

Header Text: C4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[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: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/10/2020
----	--------------	--

Header Text: C4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[12231159]
2.	Birth Date:	(b) (6)/1947
3.	Sex:	FEMALE
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: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/10/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation/Death	Sep/10/2020
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: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

eCRF Audit Trail History

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypothyroidism]
	Start Date:	UNK/UNK/2014
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Cardiovascular prevention]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	UNK/UNK/2008
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Osteoporosis]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

1.e	Line/MH Number:	[5]	
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Irritable bowl syndrome]	
	Start Date:	UNK/UNK/2019	
	Ongoing:	YES	
1.f	Line/MH Number:	[6]	
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[GERD]	
	Start Date:	UNK/UNK/2002	
	Ongoing:	YES	
1.g	Line/MH Number:	[7]	
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Menopause]	
	Start Date:	UNK/UNK/1998	
	Ongoing:	YES	
1.h	Line/MH Number:	[8]	Comments
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Melanoma]	Comments
	Start Date:	UNK/UNK/2007	Comments
	Ongoing:	NO End Date: UNK/UNK/2007	Comments
1.i	Line/MH Number:	[9]	
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Osteoarthritis]	
	Start Date:	UNK/UNK/1996	
	Ongoing:	YES	

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Eustachian Tube Dysfunction]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Dyslipidemia]
	Start Date:	UNK/UNK/2014
	Ongoing:	YES
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Monoclonal Gammopathy of Unknown Significance]
	Start Date:	Aug/17/2020
	Ongoing:	YES

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/10/2020
2.	Weight:	[50.3]
3.	Unit:	kg
4.	Height:	[154.0]
5.	Unit:	cm
6.	Body Mass Index:	[21.2]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[98.6]
	Unit:	F
	Temperature Location:	FOREHEAD

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/10/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	
	Not Done:	NOT DONE

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Sep/10/2020
2.	Randomization Number:	[257123]
3.	Randomization Group:	[]

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/10/2020
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	[BPXXJZ]
5.b	Sample ID	[BPXXK0]
5.c	Sample ID	[BPXXK1]

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/10/2020
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	[BPXXJY]
-----	-----------	----------

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[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/10/2020 15:26
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[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: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Oct/1/2020
----	-------	------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.4]
	Unit:	F
	Temperature Location:	FOREHEAD

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Oct/1/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	
	Not Done:	NOT DONE

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/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	[BPXXYY]
-----	-----------	----------

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

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:	Oct/1/2020 15:36
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

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

Date of Visit

1.	Date of Visit	Not Done _____ //	Comments
2.	Erroneous Visit	Not Done _____	Comments

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

Form Comments

eCRF Audit Trail History

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	Not Done _____ []
----	-----------	--------------------------

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

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: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

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

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

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: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

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

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

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: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

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

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET
on Jan/29/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/29/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Jan/29/2021

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Jan/29/2021
2.	Date of First Symptom Started:	Jan/15/2021
3.	Symptoms Ongoing?	YES

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?	NO
4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	NO
4.h	Symptoms:	DIARRHEA
	Was symptom present?	YES
4.i	Symptoms:	VOMITING
	Was symptom present?	NO

Symptoms - Other

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Jan/29/2021

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

5.a	Symptoms - Other Text:	[abdominal pain]
5.b	Symptoms - Other Text:	[enterocolitis]

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Jan/16/2021	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN
on Jan/29/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)
[eCRF Audit Trail History](#)
[Form Audit Trail](#)

Microbiology Specimen

1.	Actual Date of Collection:	Jan/16/2021
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	CEPHEID XPERT XPRESS SARS-COV-2 TEST
7.	Test Result:	NEGATIVE
8.	Comments/Findings/Details:	[]
9.	Trade Name Other, Specify:	[]

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Jan/29/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[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 refused.]

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
on Jan/29/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[subject has been hospitalized and is unable to provide a sample at the site.]

Aliquot

Please enter barcode for each aliquot.

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

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION
on Jan/29/2021**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete**Site No:** 1223**Site Name:** (1223) Yale New Haven Medical Center**Subject No:** 12231159**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:30[eCRF Audit Trail History](#)**Health Care Utilization**

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

Health Care Utilization Other

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

Health Care Utilization

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

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	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 **Form:** RESPIRATORY TREATMENT
on Jan/29/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

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

Respiratory Treatment

1.	What is the treatment Identifier?	Not Done _____ []	Comments
2.	Concomitant Non-drug Treatment Pre-specified:	Not Done _____	Comments
3.	Treatment:	Not Done _____	Comments
4.	Treatment:	Not Done _____ []	Comments
5.	Start Date:	Not Done _____ //	Comments
6.	Ongoing?	Not Done _____	Comments

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS
on Jan/29/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[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: [Enterocolitis] Date of Diagnosis: Jan/16/2021
3.	Toxicity Grade:	2

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.					Repeating Pages

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE
on Jan/29/2021

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

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: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

#	Category for Lab Test	Vendor Name	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 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Jan/29/2021

Form Version: 21-Aug-2020 02:49

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

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

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

#	Category for Lab Test	Vendor Name (DE RIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	Repeating Pages

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Jan/29/2021

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

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

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

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

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Jan/29/2021

Form Version: 21-Aug-2020 02:50

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

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: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Jan/29/2021

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

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: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.				Repeating Pages

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS
on Jan/29/2021

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

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: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.						Repeating Pages

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
on Jan/29/2021

Form Version: 06-Jul-2020 21:55

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

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?	

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					Repeating Pages

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING
on Jan/29/2021

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

Imaging

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

Header Text: C4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

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: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

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: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

Unplanned Assessments

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

Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Nov/5/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	OTHER
4.	Specify Status:	[patient had medical condition which precluded her from coming to visit 3]

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

Disposition - Follow-Up

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

Header Text: C4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

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

Header Text: C4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

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: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VITAL SIGNS - TEMP

Form Version: 28-Mar-2021 02:28

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

Vital Signs

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

Vital Signs Details

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

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

Lab Urinalysis

1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[]
5.	Specimen Type:	

Lab Result

6.	Sponsor ID:	[]
	Test:	
	Result:	
	Not Done:	

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

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?	

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (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: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

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: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

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: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

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: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

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: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

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

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

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: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

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: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

Further Vaccination Confirmation

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

Header Text: C4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Pancreatic Adenocarcinoma	Nov/5/2020 11:21	YES	Repeating Pages
2.	ADVERSE EVENT	2	Enterocolitis	Jan/15/2021 00:00	YES	Repeating Pages

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)
[eCRF Audit Trail History](#)
[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Pancreatic Adenocarcinoma]
4.	Start Date Time:	Nov/5/2020 11:21
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	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 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

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

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: [New development of pancreatic mass]
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?:	NOT RECOVERED/NOT 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	[2020437831]

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Not Complete

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)
[eCRF Audit Trail History](#)
[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Enterocolitis]
4.	Start Date Time:	Jan/15/2021 00:00
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	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 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: CONCOMITANT DRUG TREATMENT

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Not Complete

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

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?:	NOT RECOVERED/NOT 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	[2021046126]

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

#	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: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

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	[]

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

#	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: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

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:	//

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1. DELETED						Repeating Pages
2.	2	CONCOMITANT IMMUNOSUPPRESSIVE THERAPY	NO	Flourouracil	3,500	Repeating Pages
3.	3	CONCOMITANT IMMUNOSUPPRESSIVE THERAPY	NO	Irinotecan	180	Repeating Pages
4.	4	CONCOMITANT IMMUNOSUPPRESSIVE THERAPY	NO	Oxaliplatin	115	Repeating Pages

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Incomplete, Data Complete, Deleted, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

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

[Back to Form](#)
[eCRF Audit Trail History](#)
[Form Audit Trail](#)

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?	

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Data Complete, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)
[eCRF Audit Trail History](#)
[Form Audit Trail](#)

Concomitant Medications

1.	What is the medication identifier?	[2]
2.	Category:	CONCOMITANT IMMUNOSUPPRESSIVE THERAPY
3.	Concomitant Medications Pre-specified:	NO
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).	[Flourouracil]
5.	Dose:	[3,500]
6.	Dose Unit:	mg
7.	Dose Frequency:	ONCE
8.	Route:	INTRAVENOUS
9.	Start Date:	Jan/7/2021
10.	Ongoing?	YES

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Data Complete, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)
[eCRF Audit Trail History](#)
[Form Audit Trail](#)

Concomitant Medications

1.	What is the medication identifier?	[3]
2.	Category:	CONCOMITANT IMMUNOSUPPRESSIVE THERAPY
3.	Concomitant Medications Pre-specified:	NO
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).	[Irinotecan]
5.	Dose:	[180]
6.	Dose Unit:	mg
7.	Dose Frequency:	ONCE
8.	Route:	INTRAVENOUS
9.	Start Date:	Jan/7/2021
10.	Ongoing?	YES

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Data Complete, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)
[eCRF Audit Trail History](#)
[Form Audit Trail](#)

Concomitant Medications

1.	What is the medication identifier?	[4]
2.	Category:	CONCOMITANT IMMUNOSUPPRESSIVE THERAPY
3.	Concomitant Medications Pre-specified:	NO
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).	[Oxaliplatin]
5.	Dose:	[115]
6.	Dose Unit:	mg
7.	Dose Frequency:	ONCE
8.	Route:	INTRAVENOUS
9.	Start Date:	Jan/7/2021
10.	Ongoing?	YES

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

#	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: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

Radiation Treatment

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

Header Text: C4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

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

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

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

Header Text: C4591001

Visit: UNPLANNED_BOOSTER_CONTACT - **Form:** DATE OF VISIT

Unscheduled

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: UNPLANNED_BOOSTER_CONTACT - **Form:** BOOSTER DOSE TRIGGER FORM
Unscheduled

Form Version: 20-Feb-2021 02:20

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

Booster Dose Trigger Form

1.	Select appropriate response - Will the participant return for consent/eligibility assessment for the booster dose visit?	
----	--	--

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Not Started

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

Treatment Unblinded

1.	Date Treatment Unblinded :	//
2.	Primary Reason for Unblinding:	

Header Text: C4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

Withdrawal Of Consent

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

Header Text: C4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

Death Details

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

Cause of Death

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

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Nov/5/2020

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: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[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: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Jessica Tuan	Approved	Mar-19-2021 21:05:19 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, JessicaTuan, 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.

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-10-2020 19:41:38 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

Item	Date	User	Comment
1 h	Sep-14-2020 11:07:01 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	S/P Excision 2007

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

Item	Date	User	Comment
1 h	Sep-14-2020 11:07:01 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	S/P Excision 2007

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

Item	Date	User	Comment
1 h	Sep-14-2020 11:07:01 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	S/P Excision 2007

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

Item	Date	User	Comment
1 h	Sep-14-2020 11:07:01 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	S/P Excision 2007

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: DATE OF VISIT - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-04-2021 15:24:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: DATE OF VISIT - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

Item	Date	User	Comment
1	Mar-04-2021 15:24:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: DATE OF VISIT - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

Item	Date	User	Comment
2	Mar-04-2021 15:24:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

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: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-09-2021 15:53:40 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (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: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

Item	Date	User	Comment
1	Mar-09-2021 15:53:40 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

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: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

Item	Date	User	Comment
2	Mar-09-2021 15:53:40 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

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: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

Item	Date	User	Comment
3	Mar-09-2021 15:53:40 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

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: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

Item	Date	User	Comment
4	Mar-09-2021 15:53:40 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments on Jan/29/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

Item	Date	User	Comment
Form	Feb-17-2021 11:56:22 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done
Form	Feb-17-2021 11:56:05 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments on Jan/29/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

Item	Date	User	Comment
1	Feb-17-2021 11:56:22 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done
1	Feb-17-2021 11:56:05 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Jan/29/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

Item	Date	User	Comment
2	Feb-17-2021 11:56:22 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done
2	Feb-17-2021 11:56:05 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments on Jan/29/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

Item	Date	User	Comment
3	Feb-17-2021 11:56:22 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done
3	Feb-17-2021 11:56:05 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments on Jan/29/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

Item	Date	User	Comment
4	Feb-17-2021 11:56:22 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done
4	Feb-17-2021 11:56:05 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Jan/29/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

Item	Date	User	Comment
5	Feb-17-2021 11:56:22 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done
5	Feb-17-2021 11:56:05 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments on Jan/29/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

Item	Date	User	Comment
6	Feb-17-2021 11:56:22 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done
6	Feb-17-2021 11:56:05 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Jessica Tuan	Approved	Mar-19-2021 21:05:19 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, JessicaTuan, 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	Dec-16-2020 14:13:59 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
---------	-----	---	--	-----------------------------------

Affidavit:

N/A

Jessica Tuan	Approved	Nov-16-2020 12:12:42 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
--------------	----------	---	------	--------

Affidavit:

By my dated signature below, I, JessicaTuan, 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-11-2020 10:12:05 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
---------	-----	---	--	-----------------------------------

Affidavit:

N/A

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (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: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

Onyema Ogbuagu	Approved	Nov-10-2020 09:09:05 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
----------------	----------	---	------	--------

Affidavit:

By my dated signature below, I, OnyemaOgbuagu, 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-09-2020 16:01:58 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
---------	-----	---	--	-----------------------------------

Affidavit:

N/A

Jessica Tuan	Approved	Nov-09-2020 14:02:35 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
--------------	----------	---	------	--------

Affidavit:

By my dated signature below, I, JessicaTuan, 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-08-2020 10:20:28 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
---------	-----	---	--	-----------------------------------

Affidavit:

N/A

Onyema Ogbuagu	Approved	Nov-07-2020 13:17:38 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
----------------	----------	---	------	--------

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (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: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

Affidavit:

By my dated signature below, I, OnyemaOgbuagu, 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.

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-10-2020 19:41:00 (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-10-2020 19:41:00 (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: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

I. Consent Was:

Date	Location	User	Value	Reason
Sep-10-2020 19:41:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Sep/10/2020	Initial Entry

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Nov-09-2020 05:33:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-08-2020 10:21:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 1: Answered	Changed data per query
Nov-07-2020 11:57:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020437831 mass at pancreatic head(onset date:05Oct2020)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.
Sep-10-2020 19:40:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12231159	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-10-2020 19:40:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) 1947	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-10-2020 19:41:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-10-2020 19:41:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 19:41:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Sep-10-2020 19:41:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/10/2020	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-10-2020 19:41:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/10/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-10-2020 19:41:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-10-2020 19:41:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

1.a

Date	Location	User	Value	Reason
Sep-10-2020 19:42:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 1 : Medical History T Hypothyroidism: sm Start Date: UNK/UNK/2014 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 19:42:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 19:42:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hypothyroidism	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 19:42:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2014	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 19:42:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

I.b

Date	Location	User	Value	Reason
Sep-10-2020 19:42:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 2 ber: Medical Histor Cardiovascular p y Term: revention Start Date: UNK/UNK/2018 Ongoing: YES	Initial Entry

I.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 19:42:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 19:42:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Cardiovascular prevention	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 19:42:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2018	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 19:42:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.c

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

Sep-10-2020 19:43:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 3 : Medical History Term: Hypertension Start Date: UNK/UNK/2008 Ongoing: YES	Initial Entry
---	-----------------	-------------------------	---	---------------

I.c Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 19:43:05 (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 19:43:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hypertension	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 19:43:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2008	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 19:43:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Sep-10-2020 19:43:22 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 4	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

Time (US & Canada)			:	
			Medical History Term:	Osteoporosis
			Start Date:	UNK/UNK/2019
			Ongoing:	YES

1.d Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 19:43:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 19:43:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Osteoporosis	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 19:43:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2019	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 19:43:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.e

Date	Location	User	Value	Reason
Sep-14-2020 09:24:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Line/MH Number: 5	Transcription Error

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

			Medical History Term: Irritable bowel syndrome Start Date: UNK/UNK/2019 Ongoing: YES	
Sep-10-2020 19:43:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Term: IBS Start Date: UNK/UNK/2019 Ongoing: YES	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

I.e Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 19:43:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 5	Initial Entry

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

Date	Location	User	Value	Reason
Sep-14-2020 10:49:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Sep-14-2020 09:24:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-14-2020 09:24:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry</u> : Irritable bowel syndrome	Transcription Error
Sep-11-2020 15:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify IBS as follows...Please expand the abbreviation and clarify are you reporting IRRITABLE BOWEL SYNDROME? INFLAMMATORY BOWEL SYNDROME? Other? If so, edit. Otherwise clarify. Thank you.
Sep-10-2020 19:43:39	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry</u> :	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

(UTC-05:00) Eastern Time (US & Canada)			IBS	
--	--	--	-----	--

I.e Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 19:43:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2019	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 19:43:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Sep-10-2020 19:43:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 6 : Medical History T GERD erm: Start Date: UNK/UNK/2 002 Ongoing: YES	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

I.f Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 19:43:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 6	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 19:43:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> GERD	Initial Entry

I.f Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 19:43:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> UNK/UNK/2002	Initial Entry

I.f Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 19:43:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

I.g

Date	Location	User	Value	Reason
Sep-10-2020 19:44:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Line/MH Number 7 : Medical History T Menopause erm: Start Date: UNK/UNK/1 998 Ongoing: YES	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

I.g Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 19:44:12 (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
Nov-11-2020 14:48:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Appreciate the prompt response. Thank you.
Nov-11-2020 10:27:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 1: Answered	Changed data per query
Nov-11-2020 06:43:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Per case narrative reported to safety, there is additional Med Hx of Dyslipidemia and monoclonal gammopathy of undetermined significance (MGUS) not recorded on CRF. Please revise and update accordingly.
Nov-10-2020 23:28:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Candidate	Per case narrative reported to safety, there is additional Med Hx of Dyslipidemia and monoclonal gammopathy of undetermined significance (MGUS) not recorded on CRF. Please revise and update accordingly.

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

Sep-10-2020 19:44:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Menopause	Initial Entry
---	-----------------	---------------------	---------------------------------	---------------

I.g Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 19:44:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1998	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 19:44:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.h

Date	Location	User	Value	Reason
Sep-14-2020 11:06:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: Medical History Term: Melanoma Start Date: UNK/UNK/2007 Ongoing: NO End Date: UNK/UNK/2007	Changed Information
Sep-10-2020 19:44:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History Term: Melanoma Start Date: UNK/UNK/2007 Ongoing: YES	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

1.h Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 19:44:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 8	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 19:44:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Melanoma	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 19:44:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> UNK/UNK/2007	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Sep-14-2020 16:19:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

I.h Ongoing:

Date	Location	User	Value	Reason
Sep-14-2020 11:06:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Sep-14-2020 11:06:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2007	Changed Information
Sep-11-2020 10:03:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Please confirm if ongoing?
Sep-10-2020 19:44:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.i

Date	Location	User	Value	Reason
Sep-10-2020 19:44:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 9 : Medical History T Osteoarthritis erm: Start Date: UNK/UNK/1 996 Ongoing: YES	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

1.i Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 19:44:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 19:44:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Osteoarthritis	Initial Entry

1.i Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 19:44:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1996	Initial Entry

1.i Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 19:44:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.j

Date	Location	User	Value	Reason
Sep-10-2020 19:45:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 10 mber: Medical Histo Eustachian Tube ry Term: Dysfunction Start Date: UNK/UNK/2017 Ongoing: YES	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

1.j Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 19:45:22 (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-10-2020 19:45:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Eustachian Tube Dysfunction	Initial Entry

1.j Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 19:45:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2017	Initial Entry

1.j Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 19:45:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.k

Date	Location	User	Value	Reason
Nov-11-2020 10:12:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 11 : Medical History T Dyslipidemia erm: Start Date: UNK/UNK/2 014 Ongoing: YES	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

I.k Line/MH Number:

Date	Location	User	Value	Reason
Nov-11-2020 10:12:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 11	Initial Entry

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

Date	Location	User	Value	Reason
Feb-01-2021 11:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Response satisfies query
Jan-28-2021 12:50:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	This is not medical history prior to study entry. AE term has been updated
Jan-26-2021 12:04:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	Per SAE report subject has a MHx of pancreatic adenocarcinoma from 05Nov2020 to 2021 which is missing on CRF. Please review and update accordingly.
Nov-11-2020 10:12:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> Dyslipidemia	Initial Entry

I.k Start Date:

Date	Location	User	Value	Reason
Nov-11-2020 10:12:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> UNK/UNK/2014	Initial Entry

I.k Ongoing:

Date	Location	User	Value	Reason
Nov-11-2020 10:12:05 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

Time (US & Canada)	(b) (4)
--------------------	---------

1.1

Date	Location	User	Value	Reason
Nov-11-2020 10:27:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 12 Number: Medical History Terminology: Monoclonal Gammopathy of Unknown Significance Start Date: Aug/17/2020 Ongoing: YES	Initial Entry

1.1 Line/MH Number:

Date	Location	User	Value	Reason
Nov-11-2020 10:27:00 (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
Nov-11-2020 10:27:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Monoclonal Gammopathy of Unknown Significance	Initial Entry

1.1 Start Date:

Date	Location	User	Value	Reason
Nov-11-2020 10:27:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Aug/17/2020	Initial Entry

1.1 Ongoing:

Date	Location	User	Value	Reason
Nov-11-2020 10:27:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Sep-10-2020 19:46:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sep/10/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-10-2020 19:46:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 50.3	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-10-2020 19:46:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-10-2020 19:46:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 154.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-10-2020 19:46:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-10-2020 19:46:37 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 21.2	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

Time (US & Canada)				
--------------------	--	--	--	--

7.a

Date	Location	User	Value	Reason
Sep-10-2020 19:46:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 98.6 Temperature Unit: F Temperature Locati FOREHE on:: AD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-10-2020 19:46:37 (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-10-2020 19:46:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.6	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-10-2020 19:46:37 (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-10-2020 19:46:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Sep-10-2020 19:46:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-10-2020 19:46:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-10-2020 19:46:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/10/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-10-2020 19:46:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-10-2020 19:46:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

Sep-10-2020 19:46:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: Not Done:: NOT DONE	Initial Entry
---	-----------------	-------------------------	--	---------------

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-10-2020 19:46:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-10-2020 19:46:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-10-2020 19:46:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

1. Randomization Date :

Date	Location	User	Value	Reason
Sep-10-2020 19:47:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/10/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-10-2020 19:47:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 257123	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: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Sep-10-2020 19:47:24 (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-10-2020 19:47:24 (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-14-2020 12:46:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-11-2020 05:45:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-10-2020 19:47:24 (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-10-2020 19:47:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/10/2020	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (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: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

5.a

Date	Location	User	Value	Reason
Sep-14-2020 12:46:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sample ID: BPXXJZ	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-14-2020 12:46:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: BPXXJZ	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-14-2020 12:47:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sample ID: BPXXX0	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-14-2020 12:47:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: BPXXX0	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-14-2020 12:47:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sample ID: BPXXX1	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-14-2020 12:47:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: BPXXX1	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Sep-10-2020 19:47:32 (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-10-2020 19:47:32 (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-14-2020 16:45:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-11-2020 05:45:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-10-2020 19:47:32 (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-10-2020 19:47:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/10/2020	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

5.a

Date	Location	User	Value	Reason
Sep-14-2020 16:45:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sample ID: BPXXJY	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-14-2020 16:45:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: BPXXJY	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-10-2020 19:47:55 (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-10-2020 19:47:55 (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-10-2020 19:47:55 (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-10-2020 19:47:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/10/2020 15:26	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-10-2020 19:47:55 (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-10-2020 19:47:55 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

Time (US & Canada)

7. Route:

Date	Location	User	Value	Reason
Sep-10-2020 19:47:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-10-2020 19:47:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED O BSERVATION 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-10-2020 19:47:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-10-2020 19:48:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENICITY E-DI ARY NOT COLLECTED FOR T HIS SUBJECT	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Mar-02-2021 09:46:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Query raised for the same in SUBSTAT #1
Mar-01-2021 01:37:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Open ed	DM: Please consider updating tentative V3 date and subject recent status or else clarify. Thank you.
Feb-27-2021 12:54:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 2: Answered	Visit is not planned and subject is likely to be discontinued at this point.
Feb-26-2021 09:23:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Open ed	DM1 : Kindly provide planned V3_MONTH1_POSTVAX2_L visit. Thank you.
Feb-25-2021 13:09:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 2: Answered	this has not occurred yet.
Feb-22-2021 17:27:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: Subject should have had V3_MONTH1_POSTVAX2_L visit. Please confirm if this visit did or did not occur and consider updating dates/CRFs as necessary or as applicable (e.g. End of Treatment, etc.).
Nov-11-2020 17:38:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-11-2020 13:56:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 1: Answered	DCF submitted in Trial Manager. Subject explained her throat pain was due to intubation from having

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

				surgery.
Nov-11-2020 09:08:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Illness ed diary: As per Illness ed diary records, subject reported "Yes" for the COVID-19 symptoms or diagnosis on 07NOV2020. But no corresponding COVID Illness visit indicate symptoms present at this date. Pls update Covid illness visit or clarify.
Oct-01-2020 20:18:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/1/2020	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Oct-01-2020 20:18:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/1/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-01-2020 20:18:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 98.4 Temperature Unit: F Temperature Locati on:: FOREHE AD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-01-2020 20:18:15 (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
Oct-01-2020 20:18:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.4	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Oct-01-2020 20:18:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

2.a Temperature Location:

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

Date	Location	User	Value	Reason
Oct-01-2020 20:18:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FOREHEAD	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Oct-01-2020 20:18:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Oct-01-2020 20:18:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-01-2020 20:18:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/1/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Oct-01-2020 20:18:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Oct-01-2020 20:18:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

Oct-01-2020 20:18:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: Not Done:: NOT DONE	Initial Entry
---	-----------------	-------------------------	--	---------------

6.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-01-2020 20:18:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Oct-01-2020 20:18:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Oct-01-2020 20:18:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (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: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Oct-01-2020 20:18:31 (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-01-2020 20:18:31 (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-03-2020 12:44:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-02-2020 04:51:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-01-2020 20:18:31 (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-01-2020 20:18:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/1/2020	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (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: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

5.a

Date	Location	User	Value	Reason
Oct-03-2020 12:44:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sample ID: BPXXYY	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-03-2020 12:44:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: BPXXYY	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-01-2020 20:25:59 (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
Oct-01-2020 20:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-01-2020 20:25:59 (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
Oct-01-2020 20:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/1/2020 15:36	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-01-2020 20:25:59 (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
Oct-01-2020 20:25:59 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

Time (US & Canada)				
--------------------	--	--	--	--

7. Route:

Date	Location	User	Value	Reason
Oct-01-2020 20:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-01-2020 20:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> THE PROTOCOL SPECIFIED O BSERVATION 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
Oct-01-2020 20:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Mar-04-2021 15:24:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Not Done	Initial Entry

2. Erroneous Visit

Date	Location	User	Value	Reason
Mar-04-2021 15:24:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Not Done	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: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Mar-09-2021 15:53:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Done	Initial Entry
Mar-09-2021 15:53:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Mar-04-2021 15:27:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-09-2021 15:53:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Done	Initial Entry
Mar-09-2021 15:53:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Mar-04-2021 15:27:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-09-2021 15:53:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Not Done	Initial Entry
Mar-09-2021 15:53:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry:	Transcription Error
Mar-04-2021 15:27:38	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (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: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	NO	
--	--	---------------------	----	--

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

Date	Location	User	Value	Reason
Mar-09-2021 15:53:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Not Done	Initial Entry
Mar-09-2021 15:53:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry:	Transcription Error
Mar-04-2021 15:27:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: subject missed visit	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Jan/29/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Mar-09-2021 02:16:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	As per site confirmation - updated PD tracker
Mar-08-2021 17:10:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 4: Answered	subject is not able to come in for a convalescent visit, due to her pancreatic cancer.
Mar-08-2021 07:20:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	PDQ: Convalescent visit is missing and 35+ days (38) have passed since COVID Illness Visit. If visit occurred record data as a matching CONVA visit; if visit did not occur attempt to schedule visit even if OOW and obtain the CONVA sample else clarify.
Mar-01-2021 02:34:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	As per site confirmation - updated PD tracker
Feb-27-2021 12:51:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 1: Answered	subject refused self swab, due to ongoing medical issues.
Feb-18-2021 23:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Feb-18-2021 16:08:10 (UTC-05:00) Eastern	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Query 3: Answered	Changed data per query

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Jan/29/2021**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1223**Site Name:** (1223) Yale New Haven Medical Center**Subject No:** 12231159**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:30

Time (US & Canada)				
Feb-18-2021 07:02:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	DM: Kindly consider to update missing ILL POTEN form or else clarify. Thank you.
Feb-18-2021 05:31:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	PDQ : Details of Sample ID (barcode) and collection date for either Nasal Swab Self or Nasal Swab expected to be completed. Please check and update else clarify.
Feb-17-2021 11:47:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Feb-17-2021 11:46:14 (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.
Feb-17-2021 11:46:14 (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.
Feb-17-2021 11:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Jan/29/2021	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Jan/29/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Feb-17-2021 11:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> COVID_A	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/29/2021**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 14-Jan-2021 02:23**Form Status:** Data Complete**Site No:** 1223**Site Name:** (1223) Yale New Haven Medical Center**Subject No:** 12231159**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:30[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Feb-17-2021 11:47:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Jan/29/2021	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Feb-17-2021 11:47:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Jan/15/2021	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Feb-17-2021 11:47:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Feb-17-2021 11:47:32 (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
Feb-17-2021 11:47:32 (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
------	----------	------	-------	--------

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/29/2021

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

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

Feb-17-2021 11:47:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES	Initial Entry
---	-----------------	-----------------------	---------------------------	---------------

4.b

Date	Location	User	Value	Reason
Feb-17-2021 11:47:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Symptoms NEW OR INCREA : SED COUGH Symptom NO Present:	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Feb-17-2021 11:47:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NEW OR INCREASED COUG H	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Feb-17-2021 11:47:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Feb-17-2021 11:47:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sympto NEW OR INCREASE ms: D SHORTNESS OF BREATH Sympto NO m Prese nt:	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/29/2021

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

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

4.c Symptoms:

Date	Location	User	Value	Reason
Feb-17-2021 11:47:32 (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
Feb-17-2021 11:47:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Feb-17-2021 11:47:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Feb-17-2021 11:47:32 (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
Feb-17-2021 11:47:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Feb-17-2021 11:47:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Symptom: NEW OR INCREASED MUSCLE PAIN	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/29/2021

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

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

			Symptom NO Present:	
--	--	--	---------------------	--

4.e Symptoms:

Date	Location	User	Value	Reason
Feb-17-2021 11:47:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Feb-17-2021 11:47:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Feb-17-2021 11:47:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> Symptoms NEW LOSS OF TASTE OR SMELL Symptom NO Present:	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Feb-17-2021 11:47:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Feb-17-2021 11:47:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

4.g

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/29/2021

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

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

Date	Location	User	Value	Reason
Feb-17-2021 11:47:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Symptom NEW OR INCREASED SORE THROAT Symptom NO Present:	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Feb-17-2021 11:47:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Feb-17-2021 11:47:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Feb-17-2021 11:47:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Symptoms: DIARRHEA Symptom Present YES	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/29/2021

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

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

4.h Symptoms:

Date	Location	User	Value	Reason
Feb-17-2021 11:47:32 (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
Feb-17-2021 11:47:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> YES	Initial Entry

4.i

Date	Location	User	Value	Reason
Feb-17-2021 11:47:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> Symptoms: VOMITIN G Symptom Present NO :	Initial Entry

4.i Symptoms:

Date	Location	User	Value	Reason
Feb-17-2021 11:47:32 (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
Feb-17-2021 11:47:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-17-2021 11:47:55	ACV0PFEINFP6000	(b) (6)	<u>Data Entry:</u>	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/29/2021

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

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	Symptoms - Other: abdominal pain	
--	--	---------------------	---	--

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Feb-17-2021 11:47:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: abdominal pain	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-27-2021 12:52:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Symptoms - Other: enterocolitis	Transcription Error (DELETED)
Feb-17-2021 11:49:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Symptoms - Other: enterocolitis	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/29/2021

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

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

5.b Symptoms - Other Text:

Date	Location	User	Value	Reason
Mar-03-2021 02:09:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Feb-27-2021 12:52:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: enterocolitis	Transcription Error (DELETED)
Feb-27-2021 12:52:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-20-2021 19:59:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: ENTEROCOLITIS is already captured as a diagnosis on the ILLNESS DETAILS CRF form and should not be entered on the SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 CRF form. Please review and update
Feb-17-2021 11:49:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: enterocolitis	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Audit Trail
on Jan/29/2021

Form Version: 06-Jul-2020 21:54

Form Status:

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

Date	Location	User	Value	Reason
Feb-17-2021 11:51:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Form Created	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Jan/29/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

1. Actual Date of Collection:

Date	Location	User	Value	Reason
Feb-17-2021 11:51:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Jan/16/2021	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Feb-17-2021 11:51:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: SWABBED MATERIAL	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Feb-17-2021 11:51:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NASOPHARYNX	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Feb-17-2021 11:51:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYNDR OME CORONAVIRUS 2	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Feb-17-2021 11:51:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC TES T	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Feb-17-2021 11:52:07 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (6)	Data Entry: CEPHEID XPRT XPRESS SA	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Jan/29/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

Time (US & Canada)	(b) (4)	RS-COV-2 TEST
--------------------	---------	---------------

7. Test Result:

Date	Location	User	Value	Reason
Feb-17-2021 11:51:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> NEGATIVE	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/29/2021

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: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Feb-17-2021 11:53:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-17-2021 11:53:07 (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
Feb-17-2021 11:53:07 (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
Feb-17-2021 11:53:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: subject refused.	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/29/2021

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: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Feb-17-2021 11:54:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-17-2021 11:54:46 (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
Feb-17-2021 11:54:46 (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
Feb-17-2021 11:54:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: subject has been hospitalized and is unable to provide a sample at the site.	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Jan/29/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

I.a

Date	Location	User	Value	Reason
Feb-17-2021 11:55:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Type of Practitioner: SPECIALIST LIST Occurrence of Visits or Contacts: NO	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-17-2021 11:55:20 (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
Feb-17-2021 11:55:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Feb-17-2021 11:55:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Jan/29/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

I.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-17-2021 11:55:20 (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
Feb-17-2021 11:55:20 (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.c

Date	Location	User	Value	Reason
Feb-17-2021 11:55:20 (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

I.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-17-2021 11:55:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

I.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-17-2021 11:55:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Jan/29/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

I.d

Date	Location	User	Value	Reason
Feb-17-2021 11:55:20 (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

I.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-17-2021 11:55:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: URGENT CARE	Initial Entry

I.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-17-2021 11:55:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO	Initial Entry

I.e

Date	Location	User	Value	Reason
Feb-17-2021 11:55:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Jan/29/2021**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete**Site No:** 1223**Site Name:** (1223) Yale New Haven Medical Center**Subject No:** 12231159**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:30***1.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Feb-17-2021 11:55:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: TELEPHONE CONSULTATIO N	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-17-2021 11:55:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO	Initial Entry

1.f

Date	Location	User	Value	Reason
Feb-17-2021 11:55:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Type of Practitioner: OTH ER Occurrence of Visits or Contacts: NO	Initial Entry

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-17-2021 11:55:20 (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
Feb-17-2021 11:55:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-17-2021 11:55:20	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Jan/29/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

(UTC-05:00) Eastern
Time (US & Canada)

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

NO

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: RESPIRATORY TREATMENT - eCRF Audit Trail History on Jan/29/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

1. What is the treatment Identifier?

Date	Location	User	Value	Reason
Feb-17-2021 11:56:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Not Done	Initial Entry
Feb-17-2021 11:56:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Not Applicable	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Feb-17-2021 11:56:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Not Done	Initial Entry
Feb-17-2021 11:56:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Not Applicable	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Feb-17-2021 11:56:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Not Done	Initial Entry
Feb-17-2021 11:56:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Not Applicable	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Feb-17-2021 11:56:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Not Done	Initial Entry
Feb-17-2021 11:56:05	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History on Jan/29/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	Not Applicable	
--	--	---------------------	----------------	--

5. Start Date:

Date	Location	User	Value	Reason
Feb-17-2021 11:56:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Not Done	Initial Entry
Feb-17-2021 11:56:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Feb-17-2021 11:56:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Not Done	Initial Entry
Feb-17-2021 11:56:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Not Applicable	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: ILLNESS DETAILS - eCRF Audit Trail History on Jan/29/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

1. Category of Clinical Event:

Date	Location	User	Value	Reason
Feb-18-2021 14:42:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNES S	Initial Entry

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

Date	Location	User	Value	Reason
Feb-18-2021 14:42:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Data Entry: YES <i>Respiratory Illness Diagnosis:</i> Enterocolitis Date of Diagnosis: Jan/16/2021	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-18-2021 14:42:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Data Entry: 2	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Mar-09-2021 16:04:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Data Entry: Nov/5/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-09-2021 16:04:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Mar-11-2021 22:30:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3: Clo sed	Auto closed by Validation Check: VC_DS001_25
Mar-11-2021 15:35:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Clo sed	Close Auto Query
Mar-11-2021 15:35:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Op ened	Response to "Status" is OTHER but "Specify Status" is missing.
Mar-11-2021 15:35:02 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	auto query (autoquery)	Query 3: An swere d	Patient had medical condition at the time that precluded her from coming to Visit

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

(US & Canada)				3.
Mar-11-2021 15:35:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Data Entry : OTH ER	Patient had medical condition at the time that precluded her from coming to Visit 3.
Mar-10-2021 18:28:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3: Op ened	DMW7665967;Status is reported as Adverse Event, but there is no Adverse Event with 'Latest Action Taken with Study Treatment' reported as DRUG WITHDRAWN. Please review and update as appropriate.
Mar-10-2021 14:01:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Clo sed	Response satisfies query
Mar-10-2021 12:52:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Clo sed	Close Auto Query
Mar-10-2021 12:41:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Op ened	Response to "Status" is ADVERSE EVENT but "Specify Status" is Provided.
Mar-10-2021 12:41:02 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	auto query (autoquery)	Query 1: An swere d	She had adverse event of other medical comorbidities at that

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

(US & Canada)				time which prevented her to go to visit 3.
Mar-10-2021 12:41:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Data Entry : ADV ERSE EVE NT	She had adverse event of other medical comorbidities at that time which prevented her to go to visit 3.
Mar-10-2021 04:40:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: Per comment subject had ongoing AE at time of V3. Please review if status ADVERSE EVENT better reflects reason for missed V3
Mar-09-2021 16:04:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Data Entry : OTH ER	Initial Entry

4. Specify Status:

Date	Location	User	Value	Reason
Mar-11-2021 15:35:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Data Entry: patient had medical condition which precluded her from coming to visit 3	Initial Entry
Mar-10-2021 12:52:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Data Entry:	Changed Information
Mar-09-2021 16:04:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Data Entry: Subject has missed Visit 3 due to ongoing AE but wants to remain in the study.	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-08-2020 10:20:28 (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: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

Date	Location	User	Value	Reason
Feb-01-2021 13:14:47 (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: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Nov-08-2020 10:20:28 (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
Nov-08-2020 10:20:28 (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
Feb-08-2021 10:03:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Query on Diarrhea
Feb-04-2021 13:10:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Feb-01-2021 12:56:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 3: Answered	SAE form amended and resubmitted
Feb-01-2021 12:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 5: Closed	Response satisfies query
Jan-29-2021 11:42:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Ope ned	SAE RECON 2: Thanks for your response. Please confirm submission of updated SAE form.
Jan-28-2021	ACV0PFEINFP6000	(b) (6)	Query 4: Reissued:Ope	Response does not satisfy

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

12:51:19 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	ned	query
Jan-28-2021 12:46:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	Updated report to be submitted
Jan-28-2021 12:46:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Updated report to be submitted
Jan-28-2021 12:46:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Pancreatic Adenocarcin oma	Updated report to be submitted
Jan-28-2021 11:58:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	data will be updated
Jan-24-2021 09:33:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 5: Opened	CLINICAL_ AER#2021046126, If the subject will be receiving treatment with chemotherapy, per CRF CG V12, section 8.53., details of prohibited medications should be recorded on CRF. Kindly reassess and update the PROHIB CM accordingly. Thank you.
Jan-21-2021 05:27:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	SAE RECON:AER#2021046126,the following events 'abdominal pain, fever, enterocolitis on CT scan, likely chemotherapy- induced diarrhea' were recorded as serious in SDB but missing in AE CRF. Please confirm and update accordingly.
Jan-21-2021	ACV0PFEINFP6000	(b) (6)	Query 3: Reissued:Ope	SAE RECON 1:The term in

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

05:17:03 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	ned	SDB was still recorded as 'mass at pancreatic head'. Please submit a follow up AEM form to indicate ductal carcinoma as updated term of mass at pancreatic head
Jan-20-2021 15:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Safety update has been submitted
Dec-18-2020 08:36:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	SAE RECON:AER#2020437831, the term in AE CRF was updated to 'Ductal Adenocarcinoma' while retained as 'mass at pancreatic head' in SDB. Please confirm correct term. If safety update is required, please submit a follow-up form.
Dec-17-2020 10:29:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Closed	Response satisfies query
Dec-16-2020 14:13:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Dec-16-2020 14:13:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Ductal Adenocarcinoma	New Information
Nov-24-2020 12:39:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Opened	Per narrative, the subject underwent an "endoscopic ultrasound (EUS) with biopsy was performed on 06Nov2020". Kindly provide results for a final diagnosis. Thank you.
Nov-12-2020 07:28:05	ACV0PFEINFP6000	(b) (6)	Query 1: Closed	Per PSSR confirmation 'Event term updated to Pancreatic

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1223**Subject No:** 12231159**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Verified**Site Name:** (1223) Yale New Haven Medical Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:30

(UTC-05:00) Eastern Time (US & Canada)		(b) (4)		Mass in the Argus Database. Issue has been reconciled'
Nov-11-2020 02:32:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Can didate	SAE RECON: For PSSR review
Nov-10-2020 10:21:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 1: Answered	The term carcinoma was not used in the narrative of the SAE. The mass was described as a "neoplasm" which can be benign or malignant. The biopsy is pending and the term will be updated, as indicated, upon receiving biopsy results.
Nov-10-2020 07:12:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020437831,the term was reported as 'Mass at Pancreatic Head' in both database.Per narrative of the case this is a pancreatic carcinoma.Please confirmed and update the event term in the AE log and submit a fu SAE form.
Nov-08-2020 10:20:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Mass at Pancreatic Head	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-10-2020 12:03:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-09-2020 16:01:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-09-2020 16:01:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Nov/5/2020 11:21	Transcription Error

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

Nov-09-2020 12:32:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Please verify start date. EMR records indicate subject was admitted 05Nov2020
Nov-08-2020 10:20:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Oct/5/2020 11:21	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-08-2020 10:20:28 (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
Nov-08-2020 10:20:28 (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-17-2020 10:42:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Closed	Response satisfies query
Dec-16-2020 14:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 2: Answered	COVID test was done on 05NOV2020 and was negative. Will add this to an updated SAE form.
Nov-19-2020 14:34:27	ACV0PFEINFP6000	Giselle	Query 2: Opened	As per the request

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

(UTC-05:00) Eastern Time (US & Canada)		Castillo (b) (4)		of our Data Monitoring Committee, please include in a follow-up SAE form whether COVID testing was conducted during hospitalization – yes/no including not available/not performed. If COVID testing was performed, include the results.
Nov-09-2020 04:55:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-08-2020 10:20:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Mass at Pancreatic Head: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-08-2020 10:20:28 (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	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

			<p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	
--	--	--	--	--

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Nov-08-2020 10:20:28 (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
Nov-08-2020 10:20:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<p>Data Entry: NOT RELATED</p> <p>If Not Related to study treatment(s), this event is due to:</p> <p>OTHER</p> <p><i>If Other, specify:</i></p> <p>New development of pancreatic mass</p>	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-08-2020 10:20:28 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

Time (US & Canada)		(b) (4)	
--------------------	--	---------	--

II. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-01-2021 12:07:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Response satisfies query
Jan-28-2021 11:56:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Chemotherapy was never stopped
Jan-26-2021 12:08:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	CLINICAL_ Please advise if Chemotherapy was restarted and reasoning behind it. Thanks
Nov-08-2020 10:20:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-08-2020 10:20:28 (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
Nov-08-2020 10:20:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NOT RECOVERED/NOT RES OLVED	Initial Entry

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

Date	Location	User	Value	Reason
Nov-08-2020 10:20:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Nov-09-2020 04:55:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020437831	Initial Entry

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Not Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Feb-01-2021 13:14:47 (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
Feb-01-2021 13:14:47 (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
Feb-25-2021 17:33:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Closed	Response satisfies query
Feb-20-2021 20:00:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Feb-19-2021 15:50:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Query 2: Answered	SAE report has been sent in updating the term to enterocolitis
Feb-19-2021 02:29:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Open ed	SAE RECON: Abdominal pain, Diarrhoea, Pyrexia are reported as SAEs in Safety database but still missing in AE CRF. Please confirm and update accordingly.
Feb-17-2021 12:03:16 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Not Complete

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

Time (US & Canada)				
Feb-17-2021 12:03:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Feb-17-2021 12:03:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Enterocolitis	Changed Information
Feb-04-2021 16:33:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Opened	SAE RECON:AER#2021046126,the following events 'abdominal pain, pyrexia, enterocolitis...' were recorded as serious in SDB but missing in AE CRF. Please confirm and update accordingly.
Feb-02-2021 11:21:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: Per Prot Sect 8.1., COVID-19 listed symptom DIARRHEA should please trigger a potential COVID-19 Visit irrespective of perceived etiology or clinical significance, captured on the SOD form and a SWAB needs to be collected ASAP
Feb-01-2021 13:14:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Diarrhea	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-01-2021 13:14:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Jan/15/2021 00:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
------	----------	------	-------	--------

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Not Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

Feb-01-2021 13:17:09 (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
Feb-01-2021 13:14:47 (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
Feb-18-2021 07:46:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-17-2021 12:04:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Answer Auto Query
Feb-17-2021 12:04:34 (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	Changed Information

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Not Complete

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

			<p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	
Feb-04-2021 10:36:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-02-2021 02:55:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	If Serious is YES, then response to below questions should be selected NO or YES as appropriate. Please update.
Feb-01-2021 13:16:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 2: Answered	Original value is correct
Feb-01-2021 13:14:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Is this adverse event serious?' is reported 'Yes', but at least one seriousness criteria is missing. Please review and update as appropriate.
Feb-01-2021 13:14:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Diarrhea: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Not Complete

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

Feb-01-2021 13:14:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES Did this serious event require or prolong hospitalization? YES	Initial Entry
---	-----------------	--------------------	---	---------------

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Feb-01-2021 13:14:47 (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
Feb-19-2021 15:47:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-19-2021 15:42:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Query 1: Answered	The Fluorouracil, Irinotecan, and Oxaliplatin components of FOLFIRINOX may have attributed to AE.
Feb-19-2021 08:55:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical: pls advise which drug caused AE. Thanks
Feb-01-2021 13:14:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NOT RELATED If Not Related to study treatm ent(s), this event is due to: CONCOMITANT DRUG T REATMENT	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Not Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

Feb-01-2021 13:14:47 (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
Feb-01-2021 13:14:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-01-2021 13:14:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-01-2021 13:14:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NOT RECOVERED/NOT RES OLVED	Initial Entry

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

Date	Location	User	Value	Reason
Feb-01-2021 13:14:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Feb-04-2021 10:36:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2021046126	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Audit Trail

Form Status:

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

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

[Back to Form](#)

Date	Location	User	Value	Reason
Feb-27-2021 12:43:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Form Deleted	Transcription Error
Feb-27-2021 12:43:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Form Undeleted	Transcription Error
Feb-17-2021 12:08:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Form Deleted	Transcription Error
Jan-28-2021 12:20:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Audit Trail

Form Status:

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

Date	Location	User	Value	Reason
Jan-28-2021 12:24:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Audit Trail

Form Status:

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

Date	Location	User	Value	Reason
Jan-28-2021 12:25:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231159

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Audit Trail

Form Status:

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

Date	Location	User	Value	Reason
Jan-28-2021 12:26:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Incomplete, Data Complete, Deleted, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

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

[Back to Form](#)

1. What is the medication identifier?

Date	Location	User	Value	Reason
Feb-15-2021 16:00:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Jan-28-2021 12:20:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Feb-17-2021 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u>	Transcription Error
Jan-28-2021 12:20:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> CONCOMITANT IMMUNOS UPPRESSIVE THERAPY	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Feb-15-2021 16:00:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Jan-28-2021 12:20:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001**Visit:** Logs - Unscheduled**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Incomplete, Data Complete, Deleted, Verified**Site No:** 1223**Site Name:** (1223) Yale New Haven Medical Center**Subject No:** 12231159**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:30***** THIS REPEATING FORM HAS BEEN DELETED *****

Mar-01-2021 19:14:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-27-2021 12:43:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 1: Answered	Changed data per query
Feb-17-2021 09:44:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	CLINQUERY: Thank you for removing the Medication Name (Folinic Acid) as it was entered in error. However, the dose, dose unit, route, etc are still completed. Please verify this CRF should be BLANK and update CRF accordingly.
Feb-15-2021 16:00:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-15-2021 16:00:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry:	Transcription Error
Feb-15-2021 13:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: FOLINIC ACID is reported as a prohibited IMMUNOSUPPRESSIVE. However, while this is a part of the chemotherapy regimen, this agent itself is not immunosuppressive. Please verify it was captured as a prohibited con med in error and update CRF
Jan-28-2021 12:20:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: folinic acid	Initial Entry

5. Dose:

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Incomplete, Data Complete, Deleted, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

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

Date	Location	User	Value	Reason
Feb-17-2021 12:06:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u>	Transcription Error
Jan-28-2021 12:20:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 400	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
Feb-17-2021 12:07:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u>	Transcription Error
Jan-28-2021 12:20:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> mg	Initial Entry

7. Dose Frequency:

Date	Location	User	Value	Reason
Feb-17-2021 12:07:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u>	Transcription Error
Jan-28-2021 12:20:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> ONCE	Initial Entry

8. Route:

Date	Location	User	Value	Reason
Feb-17-2021 12:07:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u>	Transcription Error
Jan-28-2021 12:20:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> INTRAVENOUS	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Incomplete, Data Complete, Deleted, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

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

9. Start Date:

Date	Location	User	Value	Reason
Feb-17-2021 12:08:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry:	Transcription Error
Jan-28-2021 12:20:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/7/2021	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
Feb-17-2021 12:08:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry:	Transcription Error
Jan-28-2021 12:20:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

1. What is the medication identifier?

Date	Location	User	Value	Reason
Jan-28-2021 12:24:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jan-28-2021 12:24:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CONCOMITANT IMMUNOSU PPRESSIVE THERAPY	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Jan-28-2021 12:24:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Jan-28-2021 12:24:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Flourouracil	Initial Entry

5. Dose:

Date	Location	User	Value	Reason
Jan-28-2021 12:24:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (6)	Data Entry: 3,500	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

		(b) (4)		
--	--	---------	--	--

6. Dose Unit:

Date	Location	User	Value	Reason
Jan-28-2021 12:24:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> mg	Initial Entry

7. Dose Frequency:

Date	Location	User	Value	Reason
Jan-28-2021 12:24:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> ONCE	Initial Entry

8. Route:

Date	Location	User	Value	Reason
Jan-28-2021 12:24:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> INTRAVENOUS	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Jan-28-2021 12:24:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Jan/7/2021	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
Jan-28-2021 12:24:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

1. What is the medication identifier?

Date	Location	User	Value	Reason
Jan-28-2021 12:25:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jan-28-2021 12:25:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CONCOMITANT IMMUNOSU PPRESSIVE THERAPY	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Jan-28-2021 12:25:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Jan-28-2021 12:25:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Irinotecan	Initial Entry

5. Dose:

Date	Location	User	Value	Reason
Jan-28-2021 12:25:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (6)	Data Entry: 180	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

		(b) (4)		
--	--	---------	--	--

6. Dose Unit:

Date	Location	User	Value	Reason
Jan-28-2021 12:25:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> mg	Initial Entry

7. Dose Frequency:

Date	Location	User	Value	Reason
Jan-28-2021 12:25:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> ONCE	Initial Entry

8. Route:

Date	Location	User	Value	Reason
Jan-28-2021 12:25:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> INTRAVENOUS	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Jan-28-2021 12:25:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Jan/7/2021	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
Jan-28-2021 12:25:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

1. What is the medication identifier?

Date	Location	User	Value	Reason
Jan-28-2021 12:26:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jan-28-2021 12:26:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CONCOMITANT IMMUNOSU PPRESSIVE THERAPY	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Jan-28-2021 12:26:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Jan-28-2021 12:26:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oxaliplatin	Initial Entry

5. Dose:

Date	Location	User	Value	Reason
Jan-28-2021 12:26:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (6)	Data Entry: 115	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

		(b) (4)		
--	--	---------	--	--

6. Dose Unit:

Date	Location	User	Value	Reason
Jan-28-2021 12:26:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> mg	Initial Entry

7. Dose Frequency:

Date	Location	User	Value	Reason
Jan-28-2021 12:26:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> ONCE	Initial Entry

8. Route:

Date	Location	User	Value	Reason
Jan-28-2021 12:26:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> INTRAVENOUS	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Jan-28-2021 12:26:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Jan/7/2021	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
Jan-28-2021 12:26:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

I. Subject Status

Date	Location	User	Value	Reason
Mar-11-2021 15:35:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Patient had medical condition at the time that precluded her from coming to Visit 3.
Mar-10-2021 12:41:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	She had adverse event of other medical comorbidities at that time which prevented her to go to visit 3.
Mar-10-2021 04:41:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Closed	Response satisfies query
Mar-09-2021 16:04:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Initial Entry
Mar-09-2021 15:54:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 2: Answered	Changed data per query
Mar-09-2021 09:54:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Opened	CLINQUERY: V3 has not been reported yet timepoint has passed - please clarify reason for lack of V3 to determine date/status for end of first treatment phase (vax1/vax2/V3). First EOT page to be updated with this status
Mar-05-2021 01:36:04 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (6)	Query 1: Closed	Data Updated.

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001**Visit:** Subject Status - Unscheduled**Form:** SUBJECT STATUS - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Verified**Site No:** 1223**Site Name:** (1223) Yale New Haven Medical Center**Subject No:** 12231159**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:30

Time (US & Canada)		(b) (4)		
Mar-04-2021 15:25:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 1: Answered	Changed data per query
Mar-02-2021 09:47:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Visit 3 is overdue based on expected visit window. Please enter data or, if visit will never occur, mark Date of Visit as 'Not Done' with form level comment. If subject is no longer in the trial, complete the Disposition FUP form.
Sep-10-2020 19:47:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-10-2020 19:41:50 (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
Mar-11-2021 15:35:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/5/2020	Patient had medical condition at the time that precluded her from coming to Visit 3.
Mar-10-2021 12:41:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/5/2020	She had adverse event of other medical comorbidities at that time which prevented her to go to visit 3.
Mar-09-2021 16:04:46	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

(UTC-05:00) Eastern Time (US & Canada)		(autocalc)	Nov/5/2020	
Dec-18-2020 13:13:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-16-2020 14:22:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 2: Answered	subject is not well enough to come in for a visit
Dec-08-2020 15:50:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical Query: Please advise on status of Visit 3. Given AE of Pancreatic Mass, it seems visit is delayed. Please provide an update, if possible.
Nov-13-2020 12:57:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-12-2020 14:12:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 1: Answered	This visit has not occurred yet and this is pending.
Nov-11-2020 15:05:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Please complete Visit 3 and End of Treatment Forms. Thanks
Sep-10-2020 19:47:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/10/2020	Initial Entry
Sep-10-2020 19:41:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/10/2020	Initial Entry

090177e196ae301b\Final\Final On: 01-Apr-2021 04:01 (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: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

[Back to Form](#)

I. Casebook Signature

Date	Location	User	Value	Reason
Nov-07-2020 13:17:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Onyema Ogbuagu (b) (4)	Data Entry: Click Here to Enable	Initial Entry