

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** COHORT\_SELECTION

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Cohort Selection**

DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.

1.	Select appropriate response - Protocol version	24 JUL 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** MAIN INFORMED CONSENT

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/22/2020
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 06-Jul-2020 21:55

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** DEMOGRAPHY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[10971017]
2.	Birth Date:	(b) (6) 1943
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Aug/22/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

**Form Comments**

**Inclusion Criteria Not Met**

1.	Description of Inclusion Criterion Not Met	Not Applicable
----	---	----------------

**Exclusion Criteria Met**

2.	Description of Exclusion Criterion Met	Not Applicable
----	---	----------------

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** DISPOSITION - SCREENING

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation/Death	Aug/22/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971017

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Osteoarthritis]
	Start Date:	Jun/29/2020
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Lumbar Radiculopathy]
	Start Date:	Feb/4/2019
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Gout]
	Start Date:	Apr/15/2019
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Chronic Back Pain1]
	Start Date:	Oct/1/2018
	Ongoing:	YES

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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971017

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Neuropathy]
	Start Date:	Oct/1/2018
	Ongoing:	YES

1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Impotence]
	Start Date:	Apr/3/2000
	Ongoing:	YES

1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Mechanical Heart valve Replacement]
	Start Date:	Apr/3/2018
	Ongoing:	NO End Date: Apr/3/2018

1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hyperlipidemia]
	Start Date:	Apr/3/2018
	Ongoing:	YES

1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Essential Hypertension]
	Start Date:	Apr/3/2018
	Ongoing:	YES

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - BASELINE

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Aug/22/2020
2.	Weight:	[164.0]
3.	Unit:	LB
4.	Height:	[71.0]
5.	Unit:	in
6.	Body Mass Index:	[22.9]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[97.7]
	Unit:	F
	Temperature Location:	ORAL CAVITY

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** RANDOMIZATION

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Aug/22/2020
2.	Randomization Number:	[237076]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/22/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BN6B9B]
5.b	Sample ID	[BN6B9K]
5.c	Sample ID	[BN6B9L]
5.d	Sample ID	[BL9XJL]
5.e	Sample ID	[BL9XJM]

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/22/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BN6B94]
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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** VACCINATION

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/22/2020 11:48
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** REACTOGENICITY DIARY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Sep/15/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:52

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Version:** 21-Aug-2020 02:52

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - TEMP

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/15/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[97.7]
	Unit:	F
	Temperature Location:	ORAL CAVITY

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/15/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BN6B3W]
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090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** VACCINATION

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/15/2020 13:37
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Oct/14/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Version:** 21-Aug-2020 02:52

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Version:** 21-Aug-2020 02:52

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/14/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BL9XCR]
5.b	Sample ID	[BL9XCS]
5.c	Sample ID	[BN6BK6]
5.d	Sample ID	[BN6BK8]
5.e	Sample ID	[BN6BK7]

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET  
on Nov/17/2020

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Nov/17/2020
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	COVID_A
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19  
on Nov/17/2020

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Signs and Symptoms**

1.	Date of Assessment:	Nov/17/2020
2.	Date of First Symptom Started:	Oct/19/2020
3.	Symptoms Ongoing?	NO
	Date of Last Symptom Resolved:	Nov/1/2020

**Symptoms**

4.a	Symptoms:	FEVER
	Was symptom present?	NO
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	NO
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	NO
4.d	Symptoms:	CHILLS
	Was symptom present?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	NO
4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	NO
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	NO

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Nov/17/2020

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

**Symptoms - Other**

5.a	Symptoms - Other Text:	[Confusion]
5.b	Symptoms - Other Text:	[loss of appetite]
5.c	Symptoms - Other Text:	[Nausea]
5.d	Symptoms - Other Text:	[Frequent urination]
5.e	Symptoms - Other Text:	[acute encephalopathy]

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** MICROBIOLOGY SPECIMEN

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Oct/19/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** MICROBIOLOGY SPECIMEN  
on Nov/17/2020

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

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**Microbiology Specimen**

1.	Actual Date of Collection:	Oct/19/2020	
2.	Specimen Type:	SWABBED MATERIAL	
3.	Specimen Collection Location:	NASOPHARYNX	
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST	
6.	Trade Name:	OTHER	<a href="#">Comments</a>
7.	Test Result:	POSITIVE	
8.	Comments/Findings/Details	[ ]	
9.	Trade Name Other, Specify:	[NALT unknown]	

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Nov/17/2020

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

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**Electronic Sample Tracking**

1.	Data Origin	SITE	
2.	Sample Type	NASAL_SWAB_SELF	
3.	Sample Collected?	NO	<a href="#">Comments</a>
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[no sample collected.]	

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
----	-----------	-----

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB  
on Nov/17/2020

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Nov/17/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BPVC4Y]
-----	-----------	----------

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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION  
on Nov/17/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971017**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[eCRF Audit Trail History](#)**Health Care Utilization**

1.a	Physician or Healthcare Professional:	SPECIALIST
	Occurrence of Visits or Contacts:	NO
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [1]
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	NO
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	NO
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	NO
1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

**Health Care Utilization Other**

2.	Other Type of Practitioner Specify:	[ ]
----	-------------------------------------	-----

**Health Care Utilization**

3.	Has the subject been hospitalized due to potential COVID-19 illness?	YES Has the subject been in intensive care due to potential COVID-19 illness? NO
----	--	--



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** HOSPITALIZATION DETAILS

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

#	Hospitalization Category	Hospitalization Term	Admission Date	Ongoing	Form Instance
1.	HOSPITALIZATION STATUS	HOSPITAL	Oct/19/2020	NO Discharge Date:  Nov/1/2020	<a href="#">Repeating Pages</a>

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** HOSPITALIZATION DETAILS  
on Nov/17/2020

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

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**Hospitalization Details**

1.	Hospitalization Category:	HOSPITALIZATION STATUS
2.	Hospitalization Term:	HOSPITAL
3.	Admission Date:	Oct/19/2020
4.	Ongoing?	NO Discharge Date: Nov/1/2020

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** RESPIRATORY TREATMENT

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** RESPIRATORY TREATMENT  
on Nov/17/2020

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

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**Respiratory Treatment**

1.	What is the treatment Identifier?	Not Applicable _____ [ ]	<a href="#">Comments</a>
2.	Concomitant Non-drug Treatment Pre-specified:	Not Applicable _____	<a href="#">Comments</a>
3.	Treatment:	Not Applicable _____	<a href="#">Comments</a>
4.	Treatment:	Not Applicable _____ [ ]	<a href="#">Comments</a>
5.	Start Date:	Not Applicable _____ //	<a href="#">Comments</a>
6.	Ongoing?	Not Applicable _____	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS  
on Nov/17/2020

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

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**Illness Details**

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	YES Respiratory Illness Diagnosis: [COVID 19 Pneumonia]  Date of Diagnosis: Oct/19/2020
3.	Toxicity Grade:	3

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1. DELETED	SEVERE COVID-19 ILLNESS	SIGNIFICANT ACUTE NEUROLOGIC DYSFUNCTION	YES <i>Diagnosis:</i>  Acute Encephalopathy  Start Date:  Oct/19/2020  Ongoing?:  NO  End Date:  Nov/1/2020	3	<a href="#">Repeating Pages</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE  
on Nov/17/2020

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Data Complete, Deleted, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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**Illness Details**

1.	Category of Clinical Event:	SEVERE COVID-19 ILLNESS
2.	Subcategory of Clinical Event:	SIGNIFICANT ACUTE NEUROLOGIC DYSFUNCTION
3.	Was a diagnosis obtained?	YES Diagnosis: [Acute Encephalopathy]  Start Date: Oct/19/2020  Ongoing?: NO  End Date: Nov/1/2020
4.	Toxicity Grade:	3

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<b>Sponsor-Defined Identifier</b>	<b>Test:</b>	<b>Result:</b>	<a href="#">Repeating Pages</a>
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Nov/17/2020

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

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**Lab Chemistry Details**

1.	Lab Panel:	Not Applicable _____	<a href="#">Comments</a>
2.	Laboratory Name and Address	Not Applicable _____ [ ]	<a href="#">Comments</a>
3.	Collection Date:	Not Applicable _____ //	<a href="#">Comments</a>
4.	Specimen Type:	Not Applicable _____	<a href="#">Comments</a>

**Lab Result**

5.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	C Reactive Protein_PX329	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Nov/17/2020

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

5.b	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Alanine Aminotransferase_PX30	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>
5.c	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Aspartate Aminotransferase_PX28	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Nov/17/2020

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

5.d	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Alkaline Phosphatase_PX35	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Applicable _____	<a href="#">Comments</a>	
LNMT	Not Applicable _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

5.e	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Bilirubin_PX21	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Applicable _____	<a href="#">Comments</a>	
LNMT	Not Applicable _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Nov/17/2020

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

5.f	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Blood Urea Nitrogen_PX47	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Applicable _____	<a href="#">Comments</a>	
LNMT	Not Applicable _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

5.g	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Creatinine_PX48	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Applicable _____	<a href="#">Comments</a>	
LNMT	Not Applicable _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

#	Category for Lab Test	Vendor Name ( DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<b>Sponsor-Defined Identifier</b>	<b>Test:</b>	<b>Result:</b>	<a href="#">Repeating Pages</a>
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING Hematology on Nov/17/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

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**Laboratory Data Hematology**

1.	Lab Panel:	Not Applicable _____	<a href="#">Comments</a>
2.	Laboratory Name and Address	Not Applicable _____ [ ]	<a href="#">Comments</a>
3.	Collection Date:	Not Applicable _____ //	<a href="#">Comments</a>
4.	Specimen Type:	Not Applicable _____	<a href="#">Comments</a>

**Lab Result**

5.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Hemoglobin_PX1	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Nov/17/2020

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

5.b	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Hematocrit_PX2	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____	<a href="#">Comments</a>
		Low [ ] High [ ] Unit	
5.c	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Erythrocytes_PX3	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____	<a href="#">Comments</a>
		Low [ ] High [ ] Unit	

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Nov/17/2020

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

5.d	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Platelets_PX5	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____	<a href="#">Comments</a>
		Low [ ] High [ ] Unit	
5.e	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Leukocytes_PX7	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____	<a href="#">Comments</a>
		Low [ ] High [ ] Unit	

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Nov/17/2020

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

5.f	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Neutrophils_PX608	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____	<a href="#">Comments</a>
		Low [ ] High [ ] Unit	
5.g	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Eosinophils_PX609	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____	<a href="#">Comments</a>
		Low [ ] High [ ] Unit	

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Nov/17/2020

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

5.h	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Monocytes_PX612	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>
5.i	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Basophils_PX610	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
on Nov/17/2020

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

5.j	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Lymphocytes_PX611	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** VITAL SIGNS - COVID

**Form Version:** 21-Aug-2020 02:50

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

#	Date:	Vital Signs Details			Form Instance
1.	Not Applicable	<b>Record Identifier:</b>	<b>Systolic:</b>	<b>Diastolic:</b>	<a href="#">Repeating Pages</a>
		Not Applicable	Not Applicable	Not Applicable	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** VITAL SIGNS - COVID  
on Nov/17/2020

**Form Version:** 21-Aug-2020 02:50

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

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**Vital Signs**

1.	Date:	Not Applicable _____ //	<a href="#">Comments</a>
----	-------	-------------------------------	--------------------------

**Vital Signs Details**

2.a	Record Identifier:	Not Applicable _____ 1	
	Systolic:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Diastolic:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Respiratory Rate in respirations/minute:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Heart Rate in beats/minute:	Not Applicable _____ [ ]	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** VITAL SIGNS - PULSE OX ROOM AIR

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

#	Date:	Vital Signs Details		Form Instance
1.	Not Applicable	<b>Record Identifier:</b>	<b>Oxygen Saturation</b>	<a href="#">Repeating Pages</a>
		Not Applicable	Not Applicable	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR  
on Nov/17/2020

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

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**Vital Signs**

1.	Date:	Not Applicable _____ //	<a href="#">Comments</a>
----	-------	-------------------------------	--------------------------

**Vital Signs Details**

2.a	Record Identifier:	Not Applicable _____ 1	
	SPO2 Pulse Oximetry %	Not Applicable _____ [ ]	<a href="#">Comments</a>

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** OXYGENATION PARAMETERS

**Form Version:** 06-Jul-2020 21:52

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS  
on Nov/17/2020

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

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**Oxygenation Parameters**

1.	Date Time of Assessment:	Not Applicable _____ //	<a href="#">Comments</a>
2.	Arterial Blood Gases PaO2 (mmHg):	Not Applicable _____ [ ]	<a href="#">Comments</a>
3.	FiO2 (Fraction of Inhaled Oxygen):	Not Applicable _____ [ ]	<a href="#">Comments</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

**Form Version:** 06-Jul-2020 21:55

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS  
on Nov/17/2020

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

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**Concomitant Medications**

1.	What is the medication identifier?	Not Applicable _____ [ ]	<a href="#">Comments</a>
2.	Category:	Not Applicable _____	<a href="#">Comments</a>
3.	Concomitant Medications Pre-specified:	Not Applicable _____	<a href="#">Comments</a>
4.	Medication:  Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	Not Applicable _____ [ ]	<a href="#">Comments</a>
5.	Start Date:	Not Applicable _____ //	<a href="#">Comments</a>
6.	Ongoing?	Not Applicable _____	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** IMAGING

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Oct/19/2020	CHEST	X-RAY	ABNORMAL <i>If abnormal, specify findings:</i>  Left upper lobe infiltrate.	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** IMAGING  
on Nov/17/2020

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

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**Imaging**

1.	Date of Assessment:	Oct/19/2020
2.	Location of Assessment:	CHEST
3.	Type of Imaging Exam:	X-RAY
4.	Assessment:	ABNORMAL If abnormal, specify findings: [Left upper lobe infiltrate.]

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**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Dec/15/2020

**Form:** DATE OF VISIT - ILLNESS CONVALESCENT

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

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**Date of Visit**

1.	Date of Visit	Dec/15/2020
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	COVID_A1
----	-------------------------	----------

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Dec/15/2020

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/15/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BPVC75]
5.b	Sample ID	[BPVC76]
5.c	Sample ID	[ ]
5.d	Sample ID	[BL9XSH]

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Oct/17/2020

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

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**Date of Visit**

1.	Date of Visit	Oct/17/2020
2.	Erroneous Visit	ERRONEOUS VISIT



**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Oct/17/2020

**Form:** UNPLANNED VISIT

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Not Started

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

**Unplanned Assessments**

1.	Assessments	
----	-------------	--

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**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation/Death :	Oct/14/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

**Form Version:** 15-Sep-2020 21:53

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

**Disposition - Follow-Up**

1.	Date of Completion/Discontinuation/Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New  
Unscheduled Visit

**Form:** DATE OF VISIT - REPEAT SWAB

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

3.	COVID-19 Repeat Swab:	
----	-----------------------	--

**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New  
Unscheduled Visit

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

**Electronic Sample Tracking**

1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1. DELETED	ADVERSE EVENT	1	Acute encephalopathy	Oct/18/2020 21:40	YES	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	non traumatic retroperitoneal hematoma	Nov/13/2020 UNK:UNK	NO End Date Time:  Nov/15/2020 UNK: UNK	<a href="#">Repeating Pages</a>
3.	ADVERSE EVENT	3	urinary tract infection	Sep/19/2020 UNK:UNK	NO End Date Time:  Nov/1/2020 UNK: UNK	<a href="#">Repeating Pages</a>

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971017

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[+]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Acute encephalopathy]
4.	Start Date Time:	Oct/18/2020 21:40
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	3
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [COVID-19 and UTI and OPIod use]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Deleted

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

11.	Was a Concomitant Medication given?	<del>YES</del>
12.	Was a Non-Drug Treatment given?	<del>NO</del>
13.	What was the outcome of this adverse event?:	<del>RECOVERING/RESOLVING</del>
14.	Did the adverse event cause the subject to be discontinued from the study?	<del>NO</del>
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[non traumatic retroperitoneal hematoma]
4.	Start Date Time:	Nov/13/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/15/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO  Did this serious event result in death? NO  Did this serious event require or prolong hospitalization? YES  Did this serious event result in persistent or significant disability/incapacity? NO  Is this serious event life threatening? NO  Other medically important serious event YES
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [unknown]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020453104]

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[urinary tract infection]
4.	Start Date Time:	Sep/19/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/1/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [unknown]

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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**Medication Error**

1.	Category:	
2.	Medication Error (Type of Medication Error):	[ ]
3.	Start Date:	//
4.	Is the medication error still ongoing?	
5.	Latest Action Taken with Study Treatment:	
6.	Was a Concomitant Medication given?	
7.	Was a Non-Drug Treatment given?	
8.	Did the Medication Error cause the subject to be discontinued from the study?	
9.	Was this medication error associated with any adverse events?	
10.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - NON STUDY  
VACCINATIONS

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

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**Concomitant Medications**

1.	What is the medication identifier?	[ ]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication:  Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[ ]
5.	Date:	//

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)



**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						<a href="#">Repeating Pages</a>

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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**Concomitant Medications**

1.	What is the medication identifier?	[ ]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication:  Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[ ]
5.	Dose:	[ ]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
10.	Ongoing?	

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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**Radiation Treatment**

1.	Category:	
2.	What is the treatment Identifier?	[ ]
3.	Concomitant Non-drug Treatment Pre-specified:	
4.	Treatment:	[ ]
5.	Start Date:	//
6.	Ongoing?	

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

#	Transfusion Type	Date of Transfusion	Form Instance
1.	PACKED RBC	Nov/13/2020	<a href="#">Repeating Pages</a>

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** TRANSFUSIONS

**Form Status:** Data Complete, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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[Form Audit Trail](#)

1.	Transfusion Type:	PACKED RBC
2.	Date of Transfusion:	Nov/13/2020

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Not Started

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VITAL SIGNS - TEMP

**Form Version:** 20-Feb-2021 02:16

**Form Status:** Not Started

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

**Vital Signs**

1.	Date:	//
----	-------	----

**Vital Signs Details**

2.	Record Identifier:	
	Temperature:	[ ]
	Unit:	
	Temperature Location:	



**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VACCINATION

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Not Started

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

**Vaccination**

1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[ ]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 1

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

**Contact Outcome**

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 6

**Form Version:** 10-Oct-2020 16:01

**Form Status:** Not Started

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

**Contact Outcome**

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/18/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** FURTHER VACCINATION CONFIRMATION

**Form Version:** 10-Dec-2020 02:25

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	---

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** TREATMENT UNBLINDED

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Jan/18/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Not Started

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

**Withdrawal Of Consent**

1.	Withdrawal of Consent Date :	//
----	------------------------------	----

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** DEATH DETAILS CODED

**Form Status:** Not Started

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

**Death Details**

1.	Date of Collection / Notification of Death:	//
----	---	----

**Cause of Death**

2.	Cause of Death Status:	
	Cause of Death:	[ ]



**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/18/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:31

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** INFORMED CONSENT - FURTHER VACCINATION

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Informed Consent - Further Vaccination**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/18/2021
----	--------------	--

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

**Form Version:** 10-Dec-2020 02:30

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

**Form Comments**

**Inclusion Criteria Not Met**

1.	Description of Inclusion Criterion Not Met	Not Applicable _____
----	---	-------------------------

**Exclusion Criteria Met**

2.	Description of Exclusion Criterion Met	Not Applicable _____
----	---	-------------------------

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:31

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Disposition - Screening for Further Vaccination**

1.	Date of Completion/Discontinuation/Death :	Jan/18/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/18/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP2RT2]
5.b	Sample ID	[BP2RT3]
5.c	Sample ID	[BP2RT4]
5.d	Sample ID	[BHGTDW]
5.e	Sample ID	[BHGTDX]

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/18/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP2RSP]
-----	-----------	----------

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** VACCINATION

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/18/2021 13:27
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Feb/8/2021
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/8/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP2RZR]
-----	-----------	----------

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** VACCINATION

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/8/2021 12:33
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** V103\_MONTH1

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Mar/8/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V103\_MONTH1

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** CONTACT OUTCOME

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Contact Outcome**

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Mar/8/2021
3.	Comments:	[Subject has nothing new to report.]

**Header Text:** c4591001

**Visit:** V104\_MONTH6

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V104\_MONTH6

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

**Contact Outcome**

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

**Header Text:** c4591001

**Visit:** V105\_MONTH18

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V105\_MONTH18

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

**Contact Outcome**

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]



**Header Text:** c4591001

**Visit:** FURTHER\_VACCINATION\_EOT -  
Unscheduled

**Form:** DISPOSITION - TREATMENT

**Form Version:** 20-Feb-2021 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation/Death :	Mar/8/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/14/2020

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Casebook Signature Form**

1.	Casebook Signature	<a href="#">Click Here to Enable</a>
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**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

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This form requires signing by a member of each of the following signature groups:

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Tom Christensen	Approved	Mar-12-2021 09:43:12 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

**Affidavit:**

By my dated signature below, I, TomChristensen, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Aug-25-2020 17:20:38 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Nov/17/2020

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

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Item	Date	User	Comment
6	Nov-30-2020 08:25:33 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	NALT Unknown

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - Comments

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

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**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

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Item	Date	User	Comment
3	Nov-24-2020 10:40:20 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
3	Nov-19-2020 16:50:41 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
3	Nov-18-2020 09:33:51 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments  
on Nov/17/2020

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

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Item	Date	User	Comment
Form	Nov-17-2020 15:48:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments  
on Nov/17/2020

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen, Verified

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**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

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Item	Date	User	Comment
1	Nov-17-2020 15:48:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments  
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**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

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**Generated By:** (b) (4)

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Item	Date	User	Comment
2	Nov-17-2020 15:48:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments  
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**Form Version:** 06-Jul-2020 21:53

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3	Nov-17-2020 15:48:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
4	Nov-17-2020 15:48:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments  
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**Generated By:** (b) (4)

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Item	Date	User	Comment
5	Nov-17-2020 15:48:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments  
on Nov/17/2020

**Form Version:** 06-Jul-2020 21:53

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**Generated By:** (b) (4)

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Item	Date	User	Comment
6	Nov-17-2020 15:48:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

**Form Version:** 21-Aug-2020 02:49

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**Subject No:** 10971017

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Item	Date	User	Comment
1	Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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Item	Date	User	Comment
2	Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

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**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

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**Subject No:** 10971017

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**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.a	Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

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**Form Status:** Data Complete, Frozen, Verified

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5.a	Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
5.b	Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

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**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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5.b	Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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5.b	Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

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Item	Date	User	Comment
5.b	Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

**Form Version:** 21-Aug-2020 02:49

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**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

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**Generated By:** (b) (4)

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Item	Date	User	Comment
5.c	Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

**Form Version:** 21-Aug-2020 02:49

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**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

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Item	Date	User	Comment
5.c	Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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5.c	Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

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Item	Date	User	Comment
5.d	Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

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Item	Date	User	Comment
5.d	Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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5.d	Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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5.d	Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

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5.e	Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

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5.e	Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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5.e	Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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**Form Status:** Data Complete, Frozen, Verified

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5 f	Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

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Item	Date	User	Comment
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Item	Date	User	Comment
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090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

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**Header Text:** c4591001

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on Nov/17/2020

**Form Version:** 21-Aug-2020 02:50

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**Subject No:** 10971017

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Form	Nov-17-2020 15:53:52 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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Item	Date	User	Comment
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments on Nov/17/2020

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**Header Text:** c4591001

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Item	Date	User	Comment
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments  
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**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete, Frozen, Verified

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Form	Nov-17-2020 15:54:37 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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**Form Version:** 06-Jul-2020 21:52

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Item	Date	User	Comment
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**Visit:** V101\_VAX3

**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER  
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**Form Version:** 10-Dec-2020 02:30

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Item	Date	User	Comment
Form	Jan-18-2021 14:40:18 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

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This form requires signing by a member of each of the following signature groups:

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Tom Christensen	Approved	Mar-12-2021 09:43:12 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

**Affidavit:**

By my dated signature below, I, TomChristensen, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

(b) (6)	N/A	Mar-12-2021 07:48:40 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Tom Christensen	Approved	Mar-11-2021 15:38:26 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, TomChristensen, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

(b) (6)	N/A	Mar-11-2021 13:53:14 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

Tom Christensen	Approved	Mar-09-2021 16:56:51 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, TomChristensen, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

(b) (6)	N/A	Mar-09-2021 16:52:45 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Tom Christensen	Approved	Mar-09-2021 14:20:34 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, TomChristensen, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

(b) (6)	N/A	Mar-09-2021 08:13:17 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Tom Christensen	Approved	Mar-09-2021 07:38:51 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001**Visit:** Investigator Signature - Unscheduled**Form:** CASEBOOK SIGNATURE FORM - Signature History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Signed, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971017**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39**Affidavit:**

By my dated signature below, I, TomChristensen, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

(b) (6)	N/A	Mar-08-2021 14:18:07 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Tom Christensen	Approved	Feb-24-2021 16:21:05 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, TomChristensen, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

(b) (6)	N/A	Feb-08-2021 14:14:25 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Tom Christensen	Approved	Jan-20-2021 20:34:05 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, TomChristensen, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

(b) (6)	N/A	Dec-04-2020 12:59:38 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Tom Christensen	Approved	Dec-02-2020 20:11:50 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, TomChristensen, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

(b) (6)	N/A	Nov-18-2020 09:33:51 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Tom Christensen	Approved	Nov-17-2020 16:37:20 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, TomChristensen, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

(b) (6)	N/A	Nov-16-2020 17:38:35 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

Tom Christensen	Approved	Nov-16-2020 17:20:28 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, TomChristensen, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

(b) (6)	N/A	Nov-13-2020 10:54:40 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Tom Christensen	Approved	Oct-22-2020 16:13:23 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, TomChristensen, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** COHORT\_SELECTION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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**1. Select appropriate response - Protocol version**

Date	Location	User	Value	Reason
Aug-25-2020 17:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 24 JUL 2020	Initial Entry

**2 Select appropriate response What cohort does the subject belong to?**

Date	Location	User	Value	Reason
Aug-25-2020 17:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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**I. Consent Was:**

Date	Location	User	Value	Reason
Aug-25-2020 17:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Aug/22/2020	Initial Entry



Header Text: c4591001

Visit: COHORT\_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1097

Subject No: 10971017

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Subject ID**

Date	Location	User	Value	Reason
Aug-22-2020 12:59:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10971017	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Aug-22-2020 12:59:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6) 1943	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Aug-25-2020 17:20:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> MALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Aug-25-2020 17:20:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT HISPANIC OR LATINO( A) OR OF SPANISH ORIGIN	Initial Entry

**5. Race: (Check X all that apply):**

Date	Location	User	Value	Reason
Aug-25-2020 17:20:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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*I. Date of Visit*

Date	Location	User	Value	Reason
Aug-25-2020 17:20:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/22/2020	Initial Entry

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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**1. Date of Completion/Discontinuation/Death**

Date	Location	User	Value	Reason
Aug-25-2020 17:21:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/22/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Aug-25-2020 17:21:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Aug-25-2020 17:21:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1097**Subject No:** 10971017**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**I.a**

Date	Location	User	Value	Reason
Aug-25-2020 17:23:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 1 <b>Medical History Term:</b> Osteoarthritis <b>Start Date:</b> Jun/29/2020 <b>Ongoing:</b> YES	Initial Entry

**I.a Line/MH Number:**

Date	Location	User	Value	Reason
Aug-25-2020 17:23:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**I.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Aug-25-2020 17:23:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Osteoarthritis	Initial Entry

**I.a Start Date:**

Date	Location	User	Value	Reason
Aug-25-2020 17:23:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jun/29/2020	Initial Entry

**I.a Ongoing:**

Date	Location	User	Value	Reason
Aug-25-2020 17:23:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.b**

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971017

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Aug-25-2020 17:23:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Numb</b> 2 <b>er:</b> <b>Medical History</b> Lumbar Radicul <b>Term:</b> oopathy <b>Start Date:</b> Feb/4/2019 <b>Ongoing:</b> YES	Initial Entry

**1.b Line/MH Number:**

Date	Location	User	Value	Reason
Aug-25-2020 17:23:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Aug-25-2020 17:23:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Lumbar Radiculopathy	Initial Entry

**1.b Start Date:**

Date	Location	User	Value	Reason
Aug-25-2020 17:23:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/4/2019	Initial Entry

**1.b Ongoing:**

Date	Location	User	Value	Reason
Aug-25-2020 17:23:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.c**

Date	Location	User	Value	Reason
Aug-25-2020 17:23:59 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 3	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971017

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

Time (US & Canada)			<b>Medical History Term:</b> <b>Start Date:</b> Apr/15/2019 <b>Ongoing:</b> YES
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**I.c Line/MH Number:**

Date	Location	User	Value	Reason
Aug-25-2020 17:23:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

**I.c Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Aug-25-2020 17:23:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Gout	Initial Entry

**I.c Start Date:**

Date	Location	User	Value	Reason
Aug-25-2020 17:23:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Apr/15/2019	Initial Entry

**I.c Ongoing:**

Date	Location	User	Value	Reason
Aug-25-2020 17:23:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.d**

Date	Location	User	Value	Reason
Aug-25-2020 17:24:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 4 <b>Medical History Term:</b> Chronic Back Pain1	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

			<b>Start Date:</b>	Oct/1/2018	
			<b>Ongoing:</b>	YES	

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971017

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

**I.d Line/MH Number:**

Date	Location	User	Value	Reason
Aug-25-2020 17:24:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 4	Initial Entry

**I.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Aug-31-2020 15:10:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-30-2020 08:58:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	It is due to Lumbar radiculopathy
Aug-26-2020 10:52:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPDCLIN - Please review condition CHRONIC BACK PAIN and if a diagnosis/etiology of this pain is available, please add to MH as a separate entry. Example - RA,OA, Injury
Aug-25-2020 17:24:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Chronic Back Pain1	Initial Entry

**I.d Start Date:**

Date	Location	User	Value	Reason
Aug-25-2020 17:24:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Oct/1/2018	Initial Entry

**I.d Ongoing:**

Date	Location	User	Value	Reason
Aug-25-2020 17:24:30 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971017

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

Time (US & Canada)

I.e

Date	Location	User	Value	Reason
Aug-25-2020 17:25:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 5 <b>Medical History Term:</b> Neuropath <b>Start Date:</b> Oct/1/2018 <b>Ongoing:</b> YES	Initial Entry

I.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 17:25:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

I.e Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-25-2020 17:25:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Neuropathy	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 17:25:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/1/2018	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 17:25:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

I.f

Date	Location	User	Value	Reason
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090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971017

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

Aug-25-2020 17:25:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 6 <b>Medical History Term:</b> Impotence <b>Start Date:</b> Apr/3/2000 <b>Ongoing:</b> YES	Initial Entry
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*1.f Line/MH Number:*

Date	Location	User	Value	Reason
Aug-25-2020 17:25:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 6	Initial Entry

*1.f Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:*

Date	Location	User	Value	Reason
Aug-25-2020 17:25:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Impotence	Initial Entry

*1.f Start Date:*

Date	Location	User	Value	Reason
Aug-25-2020 17:25:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Apr/3/2000	Initial Entry

*1.f Ongoing:*

Date	Location	User	Value	Reason
Aug-25-2020 17:25:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

*1.g*

Date	Location	User	Value	Reason
Aug-25-2020 17:26:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 7	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971017

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

			<b>Medical History Term:</b> Mechanical Heart valve Replacement <b>Start Date:</b> Apr/3/2018 <b>Ongoing:</b> NO End Date: Apr/3/2018	
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**I.g Line/MH Number:**

Date	Location	User	Value	Reason
Aug-25-2020 17:26:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

**I.g Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Aug-25-2020 17:26:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mechanical Heart valve Replacement	Initial Entry

**I.g Start Date:**

Date	Location	User	Value	Reason
Aug-25-2020 17:26:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Apr/3/2018	Initial Entry

**I.g Ongoing:**

Date	Location	User	Value	Reason
Aug-25-2020 17:26:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: Apr/3/2018	Initial Entry

**I.h**

Date	Location	User	Value	Reason
Aug-25-2020 17:26:46 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 8	Initial Entry

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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971017

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

Time (US & Canada)			<b>Medical History Term:</b> Hyperlipidemia <b>Start Date:</b> Apr/3/2018 <b>Ongoing:</b> YES
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**I.h Line/MH Number:**

Date	Location	User	Value	Reason
Aug-25-2020 17:26:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 8	Initial Entry

**I.h Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Aug-25-2020 17:26:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hyperlipidemia	Initial Entry

**I.h Start Date:**

Date	Location	User	Value	Reason
Aug-25-2020 17:26:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Apr/3/2018	Initial Entry

**I.h Ongoing:**

Date	Location	User	Value	Reason
Aug-25-2020 17:26:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.i**

Date	Location	User	Value	Reason
Aug-25-2020 17:27:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 9 <b>Medical History Term:</b> Essential Hypertension <b>Start Date:</b> Apr/3/2018	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971017

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

			Ongoing:	YES	
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***1.i Line/MH Number:***

Date	Location	User	Value	Reason
Aug-25-2020 17:27:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 9	Initial Entry

***1.i Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Aug-25-2020 17:27:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Essential Hypertension	Initial Entry

***1.i Start Date:***

Date	Location	User	Value	Reason
Aug-25-2020 17:27:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Apr/3/2018	Initial Entry

***1.i Ongoing:***

Date	Location	User	Value	Reason
Aug-25-2020 17:27:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1097

Subject No: 10971017

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Date:**

Date	Location	User	Value	Reason
Aug-25-2020 17:28:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/22/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Aug-25-2020 17:28:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 164.0	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Aug-25-2020 17:28:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LB	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Aug-25-2020 17:28:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 71.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Aug-25-2020 17:28:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> in	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Aug-25-2020 17:28:16 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 22.9	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1097

Subject No: 10971017

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

Time (US & Canada)

7.a

Date	Location	User	Value	Reason
Aug-25-2020 17:28:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Record Identifier 1 :: Temperature: 97.7 Temperature Unit: Temperature Location: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-25-2020 17:28:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-25-2020 17:28:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 97.7	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-25-2020 17:28:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-25-2020 17:28:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** RANDOMIZATION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Aug-25-2020 17:29:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/22/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Aug-25-2020 17:29:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 237076	Initial Entry



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-25-2020 17:29:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-25-2020 17:29:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-25-2020 17:34:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-25-2020 17:29:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-25-2020 17:29:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/22/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-25-2020 17:34:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BN6B9B	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.a Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 17:34:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BN6B9B	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-25-2020 17:35:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BN6B9K	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 17:35:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BN6B9K	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-25-2020 17:35:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BN6B9L	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 17:35:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BN6B9L	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-25-2020 17:35:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BL9XJL	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

**5.d Sample ID**

Date	Location	User	Value	Reason
Aug-25-2020 17:35:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BL9XJL	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Aug-25-2020 17:36:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BL9XJM	Initial Entry

**5.e Sample ID**

Date	Location	User	Value	Reason
Aug-25-2020 17:36:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BL9XJM	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-25-2020 17:29:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-25-2020 17:29:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-25-2020 17:36:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-25-2020 17:29:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-25-2020 17:29:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/22/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-25-2020 17:36:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BN6B94	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-25-2020 17:36:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BN6B94	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1097

Subject No: 10971017

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Aug-25-2020 17:32:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Aug-25-2020 17:32:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Aug-25-2020 17:32:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Aug-25-2020 17:32:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/22/2020 11:48	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-25-2020 17:32:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Aug-25-2020 17:32:02 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1097

Subject No: 10971017

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

Time (US & Canada)

7. Route:

Date	Location	User	Value	Reason
Aug-25-2020 17:32:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-25-2020 17:32:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Aug-25-2020 17:32:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 06-Jul-2020 21:53

Site No: 1097

Subject No: 10971017

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Select appropriate response - Reactogenicity diary collection**

Date	Location	User	Value	Reason
Sep-02-2020 04:18:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep 01 2020 17 41 32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1 Answered	Transcription Error
Sep-01-2020 17:41:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES - REACTOGENICITY E-DIARY COLLECTED FO R THIS SUBJECT	Transcription Error
Sep-01-2020 06:49:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	eDiary: REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT is 'No' however VAX 1 eDiary records are available for the subject. Please verify and update. Else, confirm in query response appropriately.
Aug-25-2020 17:32:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGENICITY E- DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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**I. Date of Visit**

Date	Location	User	Value	Reason
Sep-21-2020 07:11:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	As per site confirmation - PD tracker updated
Sep-18-2020 14:23:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject forgot about appointment. Site coordinator called subject but they could not make it to get their 2nd vaccine till the following day
Sep-17-2020 06:37:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	PDQ: DOV at this visit is out of window (1 day) from DOV (22/AUG/2020) at VID1VX1L. Please either update DOV or confirm whether visit is out of window due to temporary delay of vaccination/ else provide details as appropriate.
Sep-15-2020 15:41:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/15/2020	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:52**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971017**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Sep-15-2020 15:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-15-2020 15:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FE VE R <b>Were fever or systemic symp NO</b> <b>toms present on the last day</b> <b>the Subject Diary was compl</b> <b>eted?:</b>	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
Sep-15-2020 15:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

**2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Sep-15-2020 15:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
Sep-15-2020 15:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FA TIG	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

			UE Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
--	--	--	---	--

2.b Symptom:

Date	Location	User	Value	Reason
Sep-15-2020 15:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-15-2020 15:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-15-2020 15:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Symptom::</u> HEA DA CHE  Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

2.c Symptom:

Date	Location	User	Value	Reason
Sep-15-2020 15:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-15-2020 15:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-15-2020 15:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: CH IL LS Were fever or systemic sym ptoms present on the last da y the Subject Diary was com pleted?: NO	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Sep-15-2020 15:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-15-2020 15:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.e

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Sep-15-2020 15:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> VO MIT ING  <b>Were fever or systemic sym ptoms present on the last d ay the Subject Diary was c ompleted?:</b> NO	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Sep-15-2020 15:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-15-2020 15:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Sep-15-2020 15:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DIA RR HE A  <b>Were fever or systemic sym ptoms present on the last d ay the Subject Diary was c ompleted?:</b> NO	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

2.f Symptom:

Date	Location	User	Value	Reason
Sep-15-2020 15:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-15-2020 15:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-15-2020 15:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: NEW OR WORSE NED MUS CLE PAIN  Were fever or systemi NO c symptoms present o n the last day the Sub ject Diary was compl eted?:	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Sep-15-2020 15:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR WORSE NED MUSCLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-15-2020 15:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

2.h

Date	Location	User	Value	Reason
Sep-15-2020 15:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE NED JOI NT PAIN  <b>Were fever or systemi NO c symptoms present o n the last day the Subj ect Diary was complet ed?:</b>	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Sep-15-2020 15:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENERD JOINT PA IN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-15-2020 15:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-15-2020 15:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-15-2020 16:12:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.a

Date	Location	User	Value	Reason
Sep-15-2020 15:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> RE DN ESS  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-15-2020 15:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-15-2020 15:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-15-2020 15:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> SWE LLI NG  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)



Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

**5.b Injection Site Reaction:**

Date	Location	User	Value	Reason
Sep-15-2020 15:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWELLING	Initial Entry

**5.b Were injection site reactions present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Sep-15-2020 15:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Sep-15-2020 15:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> PAIN AT INJECTION SITE  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Sep-15-2020 15:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

**5.c Were injection site reactions present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Sep-15-2020 15:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 21-Aug-2020 02:51

Site No: 1097

Subject No: 10971017

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Date:**

Date	Location	User	Value	Reason
Sep-15-2020 15:42:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/15/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-15-2020 15:42:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 97.7 <b>Temperature Unit:</b> F <b>Temperature Locat</b> ORAL CAVI <b>ion::</b> TY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-15-2020 15:42:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Sep-15-2020 15:42:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 97.7	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Sep-15-2020 15:42:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

**2.a Temperature Location:**

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Sep-15-2020 15:42:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-15-2020 15:42:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-15-2020 15:42:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-15-2020 15:43:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-15-2020 15:42:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-15-2020 15:42:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/15/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-15-2020 15:43:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BN6B3W	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

**5.a Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-15-2020 15:43:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u><b>Data Entry:</b></u> BN6B3W	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1097

Subject No: 10971017

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Sep-15-2020 15:44:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-15-2020 15:44:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-15-2020 15:44:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Sep-15-2020 15:44:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/15/2020 13:37	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-15-2020 15:44:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Sep-15-2020 15:44:16 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1097

Subject No: 10971017

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

Time (US & Canada)

(b) (4), (b) (6)

7. Route:

Date	Location	User	Value	Reason
Sep-15-2020 15:44:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-15-2020 15:44:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-15-2020 15:44:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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**I. Date of Visit**

Date	Location	User	Value	Reason
Nov-14-2020 10:12:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-13-2020 10:56:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Added to AE Log
Nov-13-2020 07:13:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020446797 acute encephalopathy(onset date:18Oct2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Oct-14-2020 15:13:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/14/2020	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)



Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-14-2020 15:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-14-2020 15:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FE VE R <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> N O	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Oct-14-2020 15:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-14-2020 15:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Oct-14-2020 15:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FA TIG	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

			UE Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
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2.b Symptom:

Date	Location	User	Value	Reason
Oct-14-2020 15:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-14-2020 15:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Oct-14-2020 15:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> HE AD AC HE  Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

2.c Symptom:

Date	Location	User	Value	Reason
Oct-14-2020 15:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-14-2020 15:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Oct-14-2020 15:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> CH IL LS <b>Were fever or systemic sym</b> NO <b>ptoms present on the last d</b> <b>ay the Subject Diary was co</b> <b>mpleted?:</b>	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Oct-14-2020 15:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-14-2020 15:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.e

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Oct-14-2020 15:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> VO MIT ING <b>Were fever or systemic sy</b> NO <b>mptoms present on the las</b> <b>t day the Subject Diary wa</b> <b>s completed?:</b>	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Oct-14-2020 15:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-14-2020 15:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Oct-14-2020 15:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DIA RR HE A <b>Were fever or systemic sy</b> NO <b>mptoms present on the last</b> <b>day the Subject Diary was</b> <b>completed?:</b>	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

2.f Symptom:

Date	Location	User	Value	Reason
Oct-14-2020 15:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-14-2020 15:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Oct-14-2020 15:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE NED MUS CLE PAI N  <b>Were fever or system NO ic symptoms present on the last day the Su bject Diary was com pleted?:</b>	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Oct-14-2020 15:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSE NED MUSC LE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-14-2020 15:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

2.h

Date	Location	User	Value	Reason
Oct-14-2020 15:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE NED JOI NT PAIN  <b>Were fever or systemi NO c symptoms present o n the last day the Sub ject Diary was compl eted?:</b>	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Oct-14-2020 15:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSE NED JOI NT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-14-2020 15:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Oct-14-2020 15:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Oct-14-2020 15:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae3ebf\Final\On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.a

Date	Location	User	Value	Reason
Oct-14-2020 15:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> RE DN ESS  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-14-2020 15:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-14-2020 15:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-14-2020 15:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> SWE LLI NG  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-14-2020 15:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-14-2020 15:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-14-2020 15:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Injection Site Reaction PAIN AT INJECTION SITE  Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-14-2020 15:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-14-2020 15:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)



Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-14-2020 15:14:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-14-2020 15:14:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-14-2020 15:27:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-14-2020 15:14:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-14-2020 15:14:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/14/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-14-2020 15:27:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BL9XCR	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.a Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 15:27:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BL9XCR	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-14-2020 15:27:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BL9XCS	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 15:27:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BL9XCS	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-14-2020 15:28:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BN6BK6	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.c Sample ID

Date	Location	User	Value	Reason
Oct-16-2020 17:27:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_BEETRK001_01
Oct-16-2020 08:44:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Corrected entry
Oct-14-2020 21:54:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW4978740; This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Oct-14-2020 15:28:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BN6BK6	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-16-2020 08:44:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BN6BK8	Transcription Error
Oct-14-2020 15:28:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BN6BK6	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.d Sample ID

Date	Location	User	Value	Reason
Oct-16-2020 17:27:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_BEETRK001_01
Oct-16-2020 08:44:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-16-2020 08:44:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BN6BK8	Transcription Error
Oct-14-2020 21:54:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW4978741;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Oct-14-2020 15:28:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BN6BK6	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-14-2020 15:28:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BN6BK7	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

*5.e Sample ID*

Date	Location	User	Value	Reason
Oct-14-2020 15:28:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BN6BK7	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Nov/17/2020

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

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*I. Date of Visit*

Date	Location	User	Value	Reason
Dec-01-2020 14:19:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Closed	Samples were collected in error. No further action is needed from the site on this issue.
Dec-01-2020 09:28:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	These samples were collected in error and there is no place in this crf to record them.
Nov-30-2020 13:57:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Reissued:Opened	Please add Serum barcodes (BPVC55, BPVC53, BPVC54)to InForm or submit SCF as applicable.
Nov-30-2020 12:17:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	Blood samples for potential Covid illness not needed, just swab. These samples codes will be marked as erroneous collection.
Nov-30-2020 11:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Opened	HOLDS: Serum barcodes BPVC55, BPVC53, BPVC54 were received by the lab for this subject. Please add barcodes to InForm or submit SCF as applicable.
Nov-30-2020 11:00:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Issuing new query for all missing barcodes

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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Nov/17/2020**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971017**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39

Nov-30-2020 10:59:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	HOLDS: Serum barcode BPVC55 was received by the lab for this subject. Please add barcode to InForm or submit SCF as applicable.
Nov-18-2020 12:26:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Nov-18-2020 09:35:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	ANSWERED
Nov-18-2020 04:25:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	DM: Date of Visit is completed but Nasal Self Swab CRF is not initiated. Please review and update the data as appropriate. Thanks
Nov-17-2020 15:44:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-17-2020 15:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Nov-17-2020 15:32:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Nov-17-2020 15:32:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Nov/17/2020

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

				as appropriate.
Nov-17-2020 15:32:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/17/2020	Initial Entry

**3. COVID-19 Illness Visit:**

Date	Location	User	Value	Reason
Nov-17-2020 15:32:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> COVID_A	Initial Entry



**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1097**Subject No:** 10971017**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Dec-01-2020 09:45:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Nov-30-2020 09:05:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	All symptoms are reported as Not Present and there is no Other Symptom reported. Please review and update as appropriate.
Nov-17-2020 15:40:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-17-2020 15:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	All symptoms are reported as Not Present and there is no Other Symptom reported. Please review and update as appropriate.
Nov-17-2020 15:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/17/2020	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Feb-01-2021 12:41:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-01-2021 08:26:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	documents uploaded
Jan-31-2021 07:21:50 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Monitor is unable to verify if visit

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Time (US & Canada)				occurred. There is no supporting documentation via Florence. Please confirm if visit occurred, if so, please upload supporting documentation to be verified. Thanks!
Nov-17-2020 15:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/19/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Dec-28-2020 13:16:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Dec-28-2020 10:36:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Symptoms resolved 1-nov-2020
Dec-24-2020 13:37:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: Please review if the symptoms are still ongoing (ACUTE ENCEPHALOPATHY added)and update as appropriate
Nov-17-2020 15:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO Date of Last Symptom Resolved:  Nov/1/2020	Initial Entry

4.a

Date	Location	User	Value	Reason
Nov-17-2020 15:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> FEVER	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

			Symptom Present: NO	
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**4.a Symptoms:**

Date	Location	User	Value	Reason
Nov-17-2020 15:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FEVER	Initial Entry

**4.a Was symptom present?**

Date	Location	User	Value	Reason
Nov-17-2020 15:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**4.b**

Date	Location	User	Value	Reason
Nov-17-2020 15:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms: NEW OR INCREAS ED COUGH  Symptom P NO resent:	Initial Entry

**4.b Symptoms:**

Date	Location	User	Value	Reason
Nov-17-2020 15:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR INCREASED COUGH	Initial Entry

**4.b Was symptom present?**

Date	Location	User	Value	Reason
Nov-17-2020 15:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**4.c**

Date	Location	User	Value	Reason
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090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1097

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Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Nov-17-2020 15:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED SHORTNESS OF BREATH <b>Symptom Present:</b> NO	Initial Entry
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4.c Symptoms:

Date	Location	User	Value	Reason
Nov-17-2020 15:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Nov-17-2020 15:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Nov-17-2020 15:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> CHILLS <b>Symptom Present:</b> NO	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Nov-17-2020 15:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Nov-17-2020 15:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

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4.e

Date	Location	User	Value	Reason
Nov-17-2020 15:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms NEW OR INCREASE : D MUSCLE PAIN Symptom NO Present:	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Nov-17-2020 15:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Nov-17-2020 15:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Nov-17-2020 15:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms: NEW LOSS OF TAS TE OR SMELL Symptom NO Present:	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Nov/17/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF  
Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971017**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39**4.f Symptoms:**

Date	Location	User	Value	Reason
Nov-17-2020 15:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW LOSS OF TASTE OR SMEL L	Initial Entry

**4.f Was symptom present?**

Date	Location	User	Value	Reason
Nov-17-2020 15:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.g**

Date	Location	User	Value	Reason
Nov-17-2020 15:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms NEW OR INCREASE : D SORE THROAT <b>Symptom NO</b> <b>Present:</b>	Initial Entry

**4.g Symptoms:**

Date	Location	User	Value	Reason
Nov-17-2020 15:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SORE TH ROAT	Initial Entry

**4.g Was symptom present?**

Date	Location	User	Value	Reason
Nov-17-2020 15:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.h**

Date	Location	User	Value	Reason
Nov-17-2020 15:39:46 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Time (US & Canada)		(b) (4), (b) (6)	Symptoms: DIARRHEA Symptom Present: NO
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4.h Symptoms:

Date	Location	User	Value	Reason
Nov-17-2020 15:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Nov-17-2020 15:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Nov-17-2020 15:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms: VOMITING Symptom Present: NO	Initial Entry

4.i Symptoms:

Date	Location	User	Value	Reason
Nov-17-2020 15:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Nov-17-2020 15:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.a

Date	Location	User	Value	Reason
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090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Dec-01-2020 09:45:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms - Other:</b> Confusion	Initial Entry
Nov-30-2020 09:05:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms - Other:</b>	Diagnosis not symptom
Nov-17-2020 15:40:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms - Ot COVID 19 Pneu her:</b> monia	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Dec-01-2020 13:25:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 1: Closed	Response satisfies query
Dec-01-2020 09:45:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Dec-01-2020 09:45:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Confusion	Initial Entry
Nov-30-2020 14:16:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 1: Reissued:Opened	CLIQUEY: thank you for your response. Please clarify whether the subject was diagnosed as COVID-19 pneumonia without any symptoms? as there are no symptoms reported in this SOD CRF. Please update as appropriate.
Nov-30-2020 09:05:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Diagnosis not symptom

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Nov-30-2020 09:05:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Diagnosis not symptom
Nov-29-2020 09:47:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 1: Opened	CLIQUEY: Diagnosis should be reported in ILL DETAILS CRF. If the subjects experienced any symptoms, please provide in this CRF.
Nov-17-2020 15:40:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COVID 19 Pneumonia	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-01-2020 09:47:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms - Other loss of appetit : e	Initial Entry

5.b Symptoms - Other Text:

Date	Location	User	Value	Reason
Dec-01-2020 09:47:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> loss of appetite	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-01-2020 09:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms - Other: Nausea	Initial Entry

5.c Symptoms - Other Text:

Date	Location	User	Value	Reason
Dec-01-2020 09:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nausea	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.d

Date	Location	User	Value	Reason
Dec-01-2020 09:49:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms - Other:</b> Frequent urination	Initial Entry

5.d Symptoms - Other Text:

Date	Location	User	Value	Reason
Dec-01-2020 09:49:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Frequent urination	Initial Entry

5.e

Date	Location	User	Value	Reason
Dec-23-2020 11:36:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms - Other:</b> acute encephalopathy	Initial Entry

5.e Symptoms - Other Text:

Date	Location	User	Value	Reason
Dec-23-2020 11:36:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> acute encephalopathy	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Audit Trail  
on Nov/17/2020

**Form Version:** 06-Jul-2020 21:54

**Form Status:**

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

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Date	Location	User	Value	Reason
Nov-17-2020 15:43:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Nov/17/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Feb-01-2021 12:42:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-01-2021 08:27:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	documents uploaded
Jan-31-2021 07:22:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Monitor is unable to verify data. There is no supporting documentation via Florence. Please upload supporting documentation to be verified. Thanks!
Nov-17-2020 15:43:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/19/2020	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Nov-17-2020 15:43:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWABBED MATERIAL	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Nov-17-2020 15:43:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NASOPHARYNX	Initial Entry

**4. Assay Code and Description:**

Date	Location	User	Value	Reason
Nov-17-2020 15:43:47 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SEVERE ACUTE RESP SYNDRO	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Nov/17/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Time (US & Canada)			ME CORONAVIRUS 2	
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5. Device Type:

Date	Location	User	Value	Reason
Nov-17-2020 15:43:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SARS-COV-2 DIAGNOSTIC TES T	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Dec-02-2020 16:51:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 4: Closed	Response satisfies query
Dec-02-2020 14:36:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	query updated
Dec-02-2020 14:21:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 4: Reissued:Opened	Medical monitor: Pease enter "NALT Unknown" instead of "Unknown"
Dec-01-2020 13:36:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-01-2020 09:13:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Dec-01-2020 09:13:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	New Information
Nov-30-2020 13:50:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: The response for "Trade Name" is missing. Please enter "NALT Unknown".
Nov-30-2020 08:27:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	Changed Information

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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History  
on Nov/17/2020**Form Version:** 06-Jul-2020 21:54**Form Status:** Data Complete, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971017**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39

Nov-30-2020 08:27:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-30-2020 08:27:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b>	Changed Information
Nov-28-2020 14:15:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 3: Closed	Response satisfies query
Nov-28-2020 14:15:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Closed	Response satisfies query
Nov-28-2020 14:15:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 5: Closed	Response satisfies query
Nov-28-2020 14:14:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 4: Reissued:Opened	Medical monitor: please enter "NALT Unknown"
Nov-25-2020 13:19:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Query 1: Reissued:Opened	Please refer CCG section 8.31.7, If the Trade Name is not known, enter "NALT Unknown".
Nov-24-2020 13:32:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Answered	Initial Entry
Nov-24-2020 13:32:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	Initial Entry
Nov-24-2020 13:32:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Initial Entry
Nov-24-2020 13:32:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Initial Entry
Nov-24-2020 13:32:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> OTHER	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History  
on Nov/17/2020

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

Nov-24-2020 13:27:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 5: Opened	Clin: For guidance how to complete this CRF form, please refer to the CRF COMPLETION REQUIREMENTS FOR INFORM section 8.31.7. page 138
Nov-24-2020 13:26:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 4: Opened	If the Trade Name is not is not available, and if it is not known whether the test was performed in a CLIA- certified laboratory or in a laboratory accredited by the ISO 15189 standard by a national or regional accredited body, please enter "NALT Unknown"
Nov-24-2020 13:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 3: Opened	Clin: If manufacturer/test kit name is not available, please indicate whether the test was performed by a laboratory accredited by the ISO 15189 standard by including the text 'ISO 15189 accredited lab' (ie SARS-CoV-2 test ISO 15189 accredited lab)
Nov-24-2020 13:26:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Opened	Clin: If manufacturer/test kit name is not available, please indicate whether the test was conducted in a CLIA- certified laboratory by including the text

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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History  
on Nov/17/2020**Form Version:** 06-Jul-2020 21:54**Form Status:** Data Complete, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971017**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39

				'CLIA-certified lab' (ie SARS-CoV-2 test CLIA-certified lab)
Nov-24-2020 10:39:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Answered	SARS Cov-2 NATT
Nov-23-2020 01:56:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Reissued:Opened	DM1: Thank you for response. Please refer CCG section 8.31.4 and select appropriate response from pre-defined dropdown list. Also refer CCG section 8.31.7, If the Trade Name is not known, enter "NALT Unknown".
Nov-20-2020 09:07:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Answered	unknown
Nov-19-2020 00:45:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	DM: The response for "Trade Name" is missing. Kindly review and update.

**7. Test Result:**

Date	Location	User	Value	Reason
Nov-17-2020 15:43:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> POSITIVE	Initial Entry

**9. Trade Name Other, Specify:**

Date	Location	User	Value	Reason
Dec-02-2020 14:35:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> NALT unknown	Changed Information
Dec-02-2020 14:33:59 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> NALT	Changed Information



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History  
on Nov/17/2020

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

Time (US & Canada)		(b) (4), (b) (6)		
Nov-17-2020 15:43:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> unknown	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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1. Data Origin

Date	Location	User	Value	Reason
Nov-24-2020 10:41:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-24-2020 10:41:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-24-2020 15:52:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Closed	Auto closed by Validation Check: VC_BEETRK001_05
Nov-24-2020 10:41:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Initial Entry
Nov-24-2020 10:41:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry</u> : NO	Initial Entry
Nov-24-2020 10:40:20 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry</u> :	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

(US & Canada)				
Nov-23-2020 03:19:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	SWAB forms should not be marked Not Done / Not Applicable. If the sample was not obtained, Sample Collected = No and Sample Comments box should be entered with reason sample not collected. Please update.
Nov-20-2020 09:21:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	no self swab Sample done.
Nov-20-2020 00:30:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Opened	DMW5429606;Sample Collected is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Nov-19-2020 21:23:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_BEETRK001_07
Nov-19-2020 16:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : Not Applicable	Initial Entry
Nov-19-2020 02:08:25 (UTC-05:00) Eastern Time	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW5416030;Sample Collected is not expected to be Not Done. Please review

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

(US & Canada)				and update appropriately or clarify
Nov-18-2020 09:33:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : Not Done	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Nov-20-2020 09:20:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> no sample collected.	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Data Origin**

Date	Location	User	Value	Reason
Nov-17-2020 15:44:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-17-2020 15:44:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-17-2020 16:50:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-17-2020 15:45:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Nov-17-2020 15:44:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	data is correct as entered.
Nov-17-2020 15:44:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-17-2020 15:44:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of Collection is more than 4 days after Date of Last Symptom Resolved on the Signs and Symptoms form in the same visit.

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

				Please review and update as appropriate.
Nov-17-2020 15:44:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Nov/17/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-17-2020 15:45:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPVC4Y	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Nov-17-2020 15:45:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPVC4Y	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/17/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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**I.a**

Date	Location	User	Value	Reason
Nov-17-2020 15:46:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> SPECIALIST <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

**I.a Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Nov-17-2020 15:46:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SPECIALIST	Initial Entry

**I.a Occurrence of Visits or Contacts:**

Date	Location	User	Value	Reason
Nov-17-2020 15:46:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**I.b**

Date	Location	User	Value	Reason
Nov-17-2020 15:46:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> EMERGENCY ROOM <b>Occurrence of Visits or Contacts:</b> YES <b>Number of Visits or Contacts:</b> 1	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/17/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971017**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39***1.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-17-2020 15:46:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EMERGENCY ROOM	Initial Entry

***1.b Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Nov-17-2020 15:46:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Number of Visits or Contacts:</i>  1	Initial Entry

***1.c***

Date	Location	User	Value	Reason
Nov-17-2020 15:46:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> PRIMARY CARE PHYSICIAN <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

***1.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-17-2020 15:46:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PRIMARY CARE PHYSICIAN	Initial Entry

***1.c Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Nov-17-2020 15:46:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.d***



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/17/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Nov-17-2020 15:46:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> URGENT CARE <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

*1.d Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Nov-17-2020 15:46:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> URGENT CARE	Initial Entry

*1.d Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Nov-17-2020 15:46:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*1.e*

Date	Location	User	Value	Reason
Nov-17-2020 15:46:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> TELEPHONE CONSULTATION <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/17/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971017**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39***1.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-17-2020 15:46:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> TELEPHONE CONSULTATION	Initial Entry

***1.e Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Nov-17-2020 15:46:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.f***

Date	Location	User	Value	Reason
Nov-17-2020 15:46:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> OTH R <b>Occurrence of Visits or C</b> NO <b>ontacts:</b>	Initial Entry

***1.f Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-17-2020 15:46:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

***1.f Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Nov-17-2020 15:46:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***3. Has the subject been hospitalized due to potential COVID-19 illness?***

Date	Location	User	Value	Reason
Dec-02-2020 10:30:35 (UTC-05:00) Eastern	ACV0PFEINFP6000	Rupal N Shah	Query 1: Closed	Response satisfies query

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/17/2020

**Form Version:** 10-Oct-2020 15:59

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

Time (US & Canada)		(b) (4)		
Dec-01-2020 14:21:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	updated hospital CRF.
Nov-30-2020 14:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 1: Reissued:Opened	CLIQUEY: thank you for your response. Given that the subject was hospitalized, please update the HOSP CRF as well other CRF with available information.
Nov-30-2020 12:13:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject went to the emergency room and was admitted to the hospital.
Nov-29-2020 09:41:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 1: Opened	CLIQUEY: If the subject was hospitalized, please complete HOSP CRF or else clarify.
Nov-17-2020 15:46:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Has the subject been in intensive care due to potential COVID-19 illness?  NO	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS - Audit Trail  
on Nov/17/2020

**Form Version:** 22-Apr-2020 21:02

**Form Status:**

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

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Date	Location	User	Value	Reason
Dec-01-2020 14:18:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Undeleted	subject was admitted to the hospital.
Nov-20-2020 10:19:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	data recorded in A/E
Nov-17-2020 15:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HOSPITALIZATION DETAILS - eCRF Audit Trail History on Nov/17/2020

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Hospitalization Category:**

Date	Location	User	Value	Reason
Nov-17-2020 15:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> HOSPITALIZATION STATUS	Initial Entry

**2. Hospitalization Term:**

Date	Location	User	Value	Reason
Nov-17-2020 15:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HOSPITAL	Initial Entry

**3. Admission Date:**

Date	Location	User	Value	Reason
Nov-20-2020 11:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-20-2020 10:19:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	data recorded in A/E
Nov-19-2020 10:31:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLIQUEY: Hospitalization:This subject had COVID-19 illness and was hospitalized. Please enter on the CRF form any available information (vital signs, pulse oxymet, respiratory treatment, lab results, imaging...). Please make every effort to obtain these
Nov-17-2020 15:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/19/2020	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS - eCRF Audit Trail History on Nov/17/2020

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

**4. Ongoing?**

Date	Location	User	Value	Reason
Nov-17-2020 15:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO Discharge Date:  Nov/1/2020	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: RESPIRATORY TREATMENT - eCRF Audit Trail History on Nov/17/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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**1. What is the treatment Identifier?**

Date	Location	User	Value	Reason
Nov-17-2020 15:48:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Concomitant Non-drug Treatment Pre-specified:**

Date	Location	User	Value	Reason
Nov-17-2020 15:48:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Treatment:**

Date	Location	User	Value	Reason
Nov-17-2020 15:48:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Treatment:**

Date	Location	User	Value	Reason
Nov-17-2020 15:48:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Start Date:**

Date	Location	User	Value	Reason
Nov-17-2020 15:48:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Ongoing?**

Date	Location	User	Value	Reason
Nov-17-2020 15:48:07	ACV0PFEINFP6000	(b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History  
on Nov/17/2020

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

(UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History  
on Nov/17/2020

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

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**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Nov-17-2020 15:49:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> POTENTIAL COVID-19 ILLNES S	Initial Entry

**2. Was a diagnosis obtained for Potential COVID-19 Illness?**

Date	Location	User	Value	Reason
Nov-17-2020 15:49:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Respiratory Illness Diagnosis:</i>  COVID 19 Pneumonia  Date of Diagnosis:  Oct/19/2020	Initial Entry

**3. Toxicity Grade:**

Date	Location	User	Value	Reason
Nov-17-2020 15:49:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Audit Trail  
on Nov/17/2020

**Form Version:** 17-Jul-2020 21:55

**Form Status:**

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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Date	Location	User	Value	Reason
Nov-20-2020 10:17:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	already recorded as an A/E
Nov-17-2020 15:51:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: ILLNESS DETAILS - SEVERE - eCRF Audit Trail History on Nov/17/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Deleted, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Nov-17-2020 15:51:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SEVERE COVID-19 ILLNESS	Initial Entry

2. Subcategory of Clinical Event:

Date	Location	User	Value	Reason
Nov-17-2020 15:51:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SIGNIFICANT ACUTE NEUROL OGIC DYSFUNCTION	Initial Entry

3. Was a diagnosis obtained?

Date	Location	User	Value	Reason
Nov-20-2020 11:55:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-20-2020 10:17:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	already recorded as an A/E
Nov-19-2020 10:33:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLIQUEY: Diagnosis should be given for events caused by significant acute renal, hepatic, or neurologic dysfunction only. Please update as this is already recorded as an AE.
Nov-17-2020 15:51:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Diagnosis:</i>  Acute Encephalopathy	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail History on Nov/17/2020

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Data Complete, Deleted, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

			Start Date: Oct/19/2020 Ongoing?: NO End Date: Nov/1/2020	
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**4. Toxicity Grade:**

Date	Location	User	Value	Reason
Nov-17-2020 15:51:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 3	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020**Form Version:** 21-Aug-2020 02:49**Site No:** 1097**Subject No:** 10971017**Generated By:** (b) (4)**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

			<b>Not Done::</b>	Not Applicable
			<b>Lab Normal Range:</b>	Not Applicable

5.a Sponsor ID:

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:49**Form Status:** Data Complete, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971017**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39**5.b Sponsor ID:**

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b Test:**

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b Result:**

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b Not Done:**

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b LNMT**

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable	Initial Entry



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

			<b>Test::</b>	Not Applicable	
			<b>Result::</b>	Not Applicable	
			<b>Not Done::</b>	Not Applicable	
			<b>Lab Normal Range:</b>	Not Applicable	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.c Sponsor ID:

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Sponsor-Defined Identifier:</u> Not Applicable	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

			<b>Test::</b>	Not Applicable	
			<b>Result::</b>	Not Applicable	
			<b>Not Done::</b>	Not Applicable	
			<b>Lab Normal Range:</b>	Not Applicable	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

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Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.d Sponsor ID:

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Sponsor-Defined Identifier:</u> Not Applicable	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

			<b>Test::</b>	Not Applicable	
			<b>Result::</b>	Not Applicable	
			<b>Not Done::</b>	Not Applicable	
			<b>Lab Normal Range:</b>	Not Applicable	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

**5.e Sponsor ID:**

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.e Test:**

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.e Result:**

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.e Not Done:**

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.e LNMT**

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.f**

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

			<b>Test::</b>	Not Applicable	
			<b>Result::</b>	Not Applicable	
			<b>Not Done::</b>	Not Applicable	
			<b>Lab Normal Range:</b>	Not Applicable	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.f Sponsor ID:

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.g

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Sponsor-Defined Identifier:</u> Not Applicable	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

			<b>Test::</b>	Not Applicable	
			<b>Result::</b>	Not Applicable	
			<b>Not Done::</b>	Not Applicable	
			<b>Lab Normal Range:</b>	Not Applicable	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

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Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

**5.g Sponsor ID:**

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

**5.g Test:**

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

**5.g Result:**

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

**5.g Not Done:**

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

**5.g LNMT**

Date	Location	User	Value	Reason
Nov-17-2020 15:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

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Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

			<b>Not Done::</b>	Not Applicable
			<b>Lab Normal Range:</b>	Not Applicable

5.a Sponsor ID:

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b

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**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

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Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry

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5.b Test:

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.b Result:

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Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Sponsor-Defined Identifier:</u> Not Applicable	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

			<b>Test::</b>	Not Applicable	
			<b>Result::</b>	Not Applicable	
			<b>Not Done::</b>	Not Applicable	
			<b>Lab Normal Range:</b>	Not Applicable	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

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Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.c Sponsor ID:

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Sponsor-Defined Identifier:</u> Not Applicable	Initial Entry

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**Site No:** 1097

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**Generated Time (GMT):** 29-Mar-2021 10:39

			<b>Test::</b>	Not Applicable	
			<b>Result::</b>	Not Applicable	
			<b>Not Done::</b>	Not Applicable	
			<b>Lab Normal Range:</b>	Not Applicable	

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Generated Time (GMT): 29-Mar-2021 10:39

5.d Sponsor ID:

Date	Location	User	Value	Reason
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5.d Test:

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

			<b>Test::</b>	Not Applicable	
			<b>Result::</b>	Not Applicable	
			<b>Not Done::</b>	Not Applicable	
			<b>Lab Normal Range:</b>	Not Applicable	

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:51**Form Status:** Data Complete, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971017**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39**5.e Sponsor ID:**

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.e Test:**

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.e Result:**

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.e Not Done:**

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.e LNMT**

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.f**

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

			<b>Test::</b>	Not Applicable	
			<b>Result::</b>	Not Applicable	
			<b>Not Done::</b>	Not Applicable	
			<b>Lab Normal Range:</b>	Not Applicable	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

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Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.f Sponsor ID:

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.g

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Sponsor-Defined Identifier:</u> Not Applicable	Initial Entry

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**Header Text:** c4591001

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**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

			<b>Test::</b>	Not Applicable	
			<b>Result::</b>	Not Applicable	
			<b>Not Done::</b>	Not Applicable	
			<b>Lab Normal Range:</b>	Not Applicable	

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:51**Form Status:** Data Complete, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971017**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39**5.g Sponsor ID:**

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g Test:**

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g Result:**

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g Not Done:**

Date	Location	User	Value	Reason
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**5.g LNMT**

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.h**

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable	Initial Entry



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

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**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

			<b>Test::</b>	Not Applicable	
			<b>Result::</b>	Not Applicable	
			<b>Not Done::</b>	Not Applicable	
			<b>Lab Normal Range:</b>	Not Applicable	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

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Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.h Sponsor ID:

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Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.i

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

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**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

			<b>Test::</b>	Not Applicable	
			<b>Result::</b>	Not Applicable	
			<b>Not Done::</b>	Not Applicable	
			<b>Lab Normal Range:</b>	Not Applicable	

Header Text: c4591001

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**5.i Sponsor ID:**

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.i Not Done:**

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.i LNMT**

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.j**

Date	Location	User	Value	Reason
Nov-17-2020 15:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sponsor-Defined Ide Not Applic	Initial Entry

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			<b>ntifier:</b>	able	
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			<b>Result::</b>	Not Applicable	
			<b>Not Done::</b>	Not Applicable	
			<b>Lab Normal Range:</b>	Not Applicable	

**Header Text:** c4591001

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**5.j Sponsor ID:**

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**5.j Not Done:**

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**5.j LNMT**

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Nov/17/2020

Form Version: 21-Aug-2020 02:50

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Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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1. Date:

Date	Location	User	Value	Reason
Nov-17-2020 15:53:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-17-2020 15:53:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> Not Applicable <b>Systolic::</b> Not Applicable <b>Diastolic::</b> Not Applicable <b>Respiratory Rate in res</b> Not Applicable <b>pirations/minute:</b> licable <b>Heart Rate in beats/mi</b> Not Applicable <b>nute:</b> licable	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-17-2020 15:53:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Nov-17-2020 15:53:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
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090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History  
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**2.a Respiratory Rate in respirations/minute:**

Date	Location	User	Value	Reason
Nov-17-2020 15:53:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a Heart Rate in beats/minute:**

Date	Location	User	Value	Reason
Nov-17-2020 15:53:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Date:**

Date	Location	User	Value	Reason
Nov-17-2020 15:54:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Nov-17-2020 15:54:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> Not Applicabl : e <b>Oxygen Saturatio</b> Not Applicabl <b>n:</b> e	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Nov-17-2020 15:54:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a SPO2 Pulse Oximetry %**

Date	Location	User	Value	Reason
Nov-17-2020 15:54:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History on Nov/17/2020

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

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**1. Date Time of Assessment:**

Date	Location	User	Value	Reason
Nov-17-2020 15:54:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Arterial Blood Gases PaO2 (mmHg):**

Date	Location	User	Value	Reason
Nov-17-2020 15:54:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. FiO2 (Fraction of Inhaled Oxygen):**

Date	Location	User	Value	Reason
Nov-17-2020 15:54:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Nov-17-2020 15:55:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Nov-17-2020 15:55:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Nov-17-2020 15:55:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Medication:**

*Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).*

Date	Location	User	Value	Reason
Nov-17-2020 15:55:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Start Date:**

Date	Location	User	Value	Reason
Nov-17-2020 15:55:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Ongoing?**

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/17/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Nov-17-2020 15:55:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** IMAGING - Audit Trail  
on Nov/17/2020

**Form Version:** 06-Jul-2020 21:53

**Form Status:**

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

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Date	Location	User	Value	Reason
Nov-17-2020 15:56:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: IMAGING - eCRF Audit Trail History  
on Nov/17/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
Nov-17-2020 15:56:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/19/2020	Initial Entry

**2. Location of Assessment:**

Date	Location	User	Value	Reason
Nov-17-2020 15:56:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHEST	Initial Entry

**3. Type of Imaging Exam:**

Date	Location	User	Value	Reason
Nov-17-2020 15:56:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> X-RAY	Initial Entry

**4. Assessment:**

Date	Location	User	Value	Reason
Nov-17-2020 15:56:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ABNORMAL <i>If abnormal, specify findings:</i>  Left upper lobe infiltrate.	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Dec/15/2020

**Form:** DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit  
Trail History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

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**1. Date of Visit**

Date	Location	User	Value	Reason
Dec-29-2020 11:41:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/15/2020	Initial Entry

**3. COVID-19 Illness Visit:**

Date	Location	User	Value	Reason
Dec-29-2020 11:41:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COVID_A1	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Dec/15/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1097**Subject No:** 10971017**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -  
eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Dec-29-2020 11:42:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Dec-29-2020 11:42:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Dec-29-2020 11:45:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-29-2020 11:42:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-29-2020 11:42:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Dec/15/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-29-2020 11:45:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPVC75	Initial Entry



**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Dec/15/2020

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -  
eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

**5.a Sample ID**

Date	Location	User	Value	Reason
Dec-29-2020 11:45:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPVC75	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Dec-29-2020 11:45:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPVC76	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Dec-29-2020 11:45:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPVC76	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Dec-30-2020 15:04:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID:	does not belong to this subject. Got very little blood and only two samples were submitted for this subject.
Dec-29-2020 11:46:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPVC77	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled Visit on Dec/15/2020

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

**5.c Sample ID**

Date	Location	User	Value	Reason
Dec-30-2020 21:31:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_BEETRK001_06
Dec-30-2020 15:04:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	does not belong to this subject. Got very little blood and only two samples were submitted for this subject.
Dec-30-2020 15:04:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	does not belong to this subject. Got very little blood and only two samples were submitted for this subject.
Dec-30-2020 07:14:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6657941; This Barcode appears to be already recorded within the study. Please review and update as appropriate.
Dec-29-2020 11:46:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPVC 77	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Dec-29-2020 11:47:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BL9XSH	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Dec/15/2020

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -  
eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

**5.d Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Dec-29-2020 11:47:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u><b>Data Entry:</b></u> BL9XSH	Initial Entry

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Oct/17/2020

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

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**I. Date of Visit**

Date	Location	User	Value	Reason
Dec-02-2020 08:27:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-02-2020 01:31:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Deleted	Query is invalid or does not apply
Dec-01-2020 15:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Dec-01-2020 15:28:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this visit.
Dec-01-2020 14:54:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	CLINREQUEST: No Updates were Made. Indicate why this Date of Visit (17-Oct-20) was entered. Was there an Unplanned Visit conducted? If yes, determine if the Unplanned Assessments CRF should be completed. Otherwise, if Erroneous, update field #2.
Dec-01-2020 14:22:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Dec-01-2020 09:21:49	ACV0PFEINFP6000	auto query	Query 2: Deleted	Close Auto Query

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Oct/17/2020

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

(UTC-05:00) Eastern Time (US & Canada)		(autoquery)		
Dec-01-2020 09:15:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this visit.
Nov-30-2020 16:49:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Please specify why this CRF was completed. If this was an Erroneous visit, please update the CRF accordingly.
Nov-30-2020 15:03:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candidate	CLINQUERY: Please specify why this CRF was completed. If this was an Erroneous visit, please update the CRF accordingly
Nov-25-2020 09:45:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/17/2020	Initial Entry

**2. Erroneous Visit**

Date	Location	User	Value	Reason
Dec-01-2020 15:28:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ERRONEOUS VISIT	Initial Entry
Dec-01-2020 09:21:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-01-2020 09:15:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ERRONEOUS VISIT	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Oct-16-2020 08:45:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/14/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-16-2020 08:45:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-16-2020 12:04:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-16-2020 08:45:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Oct-16-2020 08:45:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry
Oct-15-2020 17:13:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY:If the Participant receives all vaccinations as per protocol and the follow-up visit procedures within the 1-month post vaccination period, report the status as COMPLETED. Please complete the EOT CRF for ALL Pts that completed Visit 3.Thank you.

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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Date	Location	User	Value	Reason
Dec-23-2020 11:40:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	per medical monitor this SAE is considered invalid being that it meet endpoint and was entered in SOD form per request
Nov-13-2020 10:54:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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Date	Location	User	Value	Reason
Nov-13-2020 11:35:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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Date	Location	User	Value	Reason
Nov-16-2020 15:33:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971017

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

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**1. Category:**

Date	Location	User	Value	Reason
Nov-13-2020 10:54:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Nov-13-2020 10:54:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Dec-24-2020 13:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Closed	Response satisfies query
Dec-23-2020 11:38:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	added to SOD CRF form under other symptom and will delete this SAE entry per request
Dec-23-2020 01:58:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Reissued:Opened	Medical monitor: The SAE report is considered INVALID. Please move this event to the SOD CRF form. The hospitalization is already reported in the potential COVID-19 visit. Please get help from the CRA.
Dec-22-2020 09:32:13 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Per study protocol SAE had to be filed

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Time (US & Canada)				due to hospitalization. This was part of the hospital's diagnosis.
Dec-21-2020 16:02:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Reissued:Opened	Medical monitor: Per Prot Sect 8.3.7, please potential COVID-19 illnesses and their sequelae should not be recorded as SAE since they meets efficacy endpoint criteria. Please get help from the CRA.
Dec-18-2020 11:39:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Patient was hospitalized. This was part of his hospital diagnosis. Therefore, SAE was necessary.
Dec-18-2020 08:26:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Reissued:Opened	Medical monitor: Please move this event to the SOD CRF form
Dec-16-2020 13:47:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Please clarify data needed here, subject was hospitalized which triggered the SAE application.
Dec-15-2020 23:02:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Reissued:Opened	Medical monitor: Per Prot Sect 8.3.7, please potential COVID-19 illnesses and their sequelae should not be recorded as SAE since they meets efficacy endpoint criteria. These data should be captured only on the

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				COVID-A CRF SOD form
Dec-15-2020 22:59:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 3: Closed	Response satisfies query
Dec-15-2020 09:37:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	subject was hospitalized
Dec-15-2020 09:36:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Subject was hospitalized for the encephalopathy.
Dec-12-2020 06:21:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 3: Opened	Clin: The SAE report #2020446797 of acute encephalopathy was considered invalid in the Safety database since this event meets efficacy endpoint criteria per protocol Section 8.3.7.
Dec-12-2020 06:18:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Reissued:Opened	Clin: Per protocol section 8.3.7, please potential COVID-19 illnesses and their sequelae should not be recorded as SAE since they meets efficacy endpoint criteria. These data will be captured as efficacy assessment data only on COVID-A CRF SOD form
Dec-07-2020 13:37:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	subject was hospitalized and had other factors involved but did test positive in hospital.

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Dec-07-2020 12:07:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Opened	Clin: Per protocol section 8.3.7, please potential COVID-19 illnesses and their sequelae should not be recorded as SAE since they meets efficacy endpoint criteria. These data will be captured as efficacy assessment data only on COVID-A CRF SOD form
Nov-16-2020 17:57:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-16-2020 15:35:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	data added.
Nov-16-2020 15:27:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Clinical - no adverse event of UTI has been entered on the AE CRF, as reported in the SAE report. Please review and record if UTI is a confirmed event.
Nov-16-2020 15:00:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	updated
Nov-15-2020 12:35:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL - SAE (#2020446797) narrative reports the diagnosis of UTI in the Emergency room on 19Oct2020; however, no event of UTI appears on the AE log CRF. Please review for safety and update AE log CRF

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				accordingly.
Nov-13-2020 10:54:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Acute encephalopathy	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-16-2020 16:42:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-16-2020 13:25:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-16-2020 13:25:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/18/2020 21:40	Transcription Error
Nov-14-2020 08:24:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2020446797 ,onset date was recorded as 18Oct2020 in Safety database however, recorded as 19Oct2020 on AE CRF. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form.
Nov-13-2020 10:54:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/19/2020 21:40	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-16-2020 17:46:11 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

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Time (US & Canada)				
Nov-16-2020 17:38:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Nov-16-2020 17:38:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	New Information
Nov-16-2020 16:43:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Is the adverse event still ongoing? is blank. Please complete field
Nov-16-2020 14:32:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Nov-13-2020 10:54:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Nov/1/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-13-2020 10:54:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Dec-07-2020 05:37:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query

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Dec-07-2020 05:36:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Deleted	Close Auto Query
Dec-04-2020 12:59:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	For AE Acute encephalopathy: Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present.
Dec-04-2020 12:59:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	invalidated by SAE Safety.
Dec-04-2020 12:59:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	invalidated by SAE Safety.
Dec-04-2020 07:12:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2020446797 acute encephalopathy(onset date:18Oct2020)was invalidated in Safety database but reported serious in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Nov-14-2020 08:17:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-13-2020 10:54:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Acute encephalopathy: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-13-2020 10:54:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Is this serious event asso ciated with congenital an	Initial Entry

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			<p>omaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	
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**8. Is this adverse event the result of a study Medication Error?**

*If Yes, record the type of medication error on the Medication Error Log.*

Date	Location	User	Value	Reason
Nov-13-2020 10:54:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Nov-16-2020 16:26:30	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies

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(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		query
Nov-16-2020 15:25:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-16-2020 15:14:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Nov-16-2020 15:14:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  COVID 19 and UTI and O Piod use	New Information

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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-16-2020 15:07:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	UTI added to A/E log
Nov-15-2020 12:40:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL Event of encephalopathy reported related to COVID & UTI; however, SAE report states "1) Acute encephalopathy- multifactorial likely secondary to COVID 19 pneumonia, UTI and opioid use." Please review, harmonize reporting, & update where required
Nov-14-2020 15:13:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	Please review "If not related to study treatment other" field, the following text was indicated in the comment field [COVID-19, UTI]. Any symptoms, AEs or other key data should be collected on the

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				appropriate page. Please review and update as necessary. (b) (4)
Nov-13-2020 10:55:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment (s), this event is due to:  OTHER  <i>If Other, specify:</i>  COVID 19 and UTI	New Information
Nov-13-2020 10:54:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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Nov-13-2020 10:54:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry
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**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Nov-13-2020 10:54:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Nov-13-2020 10:54:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Nov-16-2020 16:44:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-16-2020 14:32:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Nov-16-2020 13:19:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE Acute encephalopathy: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Nov-16-2020 13:19:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error

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Generated By: (b) (4)

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Nov-16-2020 13:19:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERING/RE SOLVING	Transcription Error
Nov-14-2020 08:35:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020363610,outcome was reported as Recovering/Resolving to Safety DB however, recorded as RECOVERED/RESOLVED on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Nov-13-2020 10:54:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RE SOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Nov-13-2020 10:54:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Dec-07-2020 05:36:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	downgraded to non serious
Nov-14-2020 08:17:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2020446797	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Nov-13-2020 11:35:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-13-2020 11:35:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-12-2021 15:09:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Closed	Response satisfies query
Mar-12-2021 15:08:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Mar-11-2021 13:53:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Answered	Changed Information
Mar-11-2021 13:53:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	Changed Information
Mar-11-2021 13:53:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> non traumatic retroperitoneal h ematoma	Changed Information
Mar-11-2021 12:56:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Reissued:Opened	Clinical - AE is now unfrozen
Mar-11-2021 12:30:58 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Opened	Clinical - Event term is Non-traumatic

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Time (US & Canada)				retroperitoneal Hemorrhage; however, SAE term is Non-traumatic retroperitoneal Hematoma. Please review, harmonize reporting, and update where applicable
Mar-10-2021 10:56:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	please unfreeze this line as event term needs to be corrected and also sending in INR results on new SAE form along with updated event term today
Mar-09-2021 22:15:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Mar-09-2021 22:13:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Reissued:Opened	Clinical - Thank you; please submit a SAE update with the INR result in the lab test section
Mar-09-2021 16:56:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	He had an INR result of 1.2 on 11/17/2020
Mar-09-2021 16:55:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	completed
Mar-09-2021 13:25:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	Clinical - please submit coagulation test results to SAE (#2020453104), if available
Mar-09-2021 13:16:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Clinical - subject received transfusion for this event; please complete transfusion Log

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Nov-24-2020 23:02:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-24-2020 15:37:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Nov-24-2020 15:37:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> non traumatic retroperitoneal h emorrhage	Changed Information
Nov-24-2020 14:10:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical - Event name is Retroperitoneal hemorrhage; however, SAE event name is Non-traumatic Retroperitoneal hemorrhage. Please review, harmonize reporting, and update in the appropriate location
Nov-24-2020 12:54:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-24-2020 11:06:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	has been done.
Nov-21-2020 19:06:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	CLINICAL Thank you for entering event Retroperitoneal Hemorrhage. Please submit a SAE Safety f/u with this event (still is Hospitalization NOS).
Nov-20-2020 10:27:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Retroperitoneal Hemorrhage	Transcription Error
Nov-20-2020 10:23:43	ACV0PFEINFP6000	auto query	Query 1: Answered	New Information

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(UTC-05:00) Eastern Time (US & Canada)		(autoquery)		
Nov-20-2020 10:23:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Retroperitoneal Hemorrhage	New Information
Nov-19-2020 01:20:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL please enter an event for SAE #2020453104. If the Acute Encephalopathy event continues and is the basis for re-hospitalization, this can be a continuation (followup) of SAE #2020446797 despite some outpatient days.
Nov-13-2020 11:35:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hospitalization not otherwise specified.	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Nov-24-2020 11:14:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/13/2020 UNK:UNK	Initial Entry
Nov-24-2020 11:13:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Nov-13-2020 11:35:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/13/2020 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Jan-12-2021 13:43:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query

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Dec-28-2020 10:35:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	submitted
Dec-22-2020 14:30:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	CLINICAL SAE end date is reported as 15Nov20; however, SAE report has no end date. Please submit end date in SAE Event section at Stop date/time
Dec-22-2020 12:23:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-21-2020 15:02:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	updated
Dec-21-2020 15:02:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Nov/15/2020 UNK:UNK	updated
Dec-21-2020 14:08:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINQUERY: Please determine if this Adverse Event is still ONGOING as it has been 32 Days since Onset Date. Please update or confirm. If updated, please ensure an updated SAE Report is also submitted.
Nov-24-2020 12:55:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-24-2020 11:12:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-24-2020 11:12:59	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error

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(UTC-05:00) Eastern Time (US & Canada)		(b) (4)	YES	
Nov-21-2020 19:07:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL Event end date is 15Nov 20; however, SAE report states event is ongoing. Please review, harmonize reporting, and update in the appropriate location.
Nov-20-2020 10:26:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Nov/15/2020 UNK:UNK	New Information
Nov-13-2020 11:35:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-13-2020 11:35:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Dec-22-2020 12:23:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Closed	Response satisfies query
Dec-21-2020 15:05:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Answered	updated

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<p>Dec-21-2020 15:05:07 (UTC-05:00) Eastern Time (US &amp; Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p><b>Data Entry:</b>          YES          Is this serious event associated with congenital anomaly or birth defect?           NO           Did this serious event result in death?           NO           Did this serious event require or prolong hospitalization?           YES           Did this serious event result in persistent or significant disability/incapacity?           NO           Is this serious event life threatening?           NO           Other medically important serious event           YES</p>	<p>updated</p>
<p>Dec-21-2020 14:07:13 (UTC-05:00) Eastern Time (US &amp; Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>Query 5: Opened</p>	<p>Per the Safety Report, there are 2 Seriousness Criteria noted, Hospitalization and Medically Important Event. Therefore, please confirm the question "Other Medically Important Serious Event" should be YES and update the data. Otherwise, please</p>

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				clarify.
Nov-24-2020 14:18:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Query closed; will follow for SAE update with the requested COVID test info

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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Nov-24-2020 13:39:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	done
Nov-24-2020 12:59:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Reissued:Opened	CLINICAL Thank you; please submit this 13Nov2020 SARs Cov-2 NATT test information as a SAE safety update
Nov-24-2020 11:18:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	SARS Cov-2 NATT on 11-13-2020 is negative.
Nov-21-2020 19:10:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	CLINICAL Please update the SAE form for any COVID retest during hospitalization (for continued viral shedding)
Nov-17-2020 06:21:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	recorded in SDB
Nov-16-2020 16:48:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Candidate	Awaiting safety update
Nov-16-2020 15:18:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	has been addressed today.
Nov-14-2020 11:31:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	SAE RECON: Hospitalization not otherwise specified.

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				(Onset date: 13Nov2020) is not reported to Safety database but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF
Nov-14-2020 11:31:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query can be addressed internally
Nov-13-2020 11:56:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Nov-13-2020 11:56:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b></p> <p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p>	Transcription Error

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			NO Other medically important serious event NO	
Nov-13-2020 11:35:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Is this adverse event serious?' is reported 'Yes', but at least one seriousness criteria is missing. Please review and update as appropriate.
Nov-13-2020 11:35:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Hospitalization not otherwise specified.: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-13-2020 11:35:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**8. Is this adverse event the result of a study Medication Error?**  
*If Yes, record the type of medication error on the Medication Error Log.*

Date	Location	User	Value	Reason
Nov-13-2020 11:35:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Mar-12-2021 15:08:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-12-2021 07:48:40 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information

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Time (US & Canada)				
Mar-12-2021 07:48:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  unknown	New Information
Mar-11-2021 23:40:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	event is now unfrozen
Mar-10-2021 10:31:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	the event is not related to coumadin, line needs to be unfrozen so that site can fix entry.
Mar-09-2021 22:17:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Clinical - AE is fine (states Coumadin) - please submit a SAE update with a revised PI statement about possible SAE relationship to other Con Meds
Mar-09-2021 16:58:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Please unlock so that it can be corrected.
Mar-09-2021 13:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical - Other relationship for event is COUMADIN, however, SAE statement records PI did not feel there was a relationship with any Con Med. Please review, harmonize reporting, and

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				update where applicable
Nov-20-2020 10:31:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  Coumadin	New Information
Nov-13-2020 11:35:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  unknown at this time	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-13-2020 11:35:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-13-2020 11:35:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-13-2020 11:35:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Dec-31-2020 02:52:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Closed	Response satisfies query
Dec-22-2020 10:02:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Answered	Outcome is recovered/resolved.
Dec-22-2020 06:53:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Opened	SAE RECON:AER#2020453104 .outcome was updated to RECOVERED/RESOLVED on AE CRF while reported as Recovering/Resolving in Safety database. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Dec-21-2020 15:06:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Closed	Close Auto Query
Dec-21-2020 15:06:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLV ED	updated
Dec-21-2020 15:02:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Opened	For AE non traumatic retroperioneal hemorrhage: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Nov-25-2020 07:47:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971017

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

Nov-24-2020 11:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	Changed Information
Nov-24-2020 11:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERING/RESOLVING	Changed Information
Nov-23-2020 04:49:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	SAE RECON:AER#2020453104 ,outcome was updated to RECOVERED/RESOLVED on AE CRF while reported as Recovering/Resolving in Safety database. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Nov-20-2020 10:40:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Nov-20-2020 10:40:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	New Information
Nov-20-2020 10:39:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	For AE Retroperitoneal Hemorrhage: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Nov-20-2020 10:39:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Nov-20-2020 10:39:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERING/RESOLVING	Transcription Error

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971017

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

Nov-20-2020 10:27:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE Retroperitoneal Hemorrhage: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Nov-20-2020 10:26:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE Retroperitoneal Hemorrhage: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Nov-13-2020 11:58:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-13-2020 11:58:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RECOVERED/NO T RESOLVED	Transcription Error
Nov-13-2020 11:35:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Hospitalization not otherwise specified.: Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Nov-13-2020 11:35:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNKNOWN	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Nov-13-2020 11:35:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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**15. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
Nov-17-2020 06:20:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2020453104	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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1. Category:

Date	Location	User	Value	Reason
Nov-16-2020 15:33:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-16-2020 15:33:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-16-2020 15:33:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> urinary tract infection	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-16-2020 15:33:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/19/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-16-2020 15:33:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Nov/1/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)



Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Nov-16-2020 15:33:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 3	Initial Entry
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**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

**Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).**

Date	Location	User	Value	Reason
Nov-16-2020 15:33:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**8. Is this adverse event the result of a study Medication Error?**

**If Yes, record the type of medication error on the Medication Error Log.**

Date	Location	User	Value	Reason
Nov-16-2020 15:33:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Nov-16-2020 15:33:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  If Other, specify:  unknown	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Nov-16-2020 15:33:56 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

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Header Text: c4591001

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Site No: 1097

Subject No: 10971017

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

Time (US & Canada)

(b) (4)

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-16-2020 15:33:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-16-2020 15:33:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Nov-16-2020 15:33:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RECOVERED/RESOLVED	Initial Entry

14 Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Nov-16-2020 15:33:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** TRANSFUSIONS - Audit Trail

**Form Status:**

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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Date	Location	User	Value	Reason
Mar-09-2021 16:52:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** TRANSFUSIONS - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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**1. Transfusion Type:**

Date	Location	User	Value	Reason
Mar-09-2021 16:52:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PACKED RBC	Initial Entry

**2. Date of Transfusion:**

Date	Location	User	Value	Reason
Mar-09-2021 16:52:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/13/2020	Initial Entry

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

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*I. Date of Visit*

Date	Location	User	Value	Reason
Jan-18-2021 14:38:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Jan/18/2021	Initial Entry

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form Version:** 10-Dec-2020 02:25

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit  
Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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**1. Select appropriate response - Is participant willing to return for Vaccination 3?**

Date	Location	User	Value	Reason
Jan-19-2021 11:21:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-19-2021 06:39:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-18-2021 14:39:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-18-2021 14:39:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is willing to return for Vaccination 3 Participant is:  eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Jan-19-2021 11:21:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/18/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Jan-19-2021 11:21:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR A DDITIONAL VACCINATION	Initial Entry

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**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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*I. Date of Visit*

Date	Location	User	Value	Reason
Jan-18-2021 14:39:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/18/2021	Initial Entry



**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:31

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** INFORMED CONSENT - FURTHER VACCINATION - eCRF  
Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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**I. Consent Was:**

Date	Location	User	Value	Reason
Jan-18-2021 14:40:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Jan/18/2021	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION  
- eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Jan-18-2021 14:40:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/18/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Jan-18-2021 14:40:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> REPEAT SCREENING 1	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Jan-18-2021 14:40:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Data Origin**

Date	Location	User	Value	Reason
Jan-18-2021 14:41:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-18-2021 14:41:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-18-2021 16:34:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-18-2021 14:41:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-18-2021 14:41:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jan/18/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-18-2021 16:34:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP2RT2	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.a Sample ID

Date	Location	User	Value	Reason
Jan-18-2021 16:34:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP2RT2	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-18-2021 16:34:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BP2RT3	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-18-2021 16:34:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP2RT3	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-18-2021 16:34:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BP2RT4	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-18-2021 16:34:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP2RT4	Initial Entry

5.d

Date	Location	User	Value	Reason
Jan-18-2021 16:44:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BHGTDW	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

**5.d Sample ID**

Date	Location	User	Value	Reason
Jan-18-2021 16:44:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BHGTDW	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Jan-18-2021 16:45:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BHGTDX	Initial Entry

**5.e Sample ID**

Date	Location	User	Value	Reason
Jan-18-2021 16:45:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BHGTDX	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Data Origin**

Date	Location	User	Value	Reason
Jan-18-2021 14:41:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-18-2021 14:41:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-18-2021 16:45:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-18-2021 14:41:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-18-2021 14:41:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jan/18/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-18-2021 16:45:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP2RSP	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-18-2021 16:45:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP2RSP	Initial Entry

Header Text: c4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1097

Subject No: 10971017

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Jan-18-2021 14:42:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Jan-18-2021 14:42:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Jan-18-2021 14:42:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Jan-18-2021 14:42:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/18/2021 13:27	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Jan-18-2021 14:42:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Jan-18-2021 14:42:35 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)



Header Text: c4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1097

Subject No: 10971017

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

Time (US & Canada)

(b) (4), (b) (6)

7. Route:

Date	Location	User	Value	Reason
Jan-18-2021 14:42:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-18-2021 14:42:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-18-2021 14:42:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry

10 Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-18-2021 14:42:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Jan-18-2021 14:42:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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*I. Date of Visit*

Date	Location	User	Value	Reason
Feb-08-2021 14:14:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/8/2021	Initial Entry

Header Text: c4591001

Visit: V102\_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-08-2021 14:14:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-08-2021 14:14:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-08-2021 14:15:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-08-2021 14:14:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-08-2021 14:14:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/8/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-08-2021 14:15:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP2RZR	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-08-2021 14:15:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP2RZR	Initial Entry

Header Text: c4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1097

Subject No: 10971017

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Feb-08-2021 14:16:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Feb-08-2021 14:16:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Feb-08-2021 14:16:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Feb-08-2021 14:16:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/8/2021 12:33	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Feb-08-2021 14:16:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Feb-08-2021 14:16:05 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1097

Subject No: 10971017

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

Time (US & Canada)

(b) (4), (b) (6)

7. Route:

Date	Location	User	Value	Reason
Feb-08-2021 14:16:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-08-2021 14:16:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-08-2021 14:16:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry

10 Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-08-2021 14:16:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Feb-08-2021 14:16:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V103\_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971017

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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*I. Date of Visit*

Date	Location	User	Value	Reason
Mar-09-2021 13:07:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-09-2021 08:14:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	updated
Mar-09-2021 02:33:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Patient completed Vaccination 3 visit through the 1-month post vaccination visit after the Vaccination 4. Please complete treatment disposition CRF and update date of EOT2 to match date of visit at visit 103.
Mar-08-2021 14:18:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/8/2021	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V103\_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1097

Subject No: 10971017

Generated By: (b) (4)

Form: CONTACT OUTCOME - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Contact Type:**

Date	Location	User	Value	Reason
Mar-08-2021 14:18:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> TELEPHONE VISIT	Initial Entry

**2. Was contact made?**

Date	Location	User	Value	Reason
Mar-08-2021 14:18:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Contact:  Mar/8/2021	Initial Entry

**3. Comments:**

Date	Location	User	Value	Reason
Mar-08-2021 14:20:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Subject has nothing new to report.	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)



**Header Text:** c4591001

**Visit:** FURTHER\_VACCINATION\_EOT -  
Unscheduled

**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

**Form Version:** 20-Feb-2021 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Mar-09-2021 08:13:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/8/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Mar-09-2021 08:13:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> OPEN LABEL TREATMENT	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Mar-09-2021 08:13:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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**I. Subject Status**

Date	Location	User	Value	Reason
Oct-16-2020 08:45:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Aug-25-2020 17:29:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Aug-25-2020 17:21:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Mar-05-2021 14:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar 05 2021 07 43 39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1 Answered	a destruction form has been submitted to our monitor and she is handling it for these bar codes
Mar-04-2021 12:52:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	HOLDS: The lab has received serum sample barcodes BL9XRK, BL9XRL labeled as visit 'Covid A' (samples received 5-Dec-20). However, these barcodes have not been recorded. Please review and update if appropriate. Otherwise please clarify.

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1097

**Subject No:** 10971017

**Generated By:** (b) (4)

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

Oct-16-2020 08:45:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/14/2020	Initial Entry
Aug-25-2020 17:29:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/22/2020	Initial Entry
Aug-25-2020 17:21:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/22/2020	Initial Entry

090177e196ae3ebf\Final\Final On: 01-Apr-2021 04:59 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971017

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:39

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*I. Casebook Signature*

Date	Location	User	Value	Reason
Oct-21-2020 22:29:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry