

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1097

Subject No: 10971084

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: 10971084

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 Sep/1/2020
----	--------------	---------------------------------------------------------

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1097

Subject No: 10971084

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	[10971084]
2.	Birth Date:	(b) (6) 1935
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:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971084

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/1/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1097

Subject No: 10971084

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 Done _____
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Exclusion Criteria Met

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971084

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	Sep/1/2020
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: 10971084

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:	[Angioplasty]
	Start Date:	Oct/1/2003
	Ongoing:	NO End Date: Oct/1/2003
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Cardiac Stent Insertion]
	Start Date:	May/1/2008
	Ongoing:	NO End Date: May/1/2008
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Right Knee Replacement]
	Start Date:	May/31/2005
	Ongoing:	NO End Date: May/31/2005
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Right Rotator Cuff Repair]
	Start Date:	Nov/30/2006
	Ongoing:	NO End Date: Nov/30/2006

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971084

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:	[Appendectomy]
	Start Date:	Aug/19/2011
	Ongoing:	NO End Date: Aug/19/2011
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Bladder stone removal]
	Start Date:	Apr/21/2011
	Ongoing:	NO End Date: Apr/21/2011
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Kidney stone removal]
	Start Date:	Jun/6/2011
	Ongoing:	NO End Date: Jun/6/2011
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Left Rotator Cuff repair]
	Start Date:	Oct/5/2011
	Ongoing:	NO End Date: Oct/5/2011
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Bladder Cancer]
	Start Date:	May/1/2012
	Ongoing:	NO End Date: Dec/10/2012

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971084

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 j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HEART CATHETERIZATION]
	Start Date:	Feb/6/2013
	Ongoing:	NO End Date: Feb/6/2013
1 k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Cataract removal]
	Start Date:	UNK/UNK/2014
	Ongoing:	NO End Date: UNK/UNK/2014
1 l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Left Knee Replacement]
	Start Date:	Oct/26/2016
	Ongoing:	NO End Date: Oct/26/2016
1 m	Line/MH Number:	[13]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Obstructive Sleep Apnea]
	Start Date:	Dec/15/2008
	Ongoing:	YES
1 n	Line/MH Number:	[14]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[GERD]
	Start Date:	May/25/2020
	Ongoing:	YES

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971084

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.o	Line/MH Number:	[15]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hyperlipidemia]
	Start Date:	Jul/13/2015
	Ongoing:	YES
1.p	Line/MH Number:	[16]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	Dec/15/2015
	Ongoing:	YES
1.q	Line/MH Number:	[17]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Neuropathy]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.r	Line/MH Number:	[18]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Diabetes Mellitus Type II]
	Start Date:	Dec/15/2015
	Ongoing:	YES
1.s	Line/MH Number:	[19]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Depression]
	Start Date:	Jun/26/2018
	Ongoing:	YES
1.t	Line/MH Number:	[20]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypothyroidism]
	Start Date:	Jan/29/2019
	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: 10971084

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:	Sep/1/2020
2.	Weight:	[223.0]
3.	Unit:	LB
4.	Height:	[66.0]
5.	Unit:	in
6.	Body Mass Index:	[36.0]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[98.2]
	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: 10971084

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 :	Sep/1/2020
2.	Randomization Number:	[248946]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971084

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: Sep/1/2020
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	[BL9XLG]
5.b	Sample ID	[BL9XLH]
5.c	Sample ID	[BN6BFZ]
5.d	Sample ID	[BN6BG0]
5.e	Sample ID	[BN6BG1]

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971084

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/1/2020
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	[BN6B0F]
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090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1097

Subject No: 10971084

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/1/2020 16:15
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

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1097

Subject No: 10971084

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	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
----	---------------------------------------------------------------	------------------------------------------------------------

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971084

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/23/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1097

Subject No: 10971084

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/23/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.4]
	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: 10971084

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/23/2020
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	[BN6B5L]
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090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1097

Subject No: 10971084

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/23/2020 10:52
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

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

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

Subject No: 10971084

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	Oct/21/2020
2.	Erroneous Visit	

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971084

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/21/2020
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	[BL9XDJ]	
5.b	Sample ID	[BL9XDK]	
5.c	Sample ID	[BPVCHD]	
5.d	Sample ID	[BPVCHF]	
5.e	Sample ID	[BPVCHG]	
5.f	Sample ID	[BPVCHY]	Comments
5.g	Sample ID	[BPVCHZ]	Comments
5.h	Sample ID	[]	Comments
5.i	Sample ID	[BL9XNP]	

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971084

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: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971084

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

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

Subject Initials: ---

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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Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971084

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: V5_MONTH12_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971084

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

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

Subject Initials: ---

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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Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971084

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: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971084

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

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

Subject Initials: ---

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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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 **Form:** DATE OF VISIT - ILLNESS ONSET

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: 10971084

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	Oct/5/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A
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090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1097

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

Subject No: 10971084

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:	Oct/5/2020
2.	Date of First Symptom Started:	Oct/4/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Oct/11/2020

Symptoms

4.a	Symptoms:	FEVER
	Was symptom present?	YES
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?	YES
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

Symptoms - Other

5.	Symptoms - Other Text:	[]
----	------------------------	-----

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (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: 10971084

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.	Not Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN
Oct/05/2020

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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

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[Form Comments](#)
[eCRF Audit Trail History](#)

Microbiology Specimen

1.	Actual Date of Collection:	Not Done _____ //	Comments
2.	Specimen Type:	Not Done _____	Comments
3.	Specimen Collection Location:	Not Done _____	Comments
4.	Assay Code and Description:	Not Done _____	Comments
5.	Device Type:	Not Done _____	Comments
6.	Trade Name:	Not Done _____	Comments
7.	Test Result:	Not Done _____	Comments
8.	Comments/Findings/Details:	Not Done _____ []	Comments
9.	Trade Name Other, Specify:	Not Done _____ []	Comments

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

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: 10971084

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_SELF
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Subject called Marken to pick up his self nasal swab and they never picked it up]

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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: 10971084

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: Oct/5/2020
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	[BN6B71]
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090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 **Form:** HEALTH CARE UTILIZATION**Form Version:** 15-Sep-2020 21:53**Form Status:** Data Complete, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971084**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:	NO
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [1]
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:	YES Number of Visits or Contacts: [1]
1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [1]

Health Care Utilization Other

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

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: 10971084

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/6/2020	NO Discharge Date: Oct/11/2020	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 **Form:** HOSPITALIZATION DETAILS

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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

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[Form Audit Trail](#)

Hospitalization Details

1.	Hospitalization Category:	HOSPITALIZATION STATUS
2.	Hospitalization Term:	HOSPITAL
3.	Admission Date:	Oct/6/2020
4.	Ongoing?	NO Discharge Date: Oct/11/2020

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

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: 10971084

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.	[]			[]		Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT
Oct/05/2020

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1097

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

Subject No: 10971084

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?	[]
2.	Concomitant Non-drug Treatment Pre-specified:	
3.	Treatment:	
4.	Treatment:	[]
5.	Start Date:	//
6.	Ongoing?	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 **Form:** ILLNESS DETAILS

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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

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: [Pneumonia] Date of Diagnosis: Oct/5/2020
3.	Toxicity Grade:	3

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: 10971084

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.					Repeating Pages

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 **Form:** ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1097

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

Subject No: 10971084

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:	
2.	Subcategory of Clinical Event:	
3.	Was a diagnosis obtained?	
4.	Toxicity Grade:	

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: 10971084

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.					Sponsor-Defined Identifier	Test :	Result:	Repeating Pages

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Not Started

Site No: 1097

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

Subject No: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

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Lab Chemistry Details

1.	Lab Panel:	
2.	Laboratory Name and Address	[]
3.	Collection Date:	//
4.	Specimen Type:	

Lab Result

5.	Sponsor ID:	[]
	Test:	
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (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: 10971084

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.					Sponsor-Defined Identifier	Test:	Result:	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1097

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

Subject No: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

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Laboratory Data Hematology

1.	Lab Panel:	
2.	Laboratory Name and Address	[]
3.	Collection Date:	//
4.	Specimen Type:	

Lab Result

5.	Sponsor ID:	[]
	Test:	
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

#	Date:	Vital Signs Details			Form Instance
1.		Record Identifier:	Systolic:	Diastolic:	Repeating Pages

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID
Oct/05/2020

Form Version: 21-Aug-2020 02:50

Form Status: Not Started

Site No: 1097

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

Subject No: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

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Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	Systolic:	[]
	Diastolic:	[]
	Respiratory Rate in respirations/minute:	[]
	Heart Rate in beats/minute:	[]

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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

#	Date:	Vital Signs Details		Form Instance
1.		Record Identifier:	Oxygen Saturation	Repeating Pages

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR
Oct/05/2020

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1097

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

Subject No: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

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Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

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: 10971084

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.				Repeating Pages

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** OXYGENATION PARAMETERS
Oct/05/2020

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1097

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

Subject No: 10971084

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:	//
2.	Arterial Blood Gases PaO2 (mmHg):	[]
3.	FiO2 (Fraction of Inhaled Oxygen):	[]

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: 10971084

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.						Repeating Pages

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Form Status: Not Started

Site No: 1097

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

Subject No: 10971084

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.	Start Date:	//
6.	Ongoing?	

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

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: 10971084

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.					Repeating Pages

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING
Oct/05/2020

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1097

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

Subject No: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

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Imaging

1.	Date of Assessment:	//
2.	Location of Assessment:	
3.	Type of Imaging Exam:	
4.	Assessment:	

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT
on Nov/04/2020

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: 10971084

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/4/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A1
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090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
on Nov/04/2020

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: 10971084

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: Nov/4/2020
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	[BPVCNK]
5.b	Sample ID	[BPVCNL]
5.c	Sample ID	[BPVCNM]
5.d	Sample ID	[BL9XHB]
5.e	Sample ID	[BL9XHC]

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

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: 10971084

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 - New Unscheduled Visit

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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

Unplanned Assessments

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

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: 10971084

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/21/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1097

Subject No: 10971084

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 1 -
Unscheduled Visit on Oct/21/2020

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1097

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

Subject No: 10971084

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	Oct/21/2020
2.	Erroneous Visit	

COVID-19 Repeat Swab

3.	COVID-19 Repeat Swab:	COVID_AR1
----	-----------------------	-----------

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB 1 -
Unscheduled Visit on Oct/21/2020

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1097

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

Subject No: 10971084

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: Oct/21/2020
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	[BPVCH9]
-----	-----------	----------

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (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: 10971084

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.	ADVERSE EVENT	1	Urinary Tract Infection	Sep/29/2020 UNK:UNK	NO End Date Time: Oct/11/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	Sepsis Bacteremia	Sep/29/2020 UNK:UNK	NO End Date Time: Oct/11/2020 UNK:UNK	Repeating Pages
3. DELETED	ADVERSE EVENT	3	Bacteremia	Oct/7/2020 UNK:UNK	NO End Date Time: Oct/11/2020 UNK:UNK	Repeating Pages

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971084

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:	[1]	
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Urinary Tract Infection]	
4.	Start Date Time:	Sep/29/2020 UNK:UNK	
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/11/2020 UNK:UNK	Comments
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	
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: [Escherichia coli]	

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971084

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?	YES
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	[2020396942]

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971084

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:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Sepsis Bacteremia]
4.	Start Date Time:	Sep/29/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/11/2020 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
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: [unspecified organism]

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971084

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	[2020396942]

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971084

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]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Bacteremia]
4.	Start Date Time:	Oct/7/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/11/2020 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: [Escherichia coli unspecified]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971084

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 *****

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	[]

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

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: 10971084

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.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1097

Subject No: 10971084

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	[]

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (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: 10971084

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.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971084

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

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.	Date:	//

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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: 10971084

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.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971084

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?	

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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: 10971084

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.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971084

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?	

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971084

Generated By: (b) (4)

Form: TRANSFUSIONS

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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1.	Transfusion Type:	
2.	Date of Transfusion:	//

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

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: 10971084

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: 10971084

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: 10971084

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?	

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (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: 10971084

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: 10971084

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: V201_SURVEIL_CONSENT - 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: 10971084

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: V201_SURVEIL_CONSENT - Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1097

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

Subject No: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

Informed Consent - Asymptomatic Surveillance

1.	Consent Was:	
----	--------------	--

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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: 10971084

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	[]
----	-----------	-----

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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: 10971084

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	[]
----	-----------	-----

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: 10971084

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/15/2021
2.	Erroneous Visit	

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

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

Site No: 1097

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

Subject No: 10971084

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 and NOT 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: 10971084

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/15/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971084

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:	[]

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001	
Visit: Subject Status - Unscheduled	Form: SUBJECT STATUS
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: 10971084	Subject Initials: ---
Generated By: (b) (4)	Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Subject Status		
1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/21/2020

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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
----	--------------------	----------------------

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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

[Audit Trail](#)

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	Feb-24-2021 19:18:19 (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.

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1097

Subject No: 10971084

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	Sep-02-2020 20:00:09 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Incomplete
			Not Done

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
Comments

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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5 f	Oct-30-2020 14:34:23 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
5 f	Oct-30-2020 10:52:32 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
Comments

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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.g	Oct-30-2020 14:39:23 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
5.g	Oct-30-2020 10:52:47 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
Comments

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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5 h	Oct-30-2020 14:40:26 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
5 h	Oct-30-2020 10:53:12 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Oct-23-2020 12:48:50 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject did a self swab at home after being released from the hospital. The worldwide courier never picked up the swab, so he came to the office for an in-person visit on 21Oct2020. A nasal swab was obtained at this visit. <hr/> Not Done
Form	Oct-20-2020 09:57:51 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
1	Oct-23-2020 12:48:50 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject did a self swab at home after being released from the hospital. The worldwide courier never picked up the swab, so he came to the office for an in-person visit on 21Oct2020. A nasal swab was obtained at this visit. <hr/> Not Done
1	Oct-20-2020 09:57:51 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
2	Oct-23-2020 12:48:50 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject did a self swab at home after being released from the hospital. The worldwide courier never picked up the swab, so he came to the office for an in-person visit on 21Oct2020. A nasal swab was obtained at this visit. <hr/> Not Done
2	Oct-20-2020 09:57:51 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
3	Oct-23-2020 12:48:50 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject did a self swab at home after being released from the hospital. The worldwide courier never picked up the swab, so he came to the office for an in-person visit on 21Oct2020. A nasal swab was obtained at this visit. <hr/> Not Done
3	Oct-20-2020 09:57:51 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
4	Oct-23-2020 12:48:50 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject did a self swab at home after being released from the hospital. The worldwide courier never picked up the swab, so he came to the office for an in-person visit on 21Oct2020. A nasal swab was obtained at this visit. <hr/> Not Done
4	Oct-20-2020 09:57:51 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5	Oct-23-2020 12:48:50 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject did a self swab at home after being released from the hospital. The worldwide courier never picked up the swab, so he came to the office for an in-person visit on 21Oct2020. A nasal swab was obtained at this visit. <hr/> Not Done
5	Oct-20-2020 09:57:51 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
6	Oct-23-2020 12:48:50 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject did a self swab at home after being released from the hospital. The worldwide courier never picked up the swab, so he came to the office for an in-person visit on 21Oct2020. A nasal swab was obtained at this visit. <hr/> Not Done
6	Oct-20-2020 09:57:51 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
7	Oct-23-2020 12:48:50 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject did a self swab at home after being released from the hospital. The worldwide courier never picked up the swab, so he came to the office for an in-person visit on 21Oct2020. A nasal swab was obtained at this visit. <hr/> Not Done
7	Oct-20-2020 09:57:51 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
8	Oct-23-2020 12:48:50 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject did a self swab at home after being released from the hospital. The worldwide courier never picked up the swab, so he came to the office for an in-person visit on 21Oct2020. A nasal swab was obtained at this visit. <hr/> Not Done
8	Oct-20-2020 09:57:51 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
9	Oct-23-2020 12:48:50 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject did a self swab at home after being released from the hospital. The worldwide courier never picked up the swab, so he came to the office for an in-person visit on 21Oct2020. A nasal swab was obtained at this visit. <hr/> Not Done
9	Oct-20-2020 09:57:51 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971084

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Comments

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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Item	Date	User	Comment
5	Nov-25-2020 08:56:45 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	This was the date provided by subject for his release from the hospital.

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (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: 10971084

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	Feb-24-2021 19:18:19 (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	Feb-22-2021 11:37:11 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Tom Christensen	Approved	Jan-20-2021 20:57:12 (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-25-2020 08:55:59 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Tom Christensen	Approved	Nov-13-2020 16:04:18 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (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:** 10971084**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	Nov-04-2020 13:16:25 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Tom Christensen	Approved	Oct-30-2020 14:50:05 (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	Oct-30-2020 14:34:23 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Tom Christensen	Approved	Oct-30-2020 11:32:26 (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	Oct-29-2020 15:36:49 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

Affidavit:

N/A

Tom Christensen	Approved	Oct-28-2020 18:51:21 (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	Oct-28-2020 15:48:03 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Tom Christensen	Approved	Oct-26-2020 16:10:13 (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.

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1097

Subject No: 10971084

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
Sep-02-2020 19:58:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 24 JUL 2020	Initial Entry

2. Select appropriate response - What cohort does the subject belong to?

Date	Location	User	Value	Reason
Sep-02-2020 19:58:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971084

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
Sep-02-2020 19:59:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Sep/1/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

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

Subject No: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

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I. Subject ID

Date	Location	User	Value	Reason
Oct-14-2020 21:50:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Oct-14-2020 10:37:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Added to AE form.
Oct-14-2020 06:51:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	SAE RECON:AER#2020396942 Pneumonia(onset date:07Oct2020)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 06:51:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	invalid query. wrong AER
Oct-14-2020 06:50:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	invalid query. wrong subject
Oct-14-2020 06:50:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2020397171 Pneumonia(onset date:07Oct2020)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 06:49:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020397171 transient global amnesia(onset date:10Oct2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1097

Subject No: 10971084

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

				update is required, submit a follow-up SAE Form.
Sep-02-2020 19:58:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 10971084	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-02-2020 19:58:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> (b) (6)/1935	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-02-2020 19:59:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-02-2020 19:59:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Sep-02-2020 19:59:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> WHITE	Initial Entry

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971084

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Sep-02-2020 19:59:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/1/2020	Initial Entry

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971084

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
Sep-02-2020 20:00:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/1/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-02-2020 20:00:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-02-2020 20:00:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971084

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

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I.a

Date	Location	User	Value	Reason
Sep-10-2020 15:26:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term Angioplasty : Start Date: Oct/1/2003 Ongoing: NO End Date: Oct/1/2003	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 15:26:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

I.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-10-2020 15:26:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Angioplasty	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 15:26:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/1/2003	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 15:26:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Oct/1/2003	Initial Entry

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971084

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.b

Date	Location	User	Value	Reason
Sep-11-2020 12:18:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 2 er: Medical History Cardiac Stent Ins Term: ertion Start Date: May/1/2008 Ongoing: NO End Date: May/1/2008	Transcription Error
Sep-10-2020 15:26:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Ter Cardiac Stent m: s Start Date: May/1/2008 Ongoing: NO End Date: May/1/2008	Initial Entry

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971084

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

1.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 15:26:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 2	Initial Entry

1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-12-2020 03:31:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Sep-11-2020 12:18:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-11-2020 12:18:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Cardiac Stent Insertion	Transcription Error
Sep-11-2020 05:49:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify CARDIAC STENTS as follows...Device only reported. Are you reporting INSERTION? REMOVAL? INFECTION OF? Or other? Please update the verbatim term to further specify. Thank you.
Sep-10-2020 15:26:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Cardiac Stents	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
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090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971084

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

Sep-10-2020 15:26:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: May/1/2008	Initial Entry
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I.b Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 15:26:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: May/1/2008	Initial Entry

I.c

Date	Location	User	Value	Reason
Sep-10-2020 15:27:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Term: Right Knee Replacement Start Date: May/31/2005 Ongoing: NO End Date: May/31/2005	Initial Entry

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971084

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.c Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 15:27:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

I.c Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-10-2020 15:27:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Right Knee Replacement	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 15:27:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: May/31/2005	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 15:27:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: May/31/2005	Initial Entry

I.d

Date	Location	User	Value	Reason
Sep-10-2020 15:28:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numbe 4 r: Medical History Right Rotator Cuff Term: Repair Start Date: Nov/30/2006 Ongoing: NO End Date: Nov/30/2006	Initial Entry

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971084

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
Sep-10-2020 15:28:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

I.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-10-2020 15:28:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Right Rotator Cuff Repair	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 15:28:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/30/2006	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 15:28:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Nov/30/2006	Initial Entry

I.e

Date	Location	User	Value	Reason
Sep-11-2020 18:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 5 Medical History Term: Appendectomy Start Date: Aug/19/2011 Ongoing: NO End Date: Aug/19/2011	Transcription Error
Sep-10-2020 15:29:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5	Initial Entry

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971084

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

			Medical History Term: Appendectomy	
			Start Date: Aug/19/1935	
			Ongoing: NO	
			End Date:	
			Aug/19/2011	

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971084

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.e Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 15:29:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

I.e Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-10-2020 15:29:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Appendectomy	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Sep-11-2020 18:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/19/2011	Transcription Error
Sep-10-2020 15:29:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/19/1935	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Sep-13-2020 09:59:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Svitlana Tonkoyd (b) (4)	Query 1: Closed	data changed
Sep-11-2020 18:44:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Transcription error
Sep-11-2020 15:04:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Svitlana Tonkoyd (b) (4)	Query 1: Opened	GPD Clin: Appendectomy start and end dates differ however, per CRF completion guide section 8.7.5, surgical procedure is expected to have Start and End date the same and not to be ongoing. Please review and update as needed

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971084

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

Sep-10-2020 15:29:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Aug/19/2011	Initial Entry
-------------------------------------------------------------------	-----------------	------------------	------------------------------------------------------	---------------

If

Date	Location	User	Value	Reason
Sep-10-2020 15:29:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 6 : Medical History T Bladder stone rem erm: oval Start Date: Apr/21/2011 Ongoing: NO End Date: Apr/21/2011	Initial Entry

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1097

Subject No: 10971084

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.f Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 15:29:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

I.f Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-10-2020 15:29:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bladder stone removal	Initial Entry

I.f Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 15:29:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Apr/21/2011	Initial Entry

I.f Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 15:29:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Apr/21/2011	Initial Entry

I.g

Date	Location	User	Value	Reason
Sep-10-2020 15:30:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 7 : Medical History T Kidney stone rem erm: oval Start Date: Jun/6/2011 Ongoing: NO End Date: Jun/6/2011	Initial Entry

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971084

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.g Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 15:30:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 7	Initial Entry

I.g Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-10-2020 15:30:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Kidney stone removal	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 15:30:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Jun/6/2011	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 15:30:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO End Date: Jun/6/2011	Initial Entry

I.h

Date	Location	User	Value	Reason
Sep-10-2020 15:31:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Line/MH Number: 8 r: Medical History: Left Rotator Cuff repair Term: Start Date: Oct/5/2011 Ongoing: NO End Date: Oct/5/2011	Initial Entry

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

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Site No: 1097

Subject No: 10971084

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.h Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 15:31:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

I.h Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-10-2020 15:31:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Left Rotator Cuff repair	Initial Entry

I.h Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 15:31:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/5/2011	Initial Entry

I.h Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 15:31:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Oct/5/2011	Initial Entry

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

Subject Initials: ---

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<i>I.i</i>				
Date	Location	User	Value	Reason
Sep-10-2020 15:32:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 9 Medical History Term: Bladder Cancer Start Date: May/1/2012 Ongoing: NO End Date: Dec/10/2012	Initial Entry
<i>I.i Line/MH Number:</i>				
Date	Location	User	Value	Reason
Sep-10-2020 15:32:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry
<i>I.i Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:</i>				
Date	Location	User	Value	Reason
Sep-10-2020 15:32:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bladder Cancer	Initial Entry
<i>I.i Start Date:</i>				
Date	Location	User	Value	Reason
Sep-10-2020 15:32:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: May/1/2012	Initial Entry
<i>I.i Ongoing:</i>				
Date	Location	User	Value	Reason
Sep-10-2020 15:32:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Dec/10/2012	Initial Entry
<i>I.j</i>				

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971084

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
Sep-11-2020 12:19:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 10 Medical History Term: HEART CATHETERIZATION Start Date: Feb/6/2013 Ongoing: NO End Date: Feb/6/2013	Transcription Error
Sep-10-2020 15:34:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 10 Medical History Term: Heart Catheterization Start Date: Feb/6/2013 Ongoing: NO End Date: Feb/6/2013	Initial Entry

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971084

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

1.j Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 15:34:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10	Initial Entry

1.j Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-12-2020 03:30:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Sep-11-2020 12:19:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-11-2020 12:19:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEART CATHETERIZATION	Transcription Error
Sep-11-2020 06:35:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify HEART CATHETERIZATION as follow... Should spelling be HEART CATHETERIZATION? If so, please edit it to such. Otherwise, clarify. Thank you.
Sep-10-2020 15:34:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Heart Catheterization	Initial Entry

1.j Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 15:34:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/6/2013	Initial Entry

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Header Text: c4591001

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Subject No: 10971084

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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I.j Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 15:34:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Feb/6/2013	Initial Entry

I.k

Date	Location	User	Value	Reason
Sep-10-2020 15:34:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 11 Medical History Te Cataract removal rm: Start Date: UNK/UNK/2014 Ongoing: NO End Date: UNK/UNK/2 014	Initial Entry

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Subject No: 10971084

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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Subject Initials: ---

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1.k Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 15:34:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11	Initial Entry

1.k Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-10-2020 15:34:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Cataract removal	Initial Entry

1.k Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 15:34:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2014	Initial Entry

1.k Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 15:34:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2014	Initial Entry

1.l

Date	Location	User	Value	Reason
Sep-10-2020 15:36:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 12 r: Medical History Term: Left Knee Replacement Start Date: Oct/26/2016 Ongoing: NO End Date: Oct/26/2016	Initial Entry

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

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Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971084

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

1.1 Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 15:36:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12	Initial Entry

1.1 Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-10-2020 15:36:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Left Knee Replacement	Initial Entry

1.1 Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 15:36:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/26/2016	Initial Entry

1.1 Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 15:36:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Oct/26/2016	Initial Entry

1.m

Date	Location	User	Value	Reason
Sep-10-2020 15:36:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numbe 13 r: Medical History Obstructive Sleep Term: Apnea Start Date: Dec/15/2008 Ongoing: YES	Initial Entry

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

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Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971084

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.m Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 15:36:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 13	Initial Entry

I.m Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-10-2020 15:36:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Obstructive Sleep Apnea	Initial Entry

I.m Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 15:36:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/15/2008	Initial Entry

I.m Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 15:36:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.n

Date	Location	User	Value	Reason
Sep-10-2020 15:37:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 14 Medical History Term: GERD Start Date: May/25/2020 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Subject No: 10971084

Generated By: (b) (4)

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

Subject Initials: ---

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1.n Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 15:37:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 14	Initial Entry

1.n Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-10-2020 15:37:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: GERD	Initial Entry

1.n Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 15:37:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: May/25/2020	Initial Entry

1.n Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 15:37:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.o

Date	Location	User	Value	Reason
Sep-10-2020 15:38:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 15 Medical History Term: Hyperlipidemia Start Date: Jul/13/2015 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Site No: 1097

Subject No: 10971084

Generated By: (b) (4)

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I.o Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 15:38:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 15	Initial Entry

I.o Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-10-2020 15:38:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hyperlipidemia	Initial Entry

I.o Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 15:38:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jul/13/2015	Initial Entry

I.o Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 15:38:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.p

Date	Location	User	Value	Reason
Sep-10-2020 15:39:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 16 Medical History Term: Hypertension Start Date: Dec/15/2015 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Subject No: 10971084

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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I.p Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 15:39:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 16	Initial Entry

I.p Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-10-2020 15:39:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hypertension	Initial Entry

I.p Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 15:39:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/15/2015	Initial Entry

I.p Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 15:39:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.q

Date	Location	User	Value	Reason
Sep-10-2020 15:40:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 17 Medical History Term: Neuropathy Start Date: UNK/UNK/2015 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Subject No: 10971084

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

1.q Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 15:40:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 17	Initial Entry

1.q Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-10-2020 15:40:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Neuropathy	Initial Entry

1.q Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 15:40:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry

1.q Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 15:40:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

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<i>I.r</i>				
Date	Location	User	Value	Reason
Sep-10-2020 15:40:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numbe 18 r: Medical History Diabetes Mellitus Term: Type II Start Date: Dec/15/2015 Ongoing: YES	Initial Entry
<i>I.r Line/MH Number:</i>				
Date	Location	User	Value	Reason
Sep-10-2020 15:40:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 18	Initial Entry
<i>I.r Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:</i>				
Date	Location	User	Value	Reason
Sep-10-2020 15:40:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Diabetes Mellitus Type II	Initial Entry
<i>I.r Start Date:</i>				
Date	Location	User	Value	Reason
Sep-10-2020 15:40:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/15/2015	Initial Entry
<i>I.r Ongoing:</i>				
Date	Location	User	Value	Reason
Sep-10-2020 15:40:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
<i>I.s</i>				
Date	Location	User	Value	Reason
Sep-10-2020 15:41:14 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 19	Initial Entry

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Header Text: c4591001

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Site No: 1097

Subject No: 10971084

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

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(US & Canada)			Medical History Term: Depression	
			Start Date: Jun/26/2018	
			Ongoing: YES	

I.s Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 15:41:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 19	Initial Entry

I.s Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-10-2020 15:41:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Depression	Initial Entry

I.s Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 15:41:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jun/26/2018	Initial Entry

I.s Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 15:41:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.t

Date	Location	User	Value	Reason
Sep-10-2020 15:41:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 20 Medical History Term: Hypothyroidism Start Date: Jan/29/2019 Ongoing: YES	Initial Entry

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Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

Subject Initials: ---

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1.t Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 15:41:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 20	Initial Entry

1.t Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-10-2020 15:41:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hypothyroidism	Initial Entry

1.t Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 15:41:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/29/2019	Initial Entry

1.t Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 15:41:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

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Form Version: 21-Aug-2020 02:51

Site No: 1097

Subject No: 10971084

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: ---

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1. Date:

Date	Location	User	Value	Reason
Sep-02-2020 20:01:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sep/1/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-02-2020 20:01:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 223.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-02-2020 20:01:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-02-2020 20:01:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 66.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-02-2020 20:01:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-02-2020 20:01:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 36.0	Initial Entry

7.a

Date	Location	User	Value	Reason
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090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1097

Subject No: 10971084

Generated By: (b) (4)

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

Subject Initials: ---

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Sep-02-2020 20:01:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 98.2 Temperature Unit: F Temperature Location:: ORAL CAVITY	Initial Entry
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7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-02-2020 20:01:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-02-2020 20:01:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.2	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-02-2020 20:01:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-02-2020 20:01:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971084

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
Sep-02-2020 20:02:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/1/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-02-2020 20:02:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 248946	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:** 10971084**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-04-2020 08:35:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-04-2020 08:35:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-04-2020 08:35:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-04-2020 08:35:20 (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-04-2020 08:35:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/1/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-04-2020 08:35:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BL9XLG	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-04-2020 08:35:52 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BL9XLG	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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

(US & Canada)		(b) (4), (b) (6)	
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5.b

Date	Location	User	Value	Reason
Sep-04-2020 08:36:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BL9XLH	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-04-2020 08:36:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BL9XLH	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-04-2020 08:36:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN6BFZ	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-04-2020 08:36:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN6BFZ	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-04-2020 08:37:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN6BG0	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Sep-04-2020 08:37:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN6BG0	Initial Entry

5.e

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090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-04-2020 08:37:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN6BG1	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Sep-04-2020 08:37:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN6BG1	Initial Entry

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:** 10971084**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-04-2020 08:38:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-04-2020 08:38:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-04-2020 08:38:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-04-2020 08:38:22 (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-04-2020 08:38:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/1/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-04-2020 08:38:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN6B0F	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-04-2020 08:38:38 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN6B0F	Initial Entry

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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

(US & Canada)

(b) (4), (b) (6)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1097

Subject No: 10971084

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-02-2020 20:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-02-2020 20:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-02-2020 20:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-02-2020 20:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/1/2020 16:15	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-02-2020 20:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-02-2020 20:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
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090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1097

Subject No: 10971084

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

Sep-02-2020 20:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry
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10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-02-2020 20:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSER VATION 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-02-2020 20:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1097

Subject No: 10971084

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-05-2020 15:56:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971084

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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1. Date of Visit

Date	Location	User	Value	Reason
Sep-23-2020 15:15:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/23/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1097

Subject No: 10971084

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-23-2020 15:16:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/23/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-23-2020 15:16:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 97.4 Temperature Unit: F Temperature Location:: ORAL CAVIT Y	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-23-2020 15:16:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-23-2020 15:16:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 97.4	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-23-2020 15:16:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-23-2020 15:16:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

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: 10971084

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-23-2020 15:17:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-23-2020 15:17:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-23-2020 15:17:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-23-2020 15:17:04 (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-23-2020 15:17:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/23/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-23-2020 15:17:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN6B5L	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-23-2020 15:17:27 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN6B5L	Initial Entry

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

(US & Canada)

(b) (4), (b) (6)

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1097

Subject No: 10971084

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-23-2020 15:18:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-23-2020 15:18:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-23-2020 15:18:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-23-2020 15:18:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/23/2020 10:52	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-23-2020 15:18:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-23-2020 15:18:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
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090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1097

Subject No: 10971084

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

Sep-23-2020 15:18:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry
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10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-23-2020 15:18:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSER VATION 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-23-2020 15:18:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971084

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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1. Date of Visit

Date	Location	User	Value	Reason
Nov-10-2020 02:23:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Clos ed	entry on 15-2020 was erroneously entered.
Nov-09-2020 10:23:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Ans wered	Covid illness visit on 05-oct-2020 trial max entry on 15-2020 was erroneously entered.
Nov-09-2020 08:49:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clos ed	Response satisfies query
Nov-09-2020 03:19:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reis sued:O pened	RQ1: Response states 'The patient was answering that he HAD symptoms previously'. Please confirm if Illness edary entry on 15OCT2020 was deemed erroneous and that subject had no new symptoms.
Nov-08-2020 19:38:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Ans wered	The patient was answering that he HAD symptoms previously.
Nov-08-2020 06:31:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Ope ned	Illness edary: As per Illness edary records, subject reported "Yes" for the COVID-19 symptoms or diagnosis on 15OCT2020. But no corresponding COVID Illness visit indicate symptoms present at this date. Pls update Covid illness visit or clarify.

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

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

Subject No: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

Oct-30-2020 11:28:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 2: Clos ed	Response satisfies query
Oct-30-2020 10:53:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 2: Ans wered	Both visit dates were the same so both were done at the same time.
Oct-30-2020 10:45:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Reis sued:C andidat e	Send to (b) (6) to review.
Oct-30-2020 05:30:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4) [REDACTED]	Query 2: Ope ned	DMW5223334;The Date of Visit at Visit V3_MONTH1_POSTVAX2_L is the same as the other Date of Visit at Visit COVID_A1. Please review for duplication and update as appropriate.
Oct-29-2020 15:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Ans wered	BPVCH9 should be self swab for the COVID illness visit. Patient swabbed himself but Marken did not pick up the swab. Patient came for visit on 21October the SC swabbed the patient again and sent it in to replace the one that Marken failed to pick up
Oct-29-2020 11:55:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Ope ned	DM: Nasal Swab barcode BPVCH9 has been received by the lab for unscheduled visit. Please review and update or submit updated SCF to Pfizer VRD.
Oct-21-2020 14:45:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data E ntry: Oct/21/ 2020	Initial Entry

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (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:** 10971084**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-21-2020 14:46:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-21-2020 14:46:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-21-2020 14:46:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-21-2020 14:46:05 (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-21-2020 14:46:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/21/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-21-2020 14:46:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BL9XDJ	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-21-2020 14:46:20 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BL9XDJ	Initial Entry

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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

(US & Canada)		(b) (4), (b) (6)	
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5.b

Date	Location	User	Value	Reason
Oct-21-2020 14:46:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BL9XDK	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-21-2020 14:46:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BL9XDK	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-21-2020 14:47:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPVCHD	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-21-2020 14:47:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPVCHD	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-21-2020 14:47:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPVCHF	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Oct-21-2020 14:47:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPVCHF	Initial Entry

5.e

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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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-21-2020 14:47:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BPVCHG	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Oct-21-2020 14:47:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPVCHG	Initial Entry

5.f

Date	Location	User	Value	Reason
Feb-22-2021 12:11:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BPVCHY	Transcription Error
Feb-22-2021 11:37:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID:	New Information
Oct-30-2020 14:35:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID:	Transcription Error (DELETED)
Oct-30-2020 14:34:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID:	Initial Entry
Oct-30-2020 10:52:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: Not Applicable	Initial Entry
Oct-30-2020 10:51:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID:	Transcription Error
Oct-21-2020 16:12:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BPVCHY	Initial Entry

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

5.f Sample ID

Date	Location	User	Value	Reason
Feb-24-2021 12:47:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	data updated
Feb-24-2021 11:23:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	updated
Feb-24-2021 10:46:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM: Please update data per query response provided. Thank you.
Feb-23-2021 13:05:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	please unfreeze line and DOV for the Conv Visit, so that we can correct.
Feb-23-2021 04:36:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Opened	DMW7387640;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Feb-22-2021 12:11:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPVCHY	Transcription Error
Feb-22-2021 11:37:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	New Information
Oct-30-2020 14:48:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

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090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

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

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Subject Initials: ---

Generated By: (b) (4)

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

Oct-30-2020 14:35:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error (DELETED)
Oct-30-2020 14:34:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Oct-30-2020 10:52:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Oct-30-2020 10:51:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-30-2020 10:51:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Oct-29-2020 21:35:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW5223223;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Oct-21-2020 16:12:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPVCHY	Initial Entry

5.g

Date	Location	User	Value	Reason
Feb-22-2021 12:12:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPVCHZ	Changed Information

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
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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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

Feb-22-2021 12:12:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID:	Changed Information
Oct-30-2020 14:40:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID:	Transcription Error (DELETED)
Oct-30-2020 14:39:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID:	Initial Entry
Oct-30-2020 14:38:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: Not Applicable	Transcription Error
Oct-30-2020 14:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: Not Applicable	Transcription Error (DELETED)
Oct-30-2020 10:52:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: Not Applicable	Initial Entry
Oct-30-2020 10:51:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID:	Transcription Error
Oct-21-2020 16:13:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPVCHZ	Initial Entry

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

5.g Sample ID

Date	Location	User	Value	Reason
Feb-24-2021 12:47:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	data updated
Feb-23-2021 13:06:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	please unfreeze line so that we can correct
Feb-23-2021 04:36:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Opened	DMW7387641;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Feb-22-2021 12:12:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPVCHZ	Changed Information
Feb-22-2021 12:12:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Oct-30-2020 14:48:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-30-2020 14:40:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error (DELETED)
Oct-30-2020 14:39:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

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

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Subject Initials: ---

Generated By: (b) (4)

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Oct-30-2020 14:38:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicabl e	Transcription Error
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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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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5.g Sample ID

Date	Location	User	Value	Reason
Oct-30-2020 14:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Transcription Error (DELETED)
Oct-30-2020 10:52:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Oct-30-2020 10:51:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-30-2020 10:51:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Oct-29-2020 21:35:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW5223224;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Oct-21-2020 16:13:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPVCHZ	Initial Entry

5.h

Date	Location	User	Value	Reason
Oct-30-2020 14:41:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID:	Transcription Error (DELETED)

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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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

Oct-30-2020 14:40:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID:	Initial Entry
Oct-30-2020 10:53:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: Not Applicable	Initial Entry
Oct-30-2020 10:52:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID:	Transcription Error
Oct-21-2020 16:13:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BL9XNP	Initial Entry

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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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

5.h Sample ID

Date	Location	User	Value	Reason
Oct-30-2020 14:48:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-30-2020 14:41:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error (DELETED)
Oct-30-2020 14:40:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Oct-30-2020 10:53:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Oct-30-2020 10:52:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-30-2020 10:52:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Oct-29-2020 21:35:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW5223222;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Oct-21-2020 16:13:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BL9XNP	Initial Entry

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

5.i

Date	Location	User	Value	Reason
Feb-24-2021 09:47:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BL9XNP	Initial Entry

5.i Sample ID

Date	Location	User	Value	Reason
Feb-24-2021 09:47:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BL9XNP	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 Form: DATE OF VISIT - ILLNESS ONSET - 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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-21-2020 06:24:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Oct-20-2020 09:58:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Done
Oct-18-2020 08:56:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	DM3: Thank you for the response. However per response if data is not present in subject record then please consider adding form level comment "Not done/ not applicable" in Microbiology Specimen. Else clarify.
Oct-16-2020 10:42:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Data is not in subject record
Oct-16-2020 03:27:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	DM2: Microbiology specimen page is still not updated as requested. Please review and update.
Oct-15-2020 14:45:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Original value is correct
Oct-15-2020 07:55:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	DM1: Per site response, please add form level comment "Not done/ not applicable" in Microbiology Specimen, Illness Details and Nasal Swab self forms. Else clarify.

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090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 **Form:** DATE OF VISIT - ILLNESS ONSET - 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: 10971084 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:39

Oct-14-2020 10:41:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	We do not have that information.
Oct-09-2020 07:56:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	DM: Kindly review and complete 'Microbiology Specimen, Illness Details and Nasal Swab self form' at this visit. Thank you.
Oct-05-2020 15:57:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-05-2020 15:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Oct-05-2020 15:55:06 (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.
Oct-05-2020 15:55:06 (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 as appropriate.
Oct-05-2020 15:55:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/5/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Oct-05-2020 15:55:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971084**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Oct-05-2020 15:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/5/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Oct-29-2020 12:41:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	resolved
Oct-28-2020 15:48:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-28-2020 15:48:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/4/2020	Transcription Error
Oct-27-2020 14:17:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Please confirm if date of first symptom started should be 04Oct2020, per source note that subject fever started on 04Oct2020.
Oct-05-2020 15:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/4/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Oct-23-2020 23:56:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 1: Closed	Response satisfies query
Oct-22-2020 14:56:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Oct-22-2020 14:56:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved:	New Information

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1097

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

Subject No: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

			Oct/11/2020	
Oct-20-2020 14:21:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 1: Opened	CLIQUEY: Please clarify if the symptoms are still ongoing?
Oct-05-2020 15:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Oct-05-2020 15:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVER Symptom Present: YES	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Oct-05-2020 15:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Oct-05-2020 15:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.b

Date	Location	User	Value	Reason
Oct-05-2020 15:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASE D COUGH Symptom Present: NO	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1097

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

Subject No: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

4.b Symptoms:

Date	Location	User	Value	Reason
Oct-05-2020 15:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Oct-05-2020 15:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Oct-05-2020 15:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCREASED S s: HORTNESS OF BREATH Symptom NO Present:	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Oct-05-2020 15:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Oct-05-2020 15:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Oct-05-2020 15:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971084**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39**4.d Symptoms:**

Date	Location	User	Value	Reason
Oct-05-2020 15:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Oct-05-2020 15:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Oct-05-2020 15:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED MUSCLE PAIN Symptom P YES resent:	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Oct-05-2020 15:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED MUSCLE PAI N	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Oct-05-2020 15:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.f

Date	Location	User	Value	Reason
Oct-05-2020 15:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW LOSS OF TASTE OR SMELL Symptom Pr NO esent:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1097

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

Subject No: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

4.f Symptoms:

Date	Location	User	Value	Reason
Oct-05-2020 15:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Oct-05-2020 15:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Oct-05-2020 15:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED SORE THROAT Symptom P NO resent:	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Oct-05-2020 15:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SORE THRO AT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Oct-05-2020 15:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Oct-05-2020 15:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHEA Symptom Present: NO	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1097

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

Subject No: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

4.h Symptoms:

Date	Location	User	Value	Reason
Oct-05-2020 15:56:17 (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
Oct-05-2020 15:56:17 (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
Oct-05-2020 15:56:17 (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
Oct-05-2020 15:56:17 (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
Oct-05-2020 15:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

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I. Actual Date of Collection:

Date	Location	User	Value	Reason
Oct-26-2020 15:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-26-2020 13:53:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Oct-23-2020 15:04:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	CLIQUEY: Per CCG's 'Not Done' needs to be applied to the CRF if local test was not completed. Please update. Please refer to CCG's for guidance.
Oct-23-2020 12:48:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-23-2020 08:08:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	CLIQUEY: Per CCG's 'Not Done' needs to be applied to the CRF if local test was not completed. Please update. Please refer to CCG's for guidance.
Oct-22-2020 16:06:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Not Done
Oct-22-2020 15:16:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	CLIQUEY: Per CCG's 'Not Done' needs to be applied to the CRF if local test was not completed. Please update.
Oct-22-2020 14:44:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Not done
Oct-21-2020 14:32:20	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLIQUEY: Per

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

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: 10971084

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)		CCG's 'Not Done' needs to be applied to the CRF if local test was not completed. Please update.
Oct-21-2020 11:39:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candidate	CLIQUEY: Per CCG's 'Not Done' needs to be applied to the CRF if local test was not completed. Please update.
Oct-20-2020 09:57:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Oct-23-2020 12:48:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-20-2020 09:57:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Oct-23-2020 12:48:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-20-2020 09:57:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Oct-23-2020 12:48:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-20-2020 09:57:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

5. Device Type:

Date	Location	User	Value	Reason
Oct-23-2020 12:48:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-20-2020 09:57:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Oct-23-2020 12:48:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-20-2020 09:57:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Oct-23-2020 12:48:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-20-2020 09:57:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Oct-23-2020 12:48:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-20-2020 09:57:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Oct-23-2020 12:48:50	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

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: 10971084

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 Done	
Oct-20-2020 09:57:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

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: 10971084

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-15-2020 14:38:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-15-2020 14:38:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-26-2020 16:36:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Oct-26-2020 10:05:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	Answer Auto Query
Oct-26-2020 10:05:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Changed Information
Oct-24-2020 08:59:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Closed	Response satisfies query
Oct-24-2020 08:59:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Reissued:Opened	DM1: Per response, no sample was collected, kindly consider to update 'Sample Collected as No' or update sample ID.
Oct-22-2020 15:04:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	Subject not feeling well and concerned family called ambulance before patient could do a self nasal swab.

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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020**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:** 10971084**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39

Oct-22-2020 14:56:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: 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. Please review and update as appropriate.
Oct-22-2020 14:54:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Subject called Marken for self nasal swab pick up and they never picked it up
Oct-22-2020 08:40:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Reissued:Opened	DM: Per site response, please verify and update data for sample collection. Also, kindly update this provided reason in item#4. Else clarify.
Oct-20-2020 10:00:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	The courier (Marken) picked up the swab at the patient's home and shipped it to the lab instead of bringing it to the site. Therefore, we have no barcode. What do we need to do?
Oct-19-2020 06:45:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-16-2020 10:39:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-16-2020 10:39:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Oct-16-2020 10:39:18 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	New Information

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1097**Subject No:** 10971084**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - 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

(US & Canada)			Date of Collection: Oct/16/2020	
Oct-16-2020 10:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Oct-16-2020 10:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Oct-16-2020 10:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Transcription Error
Oct-16-2020 06:49:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-15-2020 14:42:49 (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.
Oct-15-2020 14:42:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-15-2020 14:42:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/15/2020	New Information
Oct-15-2020 14:38:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason'

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

				is missing. Please review and update as appropriate.
Oct-15-2020 14:38:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Oct-22-2020 14:53:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Subject called Marken to pick up his self nasal swab and they never picked it up	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020**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:** 10971084**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-05-2020 15:57:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-05-2020 15:57:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-05-2020 15:57:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-05-2020 15:57:02 (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-05-2020 15:57:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/5/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-05-2020 15:57:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN6B71	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-05-2020 15:57:30 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN6B71	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

(US & Canada)

(b) (4), (b) (6)

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1097

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

Subject No: 10971084

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
Oct-05-2020 15:59:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-05-2020 15:59:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-05-2020 15:59:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Oct-05-2020 15:59:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: NO	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1097

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

Subject No: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

I.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-05-2020 15:59:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY ROOM	Initial Entry

I.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-05-2020 15:59:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.c

Date	Location	User	Value	Reason
Oct-07-2020 17:06:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1	Transcription Error
Oct-05-2020 15:59:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry

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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:53**Form Status:** Data Complete, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971084**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39***1.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Oct-05-2020 15:59:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-07-2020 17:06:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Transcription Error
Oct-05-2020 15:59:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.d

Date	Location	User	Value	Reason
Oct-05-2020 15:59:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: NO	Initial Entry

1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-05-2020 15:59:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-05-2020 15:59:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1097

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

Subject No: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

Oct-05-2020 15:59:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry
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I.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-05-2020 15:59:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-05-2020 15:59:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

I.f

Date	Location	User	Value	Reason
Oct-05-2020 15:59:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTHER Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:53**Form Status:** Data Complete, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971084**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39**1.f Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Oct-05-2020 15:59:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-14-2020 10:42:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-08-2020 16:43:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	"Other" is selected , however other specific item is blank. Please review and update as appropriate.
Oct-05-2020 15:59:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

2. Other Type of Practitioner Specify:

Date	Location	User	Value	Reason
Oct-14-2020 10:42:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hospital admission	Initial Entry
Oct-09-2020 05:56:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-08-2020 16:43:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-08-2020 16:43:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Oct-08-2020 02:20:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM2: If no other type of Practitioner was consulted, please leave this field blank, Thank you.

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Form Version: 15-Sep-2020 21:53 **Form Status:** Data Complete, Frozen, Verified
Site No: 1097 **Site Name:** (1097) Main Street Physician's Care - Waterway
Subject No: 10971084 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:39

Oct-07-2020 17:06:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Added information
Oct-07-2020 04:19:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM1: Thank you for your response, If Patient visited "PCP" Please updated the same in the required field.
Oct-06-2020 16:07:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Patient went to PCP. Records have been ordered.
Oct-06-2020 04:32:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Please specify if Other Type of Practitioner was consulted, Thank you.
Oct-05-2020 15:59:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: subject came to site to get nasal swab done.	Initial Entry

3. Has the subject been hospitalized due to potential COVID-19 illness?

Date	Location	User	Value	Reason
Oct-20-2020 14:20:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Oct-20-2020 10:07:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Completed hospital form
Oct-20-2020 00:40:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 3: Opened	CLIQUEY: Given that the subject has been hospitalized, please complete HOSP CRF.
Oct-18-2020 22:22:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-15-2020 14:37:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Oct-15-2020 14:37:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Has the subject been in intensive c	New Information

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1097

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

Subject No: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

			are due to potential COVID-19 illness? NO	
Oct-15-2020 09:30:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL - recent SAE safety report for Pneumonia has hospitalization starting 05 OCT 2020. Please review response to Hospital health care utilization, and update as appropriate
Oct-07-2020 06:46:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query.
Oct-06-2020 16:07:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Oct-06-2020 16:07:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
Oct-06-2020 07:24:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for "Has the subject been hospitalized due to potential COVID-19 illness?" is missing. Kindly review and update.

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 **Form:** HOSPITALIZATION DETAILS - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1097

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

Subject No: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Oct-20-2020 10:06:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 Form: HOSPITALIZATION DETAILS - 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: 10971084

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
Oct-20-2020 10:06:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: HOSPITALIZATION STATUS	Initial Entry

2. Hospitalization Term:

Date	Location	User	Value	Reason
Oct-20-2020 10:06:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HOSPITAL	Initial Entry

3. Admission Date:

Date	Location	User	Value	Reason
Nov-09-2020 16:56:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-09-2020 10:07:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Records requested many times not yet received.
Nov-09-2020 02:29:54 (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 any available information (vital signs, pulse oxymet, respiratory treatment, lab results, imaging...). Please make every effort to obtain these information.
Nov-06-2020 13:58:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candidate	CLIQUEY: Hospitalization: This subject had COVID-19 Illness and was hospitalized. Please enter any available information (vital signs, pulse

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 **Form:** HOSPITALIZATION DETAILS - 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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

				oxymet, respiratory treatment, lab results, imaging...). Please make every effort to obtain these information.
Oct-20-2020 10:06:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/6/2020	Initial Entry

4. Ongoing?

Date	Location	User	Value	Reason
Oct-20-2020 10:06:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Discharge Date: Oct/11/2020	Initial Entry

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 Form: ILLNESS DETAILS - eCRF Audit Trail History

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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Category of Clinical Event:

Date	Location	User	Value	Reason
Oct-15-2020 14:39:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNESS	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Oct-23-2020 23:56:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 1: Closed	Response satisfies query
Oct-23-2020 11:13:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-23-2020 11:13:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Respiratory Illness Diagnosis:</i> Pneumonia Date of Diagnosis: Oct/5/2020	Changed Information
Oct-23-2020 10:33:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 1: Reissued:Opened	CLIQUEY: Thank you - SO, if subject's illness diagnosis is identified as "Pneumonia", please enter as diagnosis.
Oct-22-2020 14:49:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject had Pneumonia. Six covid tests were done on patient and all came back negative
Oct-20-2020 14:20:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 1: Opened	CLIQUEY: please review to see if the diagnosis is available.
Oct-15-2020 14:39:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 **Form:** ILLNESS DETAILS - eCRF Audit Trail History

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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

3. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-21-2020 06:26:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-20-2020 10:07:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Oct-20-2020 10:07:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry
Oct-19-2020 08:07:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for "Toxicity Grade" is missing. Kindly review and update.

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Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail on Nov/04/2020**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:** 10971084**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Date of Visit**

Date	Location	User	Value	Reason
Feb-24-2021 10:31:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/4/ 2020	Transcription Error
Oct-30-2020 11:28:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-30-2020 10:45:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Both visits were due on the same day so both were done at the same time.
Oct-30-2020 05:30:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW5223333;The Date of Visit at Visit COVID_A1 is the same as the other Date of Visit at Visit V3_MONTH1_POSTVAX2_L. Please review for duplication and update as appropriate.
Oct-29-2020 15:36:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/21 /2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Oct-29-2020 15:36:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID_A1	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled Visit
on Nov/04/2020**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:** 10971084**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-29-2020 15:37:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-29-2020 15:37:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-24-2021 10:31:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/4/2020	Transcription Error
Oct-29-2020 15:37:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-29-2020 15:37:12 (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-29-2020 15:37:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/21/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-24-2021 10:32:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPVCNK	Changed Information

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Nov/04/2020

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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

Oct-29-2020 15:37:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPVCHY	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Feb-24-2021 19:11:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-24-2021 13:54:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	updated
Feb-24-2021 12:36:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	The data is unfreeze on CRF. Please review and update.
Feb-24-2021 10:32:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPVCNK	Changed Information
Feb-23-2021 13:04:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	please unfreeze line and DOV for the Conv Visit, so that we can correct.
Feb-23-2021 04:36:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Opened	DMW7387638;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Oct-30-2020 14:48:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Nov/04/2020

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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

Oct-30-2020 10:56:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Barcode belongs to this visit
Oct-29-2020 21:35:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW5223220;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Oct-29-2020 15:37:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPVCHY	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-24-2021 10:33:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPVCNL	Changed Information
Oct-29-2020 15:38:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPVCHZ	Initial Entry

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Nov/04/2020

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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

5.b Sample ID

Date	Location	User	Value	Reason
Feb-24-2021 19:11:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-24-2021 10:33:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPVCNL	Changed Information
Feb-23-2021 13:05:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	please unfreeze line and DOV for the Conv Visit, so that we can correct.
Feb-23-2021 04:36:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Opened	DMW7387639;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Oct-30-2020 14:48:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-30-2020 10:56:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Barcode belongs to this visit
Oct-29-2020 21:35:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW5223221;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Oct-29-2020 15:38:00 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPVCHZ	Initial Entry

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Nov/04/2020

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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)				
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5.c

Date	Location	User	Value	Reason
Feb-24-2021 10:33:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPVCNM	Changed Information
Oct-29-2020 16:43:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BL9XNP	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-24-2021 10:33:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPVCNM	Changed Information
Oct-30-2020 14:48:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-30-2020 10:57:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Barcode belongs to this visit
Oct-29-2020 21:35:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW5223219;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Oct-29-2020 16:43:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BL9XNP	Initial Entry

5.d

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Nov/04/2020

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: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Feb-24-2021 10:34:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BL9XHB	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Feb-24-2021 10:34:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BL9XHB	Initial Entry

5.e

Date	Location	User	Value	Reason
Feb-24-2021 10:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BL9XHC	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Feb-24-2021 10:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BL9XHC	Initial Entry

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

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: 10971084

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-21-2020 14:48:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/21/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-21-2020 14:48:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-21-2020 14:48:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB 1 -
Unscheduled Visit on Oct/21/2020

Form: DATE OF VISIT - REPEAT SWAB - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1097

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

Subject No: 10971084

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
Nov-12-2020 02:12:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Clo sed	Response satisfies query
Nov-11-2020 15:40:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Ans wered	The timing for both visits fell on the same day. Dates are correct.
Nov-10-2020 00:51:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Rei ssued: Opene d	DM: Thank you for response. Per CRF, DOV of visit 'COVID_AR1' and 'V3_MONTH1_POSTVAX2_L' is same. Please review data recorded under these visits and update CRF as needed to avoid duplication. Else clarify in query response.
Nov-09-2020 10:10:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Ans wered	records ordered many times not received yet.
Nov-09-2020 03:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Op ened	DMW5305520;The Date of Visit at Visit COVID_AR1 is the same as the other Date of Visit at Visit V3_MONTH1_POSTVAX2_L. Please review for duplication and update as appropriate.
Nov-06-2020 15:55:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	Response satisfies query

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001
Visit: POT_COVID_REPEAT_SWAB 1 -
 Unscheduled Visit on Oct/21/2020
Form: DATE OF VISIT - REPEAT SWAB - eCRF Audit Trail History
Form Version: 10-Oct-2020 15:57
Form Status: Data Complete, Frozen, Verified
Site No: 1097
Site Name: (1097) Main Street Physician's Care - Waterway
Subject No: 10971084
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 10:39

Nov-06-2020 11:44:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ans wered	Answer Auto Query
Nov-06-2020 08:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Rei ssued: Opene d	DM1: If visit completed in error (Erroneous), please clear the data entered on RSWAB form and add a Form level comment as Not applicable. Thank you.
Nov-05-2020 16:50:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	visit took place, but according to protocol, site was advised visit was not needed. Per message received on 4Nov2020 swab was canceled.
Nov-05-2020 02:58:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Op ened	DM: This visit is marked as Erroneous; however, data is present on RSWAB form. Please confirm if visit occurred or entered in error. If in error, please clear the data entered on RSWAB form and add a Form level comment as Not applicable. Thank you.
Nov-04-2020 13:17:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Oct/2 1/202 0	Transcription Error
Nov-04-2020 13:16:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Can didate	Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this visit.
Nov-04-2020 13:16:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Oct/1 6/202 0	Initial Entry

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB 1 -
Unscheduled Visit on Oct/21/2020

Form: DATE OF VISIT - REPEAT SWAB - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1097

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

Subject No: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

2. Erroneous Visit

Date	Location	User	Value	Reason
Nov-06-2020 11:44:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Nov-04-2020 13:16:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ERRONEOUS VISIT	Initial Entry

3. COVID-19 Repeat Swab:

Date	Location	User	Value	Reason
Nov-04-2020 13:16:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID_AR1	Initial Entry

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB 1 -
Unscheduled Visit on Oct/21/2020

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB - eCRF Audit
Trail History

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1097

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

Subject No: 10971084

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-04-2020 13:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-04-2020 13:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-04-2020 13:18:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Nov-04-2020 13:17:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-04-2020 13:17:11 (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-04-2020 13:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of Collection is different from Date of Visit. Please review and update as appropriate, else clarify.
Nov-04-2020 13:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/21/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB 1 -
Unscheduled Visit on Oct/21/2020

Form Version: 10-Oct-2020 15:57

Site No: 1097

Subject No: 10971084

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB - eCRF Audit
Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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Nov-04-2020 13:18:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPVCH9	Initial Entry
-------------------------------------------------------------------	-----------------	---------------------	------------------------------------------------	---------------

5.a Sample ID

Date	Location	User	Value	Reason
Nov-04-2020 13:18:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPVCH9	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971084

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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Date	Location	User	Value	Reason
Oct-14-2020 10:35:26 (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: 10971084

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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

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Date	Location	User	Value	Reason
Dec-15-2020 13:27:35 (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: 10971084

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

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

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Date	Location	User	Value	Reason
Dec-31-2020 09:56:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	updated
Dec-15-2020 13:34:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1097

Subject No: 10971084

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: ---

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1. Category:

Date	Location	User	Value	Reason
Oct-14-2020 10:35:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-14-2020 10:35:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-17-2020 02:34:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Cl osed	Response satisfies query
Dec-15-2020 15:19:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 4: Cl osed	Discrepancy has been closed.
Dec-15-2020 13:15:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: An swered	changed per query
Dec-15-2020 13:15:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Urinary Trac t Infection	changed per query
Dec-12-2020 05:36:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 4: Op ened	Multiple concepts in the term UTI AND SEPSIS BACTEREMIA. Split the term into URINARY TRACT INFECTION and SEPSIS and BACTEREMIA and submit

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Subject No: 10971084

Generated By: (b) (4)

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Subject Initials: ---

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				separately as three separate entries. Thank you.
Dec-11-2020 08:45:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: An swered	New Information
Dec-11-2020 08:45:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UTI and Sep sis Bacterem ia	New Information
Dec-11-2020 07:17:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Rei ssued:Opene d	SAE recon form unfrozen. Please confirm term should be updated to UTI and Sepsis Bacteremia. Also, please consider to record as separate entries in AE CRF.
Dec-10-2020 11:41:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: An swered	This module is frozen
Dec-09-2020 07:32:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Op ened	SAE RECON:AER#2020396942, the term in Safety database was updated to UTI and Sepsis Bacteremia while retained as Pneumonia in AE CRF.Please confirm correct term. If safety update is required, please submit a follow-up form.
Nov-16-2020 17:53:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Cl osed	Response satisfies query
Nov-16-2020 15:49:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: An swered	Medical records have been requested to confirm medical history, no records have been received to date.
Nov-15-2020 19:32:03	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Op ened	CLINICAL SAE reports that subject is receiving

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Site No: 1097

Subject No: 10971084

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: ---

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(UTC-05:00) Eastern Time (US & Canada)				Donepezil [Aricept] for med Hx condition of memory loss. Has the subject received a diagnosis of Alzheimer's; if so, please update SAE and med Hx CRF
Oct-26-2020 22:38:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Oct-20-2020 11:59:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The patient had a COVID illness visit on October 5th, 2020. The Illness tab is completed with the information that we have. What are you asking?
Oct-20-2020 11:48:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: Per protocol section 8.1., potential COVID-19 related PNEUMONIA should have please triggered a COVID Illness Visit irrespective of perceived etiology or clinical significance and a nasal swab collected ASAP.
Oct-14-2020 10:35:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Pneumonia	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-22-2020 07:46:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-18-2020 11:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Dec-18-2020 11:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/29/2020 UNK:UNK	Changed Information

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Header Text: c4591001

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Site No: 1097

Subject No: 10971084

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

Dec-18-2020 07:04:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2020396942 ,onset date was recorded as 29Sep2020 in Safety database however, recorded as 07Oct2020 on AE CRF. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form.
Oct-14-2020 10:35:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/7/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-25-2020 22:55:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Nov-25-2020 08:55:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	New Information
Nov-25-2020 08:55:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/11/2020 UNK:UNK	New Information
Nov-24-2020 23:48:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	CLINICAL Please discuss end date of pneumonia treatment and symptoms with the subject, for reporting of SAE end date.
Nov-16-2020 17:53:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-16-2020 16:29:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	unknown, hospital records requested not yet received.
Nov-15-2020 19:27:18 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical - please record the end date

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Site No: 1097

Subject No: 10971084

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

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(US & Canada)				for pneumonia SAE, if available. If available, please send a SAE Safety update with this information as well.
Oct-26-2020 22:04:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-23-2020 12:35:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Oct-23-2020 11:54:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical - please end resolution date for pneumonia SAE, if available. If available, please send a SAE Safety update with this information as well.
Oct-14-2020 10:35:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-14-2020 10:35:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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-11-2020 15:21:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Closed	Query closed; will follow for SAE update with the requested COVID test info
Dec-07-2020 14:00:54 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Answered	SAE follow-up will be sent.

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Header Text: c4591001

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Site No: 1097

Subject No: 10971084

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: ---

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(US & Canada)				
Dec-07-2020 02:18:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Opened	CLINICAL Followup on NO Covid test performed in Hosp for Pneumonia SAE (#2020396942); this information was not included in the 30Nov20 SAE update
Dec-06-2020 12:44:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Candidate	CLINICAL Followup on NO Covid test performed in Hosp for Pneumonia SAE (#2020396942); this information was not included in the 30Nov20 SAE update
Nov-25-2020 22:54:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Closed	Query closed; will follow for SAE update with the requested COVID test info
Nov-24-2020 15:08:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	has already been submitted
Nov-24-2020 14:12:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Reissued:Opened	CLINICAL Thank you; please submit this relevant information (NO COVID Test in Hosp) as a SAE (#2020396942) update in this subject with pneumonia.
Nov-24-2020 12:06:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	Per Medical records there was no covid testing done in the hospital.
Nov-23-2020 16:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Opened	CLINICAL - please submit COVID test result during hospitalization, reported as Per the subject (performed test; Negative result) in a SAE (#2020396942) safety update

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Header Text: c4591001

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Subject No: 10971084

Generated By: (b) (4)

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Nov-16-2020 15:31:36 (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
Nov-15-2020 19:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	CLINICAL - please submit COVID test result during hospitalization (reported as Per subject: performed test; Negative result) in a SAE safety update (#2020396942)
Oct-26-2020 22:30:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Query closed; will follow for SAE update with COVID test date and results
Oct-26-2020 22:06:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Query closed; will follow for SAE update with hosp COVID test result, when med records arrive
Oct-26-2020 13:50:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Per patient, test was performed in the hospital and was negative. We do not have a copy of the results from his records. Will update when a hard copy is received.

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Header Text: c4591001

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Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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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
Oct-25-2020 21:35:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	COVID testing has not been reported in the SAE submitted to safety. Please submit a follow-up SAE form [#2020369942] to provide whether COVID testing was performed (yes/no) and if yes, the results.
Oct-23-2020 12:42:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	COVID testing was performed in the hospital, however we have not received a copy of these records at the present time.
Oct-23-2020 11:51:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical - COVID testing has not been reported in the SAE submitted to safety. Please submit a follow-up SAE form [#2020396942] to provide whether COVID testing was performed (yes/no) and if yes, the results.
Oct-14-2020 21:49:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-14-2020 10:35:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Pneumonia: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.

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Header Text: c4591001

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Generated By: (b) (4)

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Subject Initials: ---

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Oct-14-2020 10:35:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</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> <p>NO</p> <p>Other medically important serious event</p> <p>YES</p>	Initial Entry
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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
Oct-14-2020 10:35:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>NO</p>	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Dec-15-2020 13:35:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: 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: 10971084

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

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Dec-15-2020 13:19:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Dec-15-2020 13:19:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s) , this event is due to: OTHER <i>If Other, specify:</i> Escherichia coli	New Information
Dec-15-2020 12:19:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL Please update Other cause for new event of UTI /sepsis. Infecting organism reported to be E. coli in SAE update.
Oct-14-2020 10:35:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s) , this event is due to: OTHER <i>If Other, specify:</i> Pt contracted pneumonia from unknown source	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-14-2020 10:35:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-14-2020 10:35:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971084

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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Date	Location	User	Value	Reason
Oct-14-2020 10:35:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Dec-01-2020 07:04:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-30-2020 12:34:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	SAE updated to read Recovered resolved.
Nov-26-2020 05:00:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2020396942 ,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-25-2020 08:57:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-25-2020 08:57:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Changed Information
Nov-25-2020 08:55:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Pneumonia: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Oct-14-2020 10:35:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
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Oct-14-2020 10:35:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Oct-14-2020 21:49:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020396942	Initial Entry

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Header Text: c4591001

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Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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1. Category:

Date	Location	User	Value	Reason
Dec-15-2020 13:27:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Dec-15-2020 13:27:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-18-2020 07:00:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-17-2020 10:31:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	changed per query request
Dec-17-2020 10:31:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sepsis Bacteremia	changed per query request
Dec-17-2020 02:39:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2020396942, term in Safety database was recorded as SEPSIS BACTEREMIA while recorded as Sepsis in AE CRF. Please confirm correct term and update accordingly. If safety update is required, please submit a follow-up form.
Dec-15-2020 13:27:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sepsis	Initial Entry

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4. Start Date Time:

Date	Location	User	Value	Reason
Dec-22-2020 07:46:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-18-2020 11:25:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Dec-18-2020 11:25:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/29/2020 UNK:UNK	Changed Information
Dec-18-2020 07:05:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2020396942 .onset date was recorded as 29Sep2020 in Safety database however, recorded as 07Oct2020 on AE CRF. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form.
Dec-15-2020 13:27:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/7/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-15-2020 13:27:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/11/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-15-2020 13:27:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

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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-18-2020 07:06:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-18-2020 07:00:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Dec-17-2020 10:33:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	For AE Sepsis Bacteremia: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-17-2020 10:33:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	changed per query request
Dec-17-2020 10:33:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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?	changed per query request

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			NO Other medically important serious event YES	
Dec-17-2020 02:44:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020396942 Sepsis Bacteremia (onset date:07Oct2020)was reported as serious in Safety database but nonserious in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Dec-15-2020 13:27:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication on the Medication Error Log.

Date	Location	User	Value	Reason
Dec-15-2020 13:27:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Dec-15-2020 13:27:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: unspecified organism	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-15-2020 13:27:35 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

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(US & Canada)		(b) (4), (b) (6)	
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Dec-15-2020 13:27:35 (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
Dec-15-2020 13:27:35 (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
Dec-15-2020 13:27:35 (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
Dec-15-2020 13:27:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Dec-18-2020 07:00:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 2020396942	Initial Entry

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

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1. Category:

Date	Location	User	Value	Reason
Dec-15-2020 13:34:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Dec-15-2020 13:34:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-04-2021 04:30:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	event inactivated in Inform
Dec-31-2020 09:56:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	updated
Dec-31-2020 02:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	SAE RECON 2: Please inactivate form per query response below.
Dec-22-2020 09:39:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	#3 can be inactivated. Thank you.
Dec-22-2020 07:51:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	SAE RECON1: Apolgoy for the confusion. AE#2 was already updated tp SEPSIS BACTEREMIA which matched Safety database. No other SAE recon issue. If AE#3 was only a split event term, please confirm if this can be

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				inactivated.
Dec-18-2020 11:28:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	This is the same AE report. Sepsis and Bacteremia were separated to satisfy previous query. Please clarify which way you would like it to be stated.
Dec-18-2020 06:59:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: Please confirm if AE#3 is a duplicate of AE#2.
Dec-15-2020 13:34:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bacteremia	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-15-2020 13:34:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/7/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-15-2020 13:34:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/11/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-15-2020 13:34:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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

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medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Dec-15-2020 13:34:01 (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
Dec-15-2020 13:34:01 (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
Dec-15-2020 13:34:01 (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), t his event is due to: OTHER If Other, specify: Escherichia coli unspecified	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-15-2020 13:34:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Dec-15-2020 13:34:01 (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
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Header Text: c4591001

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Subject No: 10971084

Generated By: (b) (4)

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Dec-15-2020 13:34:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Dec-15-2020 13:34:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Dec-15-2020 13:34:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Header Text: c4591001

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-20-2021 16:50:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/15/2021	Initial Entry

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled **Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1097

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

Subject No: 10971084

Subject Initials: ---

Generated By: (b) (4)

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

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I. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Feb-24-2021 08:26:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2	Transcription Error
Feb-02-2021 11:40:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-01-2021 16:21:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	document uploaded in system today
Feb-01-2021 12:08:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Monitor is unable to verify if visit occurred. There is no supporting documentation via Florence. Please confirm if visit occurred, if so, please upload supporting documentation to be verified. Thanks!
Jan-20-2021 16:50:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is NOT willing to return for Vaccination 3 OR otherwise not eligible	Initial Entry

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971084

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-20-2021 16:50:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/15/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-24-2021 16:13:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_DS001_35
Feb-24-2021 08:26:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Feb-24-2021 00:54:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Re issued: Opened	DM: Page unfreeze kindly verify and consider updating correct data. Thank you.
Feb-23-2021 12:49:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	please unfreeze the page that we need to update to fix, FURTHER VACCINATION CONFIRMATION
Feb-22-2021 18:54:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Re issued: Opened	DM RQ: Per CCG, if the subject is eligible prior to determining whether or not placebo was given at V1/V2, consider entering Participant is willing to return for Vaccination 3 and eligible and NOT confirmed to have received only placebo at Vaccination 1/2

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971084

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

Feb-22-2021 09:27:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	pt received real IP at the beginning of study and does not qualify for additional vaccinations
Feb-22-2021 08:23:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7349445;Primary Reason for Unblinding is "ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION", but "Participant is willing to return for Vaccination 3" is not selected in the Further Vaccination Confirmation CRF. Please review and update as appropriate.
Jan-20-2021 16:50:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971084

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

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1. Subject Status

Date	Location	User	Value	Reason
Oct-21-2020 14:48:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-02-2020 20:02:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-02-2020 20:00:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-21-2020 14:48:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/21/2020	Initial Entry
Sep-02-2020 20:02:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/1/2020	Initial Entry
Sep-02-2020 20:00:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/1/2020	Initial Entry

090177e196ae3eae\Final\Final On: 01-Apr-2021 04:58 (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: 10971084

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 23:08:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry