:51:55
User entered '01/Dec/2020 17:11'	System	01 Dec 2020 17:11:27

US3452203

Folder: SAE USA-US208-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:44:45

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 15:32:10
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 18:51:55
User entered '1'	(b) (4), (b) (6)	01 Dec 2020 17:11:27

US3452203

Folder: SAE USA-US208-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:44:45

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:51:55
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 17:11:19
User entered 'USA-US208-2020-MRNA-1273-P301000010'	System	01 Dec 2020 17:10:56

US3452203

Folder: SAE USA-US208-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:44:45

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 18:51:55
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 17:11:19
User entered 'No (N)'	System	01 Dec 2020 17:10:56

US3452203

Folder: SAE USA-US208-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:44:45

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4)	03 Dec 2020 18:51:55
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 17:11:19
User entered 'No (N)'	System	01 Dec 2020 17:10:56

US3452203

Folder: SAE USA-US208-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:44:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4)	03 Dec 2020 18:51:55
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 17:11:19
User entered 'No (N)'	System	01 Dec 2020 17:10:56

US3452203

Folder: SAE USA-US208-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:44:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:51:55
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 17:11:19
User entered 'No (N)'	System	01 Dec 2020 17:10:56

US3452203

Folder: SAE USA-US208-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:44:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4)	03 Dec 2020 18:51:55
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 17:11:19
User entered 'No (N)'	System	01 Dec 2020 17:10:56

US3452203

Folder: SAE USA-US208-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:44:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:51:55
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 17:11:19
User entered 'No (N)'	System	01 Dec 2020 17:10:56

US3452203

Folder: SAE USA-US208-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:44:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4)	03 Dec 2020 18:51:55
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 17:11:19
User entered 'No (N)'	System	01 Dec 2020 17:10:56

US3452203

Folder: SAE USA-US208-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:44:45

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 15:32:10
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 18:51:55
User entered 'US'	System	01 Dec 2020 17:11:27

US3452203

Folder: SAE USA-US208-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:44:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	14 Dec 2020 15:32:31
User entered '1'	System	01 Dec 2020 17:11:27

US3452203

Folder: SAE USA-US208-2020-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:44:45

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4)	15 Dec 2020 21:32:17
	(b) (4), (b) (6)	
User entered '14/Dec/2020 10:32'	System	14 Dec 2020 15:32:31

US3452203

Folder: SAE USA-US208-2020-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:44:45

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:32:17
User entered '1'	(b) (4), (b) (6)	14 Dec 2020 15:32:31