

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

Form: COHORT_SELECTION

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](#)

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: 12231058

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

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

Form: DEMOGRAPHY

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](#)

Demography

1.	Subject ID	[12231058]
2.	Birth Date:	(b) (6)/1956
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: 12231058

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/1/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1223

Subject No: 12231058

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 _____
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Exclusion Criteria Met

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

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231058

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/1/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231058

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:	[diabetes type II]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[hypercholesterolemia]
	Start Date:	Apr/UNK/2020
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[depression]
	Start Date:	UNK/UNK/1980
	Ongoing:	YES

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1223

Subject No: 12231058

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/1/2020
2.	Weight:	[74.6]
3.	Unit:	kg
4.	Height:	[165.0]
5.	Unit:	cm
6.	Body Mass Index:	[27.4]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.2]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1223

Subject No: 12231058

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/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

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001
Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:03
Site No: 1223
Subject No: 12231058
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/1/2020
2.	Randomization Number:	[247503]
3.	Randomization Group:	[]

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231058

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/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	[BPHVJ7]
5.b	Sample ID	[BPHVJ8]
5.c	Sample ID	[BPOXWJ]
5.d	Sample ID	[BPOXWK]
5.e	Sample ID	[BPOXWL]

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231058

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/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	[BPOXWH]
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1223

Subject No: 12231058

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/1/2020 12:47
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1223

Subject No: 12231058

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	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
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Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231058

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/23/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:52

Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

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 Symptoms Diary - Symptom Resolved Dates

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

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:52

Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

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

3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1223

Subject No: 12231058

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:	Sep/23/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.7]
	Unit:	F
	Temperature Location:	FOREHEAD

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1223

Subject No: 12231058

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/23/2020
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

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231058

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/23/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

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

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1223

Subject No: 12231058

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/23/2020 12:50
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

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	Oct/22/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 21-Aug-2020 02:52

Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

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 Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	YES Ongoing? NO Stop Date: Sep/29/2020
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERD MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 21-Aug-2020 02:52

Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

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

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

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231058

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: Oct/22/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR37X4]
5.b	Sample ID	[BR37X5]
5.c	Sample ID	[BR37X6]

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Feb/12/2021

Form: DATE OF VISIT - ILLNESS ONSET

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: 12231058

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	Feb/12/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A
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Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on
Feb/12/2021**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19**Form Version:** 14-Jan-2021 02:23**Form Status:** Data Complete, Frozen, Verified**Site No:** 1223**Site Name:** (1223) Yale New Haven Medical Center**Subject No:** 12231058**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:	Feb/12/2021
2.	Date of First Symptom Started:	Feb/3/2021
3.	Symptoms Ongoing?	YES

Symptoms

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

Symptoms - Other

5.a	Symptoms - Other Text:	[swollen glands]
5.b	Symptoms - Other Text:	[swollen tonsils]

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: 12231058

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.	Feb/3/2021	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/12/2021

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

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[Form Audit Trail](#)

Microbiology Specimen

1.	Actual Date of Collection:	Feb/3/2021
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:	OTHER
7.	Test Result:	NEGATIVE
8.	Comments/Findings/Details:	[]
9.	Trade Name Other, Specify:	[CLIA CERTIFIED LAB]

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/12/2021

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

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: 12231058

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?	YES Date of Collection: Feb/4/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[CV46666]
-----	-----------	-----------

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/12/2021

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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: 12231058

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 did not come to site to swab]

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Feb/12/2021

Form: HEALTH CARE UTILIZATION

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

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:	YES
	Number of Visits or Contacts:	[1]
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	NO
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	NO
1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

Health Care Utilization Other

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

Health Care Utilization

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

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: HOSPITALIZATION DETAILS

Form Version: 22-Apr-2020 21:02

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

#	Hospitalization Category	Hospitalization Term	Admission Date	Ongoing	Form Instance
1.	HOSPITALIZATION STATUS	HOSPITAL	Feb/9/2021	NO Discharge Date: Feb/12/2021	Repeating Pages

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Feb/12/2021

Form: HOSPITALIZATION DETAILS

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

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[Form Audit Trail](#)

Hospitalization Details

1.	Hospitalization Category:	HOSPITALIZATION STATUS
2.	Hospitalization Term:	HOSPITAL
3.	Admission Date:	Feb/9/2021
4.	Ongoing?	NO Discharge Date: Feb/12/2021

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: 12231058

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.						Repeating Pages

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Feb/12/2021

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

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Respiratory Treatment

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/12/2021

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

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?	NO
3.	Toxicity Grade:	3

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Feb/12/2021

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

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Illness Details

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

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

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 on Feb/12/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

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

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/12/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

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Laboratory Data Hematology

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

Lab Result

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

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (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: 12231058

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Feb/12/2021

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

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Vital Signs

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

Vital Signs Details

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

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

#	Date:	Vital Signs Details	Form Instance		
1.		<table border="1"><tr><td>Record Identifier:</td><td>Oxygen Saturation</td></tr></table>	Record Identifier:	Oxygen Saturation	Repeating Pages
Record Identifier:	Oxygen Saturation				

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Feb/12/2021

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

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Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Feb/12/2021

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

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Oxygenation Parameters

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

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

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: 12231058

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

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/12/2021

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

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Concomitant Medications

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

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (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: 12231058

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 on Feb/12/2021 **Form:** IMAGING

Form Version: 06-Jul-2020 21:53 **Form Status:** Not Started

Site No: 1223 **Site Name:** (1223) Yale New Haven Medical Center

Subject No: 12231058 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:30

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Imaging

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

Header Text: C4591001

Visit: POT_COVID_CONVA - 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: 12231058

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:	
----	-------------------------	--

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: 12231058

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	[]
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090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

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: 12231058

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: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

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 :	Oct/22/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1223

Subject No: 12231058

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: 12231058

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: 12231058

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	[]
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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: 12231058

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: 12231058

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: 12231058

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:	

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form Version: 10-Dec-2020 02:26

Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

Form: VACCINATION

Form Status: Not Started

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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?	

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001
Visit: Unplanned Vaccination - Unscheduled
Form Version: 10-Oct-2020 15:57
Site No: 1223
Subject No: 12231058
Generated By: (b) (4)

Form: CONTACT OUTCOME - MONTH 1
Form Status: Not Started
Site Name: (1223) Yale New Haven Medical Center
Subject Initials: ---
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 Version: 10-Oct-2020 16:01

Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

Form: CONTACT OUTCOME - MONTH 6

Form Status: Not Started

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

Contact Outcome

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

Header Text: C4591001

Visit: Potential ReVax Initial Contact - Unscheduled **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

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	Feb/12/2021
2.	Erroneous Visit	

Header Text: C4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per other protocol allowance(s) and confirmed to have received only placebo at Vaccination 1/2
----	---	--

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231058

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	Mar/2/2021
2.	Erroneous Visit	

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER 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](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Mar/2/2021
----	--------------	---

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:30

Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER 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

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

Form: DISPOSITION - SCREENING FOR FURTHER 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](#)

Disposition - Screening for Further Vaccination

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

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 20-Feb-2021 02:14

Site No: 1223

Subject No: 12231058

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:	Mar/2/2021
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

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231058

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: Mar/2/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR188L]
5.b	Sample ID	[BR188M]
5.c	Sample ID	[BR188N]

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231058

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: Mar/2/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR188K]
-----	-----------	----------

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1223

Subject No: 12231058

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	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Mar/2/2021 10:50
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, 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	Mar/23/2021
2.	Erroneous Visit	

Header Text: C4591001

Visit: V102_VAX4

Form Version: 20-Feb-2021 02:14

Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, 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:	Mar/23/2021
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

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, 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: Mar/23/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRJ4FY]
-----	-----------	----------

Header Text: C4591001
Visit: V102_VAX4 **Form:** VACCINATION
Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Frozen, Verified
Site No: 1223 **Site Name:** (1223) Yale New Haven Medical Center
Subject No: 12231058 **Subject Initials:** ---
Generated By: (b) (4) **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	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Mar/23/2021 10:46
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231058

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: V103_MONTH1
Form Version: 22-Apr-2020 21:04
Site No: 1223
Subject No: 12231058
Generated By: (b) (4)

Form: CONTACT OUTCOME
Form Status: Not Started
Site Name: (1223) Yale New Haven Medical Center
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 13:30

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

Header Text: C4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231058

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: V104_MONTH6
Form Version: 22-Apr-2020 21:04
Site No: 1223
Subject No: 12231058
Generated By: (b) (4)

Form: CONTACT OUTCOME
Form Status: Not Started
Site Name: (1223) Yale New Haven Medical Center
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 13:30

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

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231058

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: V105_MONTH18
Form Version: 22-Apr-2020 21:04
Site No: 1223
Subject No: 12231058
Generated By: (b) (4)

Form: CONTACT OUTCOME
Form Status: Not Started
Site Name: (1223) Yale New Haven Medical Center
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 13:30

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

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

Disposition - Treatment

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

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: 12231058

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	Shortness of breath	Feb/3/2021 00:00	NO End Date Time: Feb/12/2021 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	fatigue	Mar/3/2021 09:00	NO End Date Time: Mar/4/2021 09:00	Repeating Pages
3.	ADVERSE EVENT	3	injection site pain	Mar/2/2021 15:00	NO End Date Time: Mar/4/2021 09:00	Repeating Pages

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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[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)	[Shortness of breath]
4.	Start Date Time:	Feb/3/2021 00:00
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/12/2021 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event YES
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Unknown etiology]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED WITH SEQUELAE
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021156172]

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[fatigue]
4.	Start Date Time:	Mar/3/2021 09:00
5.	Is the adverse event still ongoing?	NO End Date Time: Mar/4/2021 09:00
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001		
Visit: Logs - Unscheduled		Form: ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02		Form Status: Data Complete, Frozen
Site No: 1223		Site Name: (1223) Yale New Haven Medical Center
Subject No: 12231058		Subject Initials: ---
Generated By: (b) (4)		Generated Time (GMT): 29-Mar-2021 13:30
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[injection site pain]
4.	Start Date Time:	Mar/2/2021 15:00
5.	Is the adverse event still ongoing?	NO End Date Time: Mar/4/2021 09:00
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

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	[]
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090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (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: 12231058

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: 12231058

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

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Medication Error

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

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (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: 12231058

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.	1	VACCINATIONS	NO	Influenza vaccine	Oct/12/2020	Repeating Pages

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

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

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Concomitant Medications

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
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).	[Influenza vaccine]
5.	Date:	Oct/12/2020

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (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: 12231058

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.						Repeating Pages

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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Concomitant Medications

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

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (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: 12231058

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: 12231058

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?	

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

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: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231058

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: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Feb/12/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

Withdrawal Of Consent

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

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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: 12231058

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	FOLLOW-UP
2.	Subject Status Date	Oct/22/2020

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
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Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

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-24-2021 18:03:01 (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.

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1223

Subject No: 12231058

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

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Item	Date	User	Comment
Form	Sep-01-2020 19:25:26 (UTC-05:00) Eastern Time (US & Canada)	(b)(4),(b)(6)	Not Applicable

Header Text: C4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Mar-04-2021 15:36:31 (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: 12231058

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-24-2021 18:03:01 (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.

Suzana Mutc	N/A	Mar-24-2021 15:04:37 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Jessica Tuan	Approved	Mar-23-2021 18:03:43 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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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	Mar-23-2021 13:52:58 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Jessica Tuan	Approved	Mar-19-2021 17:27:20 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

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	Feb-15-2021 15:40:17 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Onyema Ogbuagu	Approved	Oct-30-2020 14:24:21 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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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.

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1223

Subject No: 12231058

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

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-01-2020 19:24:15 (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-01-2020 19:24:15 (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: 12231058

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

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I. Consent Was:

Date	Location	User	Value	Reason
Sep-01-2020 19:24:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: OBTAINED Date Written Consent Obtained Sep/1/2020	Initial Entry

Header Text: C4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

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1. Subject ID

Date	Location	User	Value	Reason
Sep-01-2020 19:24:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 12231058	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-01-2020 19:22:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> (b) (6) 1956	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-01-2020 19:25:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-01-2020 19:25:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 19:25:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> WHITE	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231058

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

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I. Date of Visit

Date	Location	User	Value	Reason
Sep-03-2020 18:42:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Closed	Response satisfies query
Sep-03-2020 15:27:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Answered	query answered
Sep-02-2020 13:37:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Opened	ClinQuery: Please update Vaccine Treatment page
Sep-01-2020 19:25:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sep/1/2020	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231058

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

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-01-2020 19:25:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sep/1/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-01-2020 19:25:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-01-2020 19:25:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231058

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

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I.a

Date	Location	User	Value	Reason
Sep-01-2020 19:27:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term diabetes type II : Start Date: UNK/UNK/200 0 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 19:27:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 19:27:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: diabetes type II	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 19:27:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: UNK/UNK/2000	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 19:27:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES	Initial Entry

I.b

Date	Location	User	Value	Reason
Sep-01-2020 19:28:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231058

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: hypercholesterolemia Start Date: Apr/UNK/2020 Ongoing: YES
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1.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 19:28:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 19:28:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: hypercholesterolemia	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 19:28:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Apr/UNK/2020	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 19:28:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Sep-01-2020 19:28:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Term: depression Start Date: UNK/UNK/1980 Ongoing: YES	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231058

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.c Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 19:28:59 (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-01-2020 19:28:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: depression	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 19:28:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: UNK/UNK/1980	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 19:28:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1223

Subject No: 12231058

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-01-2020 19:32:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> Sep/1/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-01-2020 19:32:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> 74.6	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-01-2020 19:32:33 (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-01-2020 19:32:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> 165.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-01-2020 19:32:33 (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-01-2020 19:32:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 27.4	Initial Entry

7.a

Date	Location	User	Value	Reason
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090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1223

Subject No: 12231058

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

Sep-01-2020 19:32:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Record Identifier:: 1 Temperature: 97.2 Temperature Unit: F Temperature Location:: ORAL CAVITY	Initial Entry
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7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-01-2020 19:32:33 (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-01-2020 19:32:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: 97.2	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-01-2020 19:32:33 (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-01-2020 19:32:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - 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

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-01-2020 19:33:01 (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-01-2020 19:33:01 (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-01-2020 19:33:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sep/1/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-01-2020 19:33:01 (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-01-2020 19:33:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-01-2020 19:33:01 (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

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - 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

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-01-2020 19:33:01 (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-01-2020 19:33:01 (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-01-2020 19:33:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NOT DONE	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231058

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

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1. Randomization Date :

Date	Location	User	Value	Reason
Sep-01-2020 19:33:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sep/1/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-01-2020 19:33:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: 247503	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: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Sep-01-2020 19:34:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-01-2020 19:34:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-03-2020 17:26:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Sep-03-2020 17:26:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-03-2020 17:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-03-2020 01:58:43 (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-01-2020 19:34:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-01-2020 19:34:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: YES Date of Collection: Sep/1/2020	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001
 Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

5.a

Date	Location	User	Value	Reason
Sep-03-2020 17:26:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Sample ID: BPHVJ7	Transcription Error (DELETED)
Sep-03-2020 17:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Sample ID: BPHVJ7	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 17:26:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> BPHVJ7	Transcription Error (DELETED)
Sep-03-2020 17:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> BPHVJ7	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-03-2020 17:26:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Sample ID: BPHVJ8	Transcription Error (DELETED)
Sep-03-2020 17:10:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Sample ID: BPHVJ8	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 17:26:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> BPHVJ8	Transcription Error (DELETED)
Sep-03-2020 17:10:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> BPHVJ8	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-03-2020 17:26:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Sample ID: BP0XWJ	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001
Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03
Site No: 1223
Subject No: 12231058
Generated By: (b) (4)

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

5.c Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 17:26:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> BPOXWJ	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-03-2020 17:26:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Sample ID: BPOXWK	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 17:26:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> BPOXWK	Initial Entry

5.e

Date	Location	User	Value	Reason
Sep-03-2020 17:26:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Sample ID: BPOXWL	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 17:26:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> BPOXWL	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1223**Site Name:** (1223) Yale New Haven Medical Center**Subject No:** 12231058**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-01-2020 19:34:24 (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-01-2020 19:34:24 (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-03-2020 17:11:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-03-2020 01:59:08 (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-01-2020 19:34:24 (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-01-2020 19:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: YES Date of Collection: Sep/1/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-03-2020 17:11:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BPOXWH	Initial Entry

5.a Sample ID

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: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-03-2020 17:11:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BPOXWH	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1223

Subject No: 12231058

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-03-2020 15:08:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<u>Data Entry:</u> NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-03-2020 15:08:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-03-2020 15:08:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-03-2020 15:08:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<u>Data Entry:</u> Sep/1/2020 12:47	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-03-2020 15:08:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-03-2020 15:08:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<u>Data Entry:</u> LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
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090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1223

Subject No: 12231058

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

Sep-03-2020 15:08:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry
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10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-03-2020 15:08:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION 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-03-2020 15:08:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: YES	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1223

Subject No: 12231058

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

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I. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-02-2020 16:39:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT	New Information
Sep-01-2020 19:34:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJ ECT	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231058

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

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I. Date of Visit

Date	Location	User	Value	Reason
Sep-23-2020 16:28:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> Sep/23/2020	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES
- eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

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1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-29-2020 15:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-29-2020 15:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> <u>Symptom::</u> Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry FE VE R NO

2.a Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 15:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> FEVER	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-29-2020 15:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-29-2020 15:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> <u>Symptom::</u> Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry FAT IGU E NO

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES
- eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

2.b Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 15:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-29-2020 15:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-29-2020 15:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> Symptom:: HEA DAC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed? NO :	Initial Entry

2.c Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 15:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-29-2020 15:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-29-2020 15:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> Symptom:: CH ILL S	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
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2.d Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 15:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-29-2020 15:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Sep-29-2020 15:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> Symptom:: VO MITI NG Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 15:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-29-2020 15:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
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090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES
- eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

Sep-29-2020 15:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Symptom:: DIA RRH EA Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry
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2.f Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 15:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-29-2020 15:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-29-2020 15:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Symptom:: NEW OR WORSENE D MUSCLE PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 15:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NEW OR WORSENE D MUSCLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-29-2020 15:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES
- eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

2.h

Date	Location	User	Value	Reason
Sep-29-2020 15:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Symptom:: NEW OR WORSE ED JOINT PAIN Were fever or systemic s NO ymptoms present on the l ast day the Subject Diary was completed?:	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 15:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NEW OR WORSE NED JOINT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-29-2020 15:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-29-2020 15:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-29-2020 15:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-29-2020 15:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Injection Site Reaction:: RED NES	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES
- eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

			S	
			Were injection site reactions present on the last day the Subject Diary was completed?:	NO

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-29-2020 15:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-29-2020 15:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-29-2020 15:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> Injection Site Reaction:: SWELLING Were injection site reactions present on the last day the Subject Diary was completed?:	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-29-2020 15:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-29-2020 15:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
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090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES
- eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

Sep-29-2020 15:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Injection Site Reaction:: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry
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5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-29-2020 15:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-29-2020 15:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1223

Subject No: 12231058

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

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I. Date:

Date	Location	User	Value	Reason
Sep-23-2020 16:30:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sep/23/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-23-2020 16:30:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Record Identifier:: 1 Temperature: 98.7 Temperature Unit: F Temperature Location: FOREHEA :	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-23-2020 16:30:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-23-2020 16:30:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: 98.7	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-23-2020 16:30:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-23-2020 16:30:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: FOREHEAD	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - 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

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-23-2020 16:31:38 (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-23-2020 16:31:38 (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-23-2020 16:31:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sep/23/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-23-2020 16:31:38 (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-23-2020 16:31:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-23-2020 16:31:38 (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

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - 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

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-23-2020 16:31:38 (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-23-2020 16:31:38 (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-23-2020 16:31:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NOT DONE	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (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:** 12231058**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-23-2020 16:31:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-23-2020 16:31:54 (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-24-2020 11:23:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-24-2020 05:31:46 (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-23-2020 16:31:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-23-2020 16:31:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES Date of Collection: Sep/23/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-24-2020 11:23:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BPXXTG	Initial Entry

5.a Sample ID

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: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-24-2020 11:23:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> BPXXTG	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1223

Subject No: 12231058

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-23-2020 16:32:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-23-2020 16:32:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-23-2020 16:32:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-23-2020 16:32:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sep/23/2020 12:50	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-23-2020 16:32:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-23-2020 16:32:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
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090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1223

Subject No: 12231058

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

Sep-23-2020 16:32:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry
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10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-23-2020 16:32:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-23-2020 16:32:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231058

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

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I. Date of Visit

Date	Location	User	Value	Reason
Oct-22-2020 11:29:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Oct/22/2020	Initial Entry

Header Text: C4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES
- eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:52**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1223**Site Name:** (1223) Yale New Haven Medical Center**Subject No:** 12231058**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:30[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Oct-23-2020 16:29:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-23-2020 16:29:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Symptom:: FE VE R Were fever or systemic symptoms NO present on the last day the Subjec t Diary was completed?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Oct-23-2020 16:29:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: FEVER	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-23-2020 16:29:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Oct-28-2020 18:39:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Symptom:: FATIGUE	New Information

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES
- eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

			<p>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</p> <p>YES Ongoing ?</p> <p>NO</p> <p>Stop Date:</p> <p>Sep/ 29/2 020</p>	
<p>Oct-23-2020 16:29:39 (UTC-05:00) Eastern Time (US & Canada)</p>	ACV0PFEINFP6000	(b)(4),(b)(6)	<p>Data Entry:</p> <p>Symptom:: FAT IGU E</p> <p>Were fever or systemic symptoms present on the last day the Subject Diary was completed?: YE S</p>	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES
- eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

2.b Symptom:

Date	Location	User	Value	Reason
Oct-23-2020 16:29:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-29-2020 07:55:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Closed	Response satisfies query
Oct-28-2020 18:39:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Oct-28-2020 18:39:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES Ongoing? NO Stop Date: Sep/29/2020	New Information
Oct-26-2020 04:40:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Opened	DM: If yes, please update end date or ongoing details. Thank you.
Oct-23-2020 16:29:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: YES	Initial Entry

2.c

Date	Location	User	Value	Reason
Oct-23-2020 16:29:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Symptom:: HEA DAC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES
- eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

2.c Symptom:

Date	Location	User	Value	Reason
Oct-23-2020 16:29:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-23-2020 16:29:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Oct-23-2020 16:29:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Symptom:: CH ILL S Were fever or systemic symptom NO s present on the last day the Subj ect Diary was completed?:	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Oct-23-2020 16:29:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-23-2020 16:29:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Oct-23-2020 16:29:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Symptom:: VO MITI NG	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	NO
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2.e Symptom:

Date	Location	User	Value	Reason
Oct-23-2020 16:29:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<u>Data Entry:</u> VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-23-2020 16:29:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<u>Data Entry:</u> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Oct-23-2020 16:29:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<u>Data Entry:</u> <u>Symptom::</u> DIA RRH EA Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

2.f Symptom:

Date	Location	User	Value	Reason
Oct-23-2020 16:29:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<u>Data Entry:</u> DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-23-2020 16:29:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<u>Data Entry:</u> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Oct-23-2020 16:29:39	ACV0PFEINFP6000	(b) (6)	<u>Data Entry:</u>	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-05:00) Eastern Time (US & Canada)		(b) (4)	Symptom:: NEW OR WORSENE D MUSCL E PAIN Were fever or systemic sy NO mptoms present on the last day the Subject Diary was completed?:	
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2.g Symptom:

Date	Location	User	Value	Reason
Oct-23-2020 16:29:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: NEW OR WORSENE MUSCLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-23-2020 16:29:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Oct-23-2020 16:29:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Symptom:: NEW OR WORSENE ED JOINT PAIN Were fever or systemic sy NO mptoms present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

2.h Symptom:

Date	Location	User	Value	Reason
Oct-23-2020 16:29:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: NEW OR WORSENERD JOINT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-23-2020 16:29:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Oct-23-2020 16:29:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Oct-23-2020 16:29:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-23-2020 16:29:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Injection Site Reaction:: RED NES S Were injection site reactions pre NO sent on the last day the Subject Diary was completed?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-23-2020 16:29:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-23-2020 16:29:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-23-2020 16:29:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Injection Site Reaction:: SWE LLIN G Were injection site reactions pr NO esent on the last day the Subjec t Diary was completed?:	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-23-2020 16:29:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-23-2020 16:29:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-23-2020 16:29:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Injection Site Reaction:: PAIN AT INJECTI ON SITE Were injection site reaction NO s present on the last day the Subject Diary was complete d?:	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES
- eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-23-2020 16:29:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-23-2020 16:29:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: NO	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:** 12231058**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-22-2020 11:29:54 (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-22-2020 11:29:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-23-2020 10:44:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-23-2020 02:12:01 (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-22-2020 11:29:54 (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-22-2020 11:29:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: YES Date of Collection: Oct/22/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-23-2020 10:44:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BR37X4	Initial Entry

5.a Sample ID

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: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-23-2020 10:44:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BR37X4	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-23-2020 10:44:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BR37X5	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-23-2020 10:44:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BR37X5	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-23-2020 10:44:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BR37X6	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-23-2020 10:44:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BR37X6	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on
Feb/12/2021**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1223**Site Name:** (1223) Yale New Haven Medical Center**Subject No:** 12231058**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:30[Back to Form](#)**1. Date of Visit**

Date	Location	User	Value	Reason
Feb-15-2021 15:43:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-15-2021 15:41:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Feb-15-2021 15:40:15 (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-15-2021 15:40:15 (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-15-2021 15:40:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Feb/12/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Feb-15-2021 15:40:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on
Feb/12/2021**Form Version:** 14-Jan-2021 02:23**Site No:** 1223**Subject No:** 12231058**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit
Trail History**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](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Feb-15-2021 15:41:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Feb/12/2021	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Feb-18-2021 14:11:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Data Entry: Feb/3/2021	Changed Information
Feb-15-2021 15:41:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Feb/4/2021	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Mar-12-2021 08:54:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Closed	Response satisfies query
Mar-11-2021 16:52:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Query 1: Answered	Called subject today and symptoms are still ongoing.
Mar-11-2021 15:49:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Opened	Clin: As subject was recently vaccinated on 02Mar2021, please clarify whether the reported symptoms are still ongoing. If symptoms have ended, please update 'Symptoms Ongoing' to 'NO' and add Date of Last Symptom Resolved on the CRF.
Feb-15-2021 15:41:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES	Initial Entry

4.a

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/12/2021

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

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

Feb-15-2021 15:41:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry
Feb-15-2021 15:41:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Symptoms: FEVER Symptom Present:	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Feb-15-2021 15:41:33 (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
Feb-15-2021 15:41:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Feb-15-2021 15:41:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Present: NO	Initial Entry
Feb-15-2021 15:41:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Present:	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/12/2021

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

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

4.b Symptoms:

Date	Location	User	Value	Reason
Feb-15-2021 15:41:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Feb-15-2021 15:41:47 (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-15-2021 15:41:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Symptom NEW OR INCREASED S s: HORTNESS OF BREATH Symptom YES Present:	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Feb-15-2021 15:41:33 (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-15-2021 15:41:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES	Initial Entry

4.d

Date	Location	User	Value	Reason
Feb-15-2021 15:41:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/12/2021

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

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

4.d Symptoms:

Date	Location	User	Value	Reason
Feb-15-2021 15:41:33 (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-15-2021 15:41:33 (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-15-2021 15:41:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Symptoms: NEW OR INCREASED MUSCLE PAIN Symptom P NO resent:	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Feb-15-2021 15:41:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NEW OR INCREASED MUSCLE PAI N	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Feb-15-2021 15:41:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Feb-15-2021 15:41:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Symptoms: NEW LOSS OF TASTE OR SMELL Symptom Pr NO esent:	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/12/2021

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

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

4.f Symptoms:

Date	Location	User	Value	Reason
Feb-15-2021 15:41:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Feb-15-2021 15:41:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Feb-15-2021 15:41:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Symptoms: NEW OR INCREASED SORE THROAT Symptom P NO resent:	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Feb-15-2021 15:41:33 (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-15-2021 15:41:33 (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-15-2021 15:41:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Symptoms: DIARRHEA Symptom Present: NO	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on
Feb/12/2021**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit
Trail History**Form Version:** 14-Jan-2021 02:23**Form Status:** Data Complete, Frozen, Verified**Site No:** 1223**Site Name:** (1223) Yale New Haven Medical Center**Subject No:** 12231058**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:30**4.h Symptoms:**

Date	Location	User	Value	Reason
Feb-15-2021 15:41:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Feb-15-2021 15:41:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Feb-15-2021 15:41:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Symptoms: VOMITING Symptom Present: NO	Initial Entry

4.i Symptoms:

Date	Location	User	Value	Reason
Feb-15-2021 15:41:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Feb-15-2021 15:41:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-15-2021 15:42:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Symptoms - Other: swollen glands	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Feb-15-2021 15:42:05 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (6)	Data Entry: swollen glands	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/12/2021

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

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Feb-15-2021 15:42:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Symptoms - Other: swollen tonsils	Initial Entry

5.b Symptoms - Other Text:

Date	Location	User	Value	Reason
Feb-15-2021 15:42:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: swollen tonsils	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Feb/12/2021

Form: MICROBIOLOGY SPECIMEN - Audit Trail

Form Version: 06-Jul-2020 21:54

Form Status:

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Feb-15-2021 15:43:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Form Created	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/12/2021

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Feb-15-2021 15:43:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Feb/3/2021	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Feb-15-2021 15:43:25 (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-15-2021 15:43:25 (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-15-2021 15:43:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYNDROME C ORONAVIRUS 2	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Feb-15-2021 15:43:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC TEST	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Feb-15-2021 15:43:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: OTHER	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
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090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/12/2021

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

Feb-15-2021 15:43:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NEGATIVE	Initial Entry
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9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Feb-18-2021 00:35:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Closed	Response satisfies query
Feb-17-2021 15:29:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Feb-17-2021 15:29:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: CLIA CERTIFIED LAB	Changed Information
Feb-17-2021 03:18:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	Trade name Manufacturer name provided as "CVS PCR" does not uniquely match with the FDA List. Kindly update data as requested else please confirm and add text "CLIA certified lab", Thank you. (b) (4)
Feb-15-2021 15:43:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: CVS PCR	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on
Feb/12/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1223**Subject No:** 12231058**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF
Audit Trail History**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](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-15-2021 15:43:45 (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-15-2021 15:43:45 (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 10:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-17-2021 08:22:22 (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.
Feb-15-2021 15:43:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-15-2021 15:43:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES Date of Collection: Feb/4/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-17-2021 10:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Suzana Mutic (b) (4)	Data Entry: Sample ID: CV46666	Initial Entry

5.a Sample ID

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/12/2021

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

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

Form Status: Data Complete, 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
Feb-17-2021 10:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Suzana Mutic (b) (4)	<u>Data Entry:</u> CV46666	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/12/2021

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: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Feb-15-2021 15:44:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-15-2021 15:44:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-15-2021 15:44:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> 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-15-2021 15:44:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> subject did not come to site to swab	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/12/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

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I.a

Date	Location	User	Value	Reason
Feb-15-2021 15:44:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-15-2021 15:44:59 (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-15-2021 15:44:59 (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-15-2021 15:44:59 (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

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on
Feb/12/2021**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete, Frozen, Verified**Site No:** 1223**Site Name:** (1223) Yale New Haven Medical Center**Subject No:** 12231058**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:30***1.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Feb-15-2021 15:44:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: EMERGENCY ROOM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-15-2021 15:44:59 (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

1.c

Date	Location	User	Value	Reason
Feb-15-2021 15:44:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-15-2021 15:44:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-15-2021 15:44:59 (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

1.d

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/12/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

Feb-15-2021 15:44:59 (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
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1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-15-2021 15:44:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-15-2021 15:44:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Feb-15-2021 15:44:59 (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

1.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-15-2021 15:44:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-15-2021 15:44:59 (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-15-2021 15:45:09	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/12/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

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)	Type of Practitioner: OTHE R Occurrence of Visits or Cont acts: NO	
Feb-15-2021 15:44:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Type of Practitioner: OTHE R Occurrence of Visits or Cont acts:	Initial Entry

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-15-2021 15:44:59 (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-15-2021 15:45:09 (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-15-2021 15:44:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES Has the subject been in intensive care due to potential COVID-19 illness? NO	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/12/2021

Form: HOSPITALIZATION DETAILS - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Feb-15-2021 15:45:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Form Created	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/12/2021

Form: HOSPITALIZATION DETAILS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

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1. Hospitalization Category:

Date	Location	User	Value	Reason
Feb-15-2021 15:45:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: HOSPITALIZATION STATUS	Initial Entry

2. Hospitalization Term:

Date	Location	User	Value	Reason
Feb-15-2021 15:45:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: HOSPITAL	Initial Entry

3. Admission Date:

Date	Location	User	Value	Reason
Mar-05-2021 13:42:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Closed	Follow up with CRA offline.
Mar-05-2021 12:57:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Answered	hospital records are pending.
Mar-02-2021 14:54:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Reissued:Opened	CLIQUEY: As subject was confirmed hospitalized please enter any available information (vital signs, pulse oxymet, respiratory treatment, lab results, imaging...). Please make every effort to obtain these information.
Mar-02-2021 14:11:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Query 1: Answered	Yes she was hospitalized.
Feb-23-2021 15:08:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Reissued:Opened	CLIQUEY: Please confirm if subject was hospitalized due to COV ILL? if so please complete any of the assessment CRF's within this visit.

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/12/2021

Form: HOSPITALIZATION DETAILS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

Feb-23-2021 15:01:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Query 1: Answered	Original value is correct
Feb-16-2021 11:09:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Opened	CLIQUEY: Hospitalization: This subject had COVID-19 Illness and was hospitalized. Please enter any available information (vital signs, pulse oxymet, respiratory treatment, lab results, imaging...). Please make every effort to obtain these information.
Feb-15-2021 15:45:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Feb/9/2021	Initial Entry

4. Ongoing?

Date	Location	User	Value	Reason
Feb-15-2021 15:48:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO Discharge Date: Feb/12/2021	New Information
Feb-15-2021 15:45:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Feb/12/2021

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Feb-15-2021 15:47:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNESS	Initial Entry

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

Date	Location	User	Value	Reason
Feb-15-2021 15:47:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-15-2021 15:47:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: 3	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-22-2020 11:31:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Oct/22/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-22-2020 11:31:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-22-2020 11:31:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-23-2021 15:24:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Feb/12/2021	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Feb-23-2021 18:11:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-23-2021 15:25:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-23-2021 15:25:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6) [Redacted] [Redacted]	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per other protocol allowance (s) and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231058

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

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I. Date of Visit

Date	Location	User	Value	Reason
Mar-04-2021 15:36:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Mar/2/2021	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

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I. Consent Was:

Date	Location	User	Value	Reason
Mar-04-2021 15:36:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: OBTAINED Date Written Consent Obtained Mar/2/2021	Initial Entry

Header Text: C4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF
Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Mar-04-2021 15:36:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Mar/2/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-04-2021 15:36:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Mar-04-2021 15:36:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 20-Feb-2021 02:14

Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - 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

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1. Lab Panel:

Date	Location	User	Value	Reason
Mar-04-2021 15:37:31 (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
Mar-04-2021 15:37:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Mar-04-2021 15:37:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Mar/2/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Mar-04-2021 15:37:31 (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
Mar-04-2021 15:37:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Mar-04-2021 15:37:31 (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

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 20-Feb-2021 02:14

Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - 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

6.a Sponsor ID:

Date	Location	User	Value	Reason
Mar-04-2021 15:37:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Mar-04-2021 15:37:31 (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
Mar-04-2021 15:37:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NOT DONE	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001**Visit:** V101_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1223**Site Name:** (1223) Yale New Haven Medical Center**Subject No:** 12231058**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-04-2021 15:37:47 (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-04-2021 15:37:47 (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-05-2021 13:26:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-05-2021 05:17:43 (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.
Mar-04-2021 15:37:47 (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.
Mar-04-2021 15:37:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES Date of Collection: Mar/2/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-05-2021 13:26:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BR188L	Initial Entry

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Mar-05-2021 13:26:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BR188L	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-05-2021 13:27:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BR188M	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-05-2021 13:27:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BR188M	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-05-2021 13:27:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BR188N	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-05-2021 13:27:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BR188N	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001**Visit:** V101_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1223**Site Name:** (1223) Yale New Haven Medical Center**Subject No:** 12231058**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-04-2021 15:38:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-04-2021 15:38:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-05-2021 11:43:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-05-2021 05:17:43 (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.
Mar-04-2021 15:38:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-04-2021 15:38:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES Date of Collection: Mar/2/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-05-2021 11:43:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BR188K	Initial Entry

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Mar-05-2021 11:43:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> BR188K	Initial Entry

Header Text: C4591001**Visit:** V101_VAX3**Form Version:** 10-Dec-2020 02:26**Site No:** 1223**Subject No:** 12231058**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
Mar-04-2021 15:38:42 (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
Mar-04-2021 15:38:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Mar-04-2021 15:38:42 (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
Mar-04-2021 15:38:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Mar/2/2021 10:50	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Mar-04-2021 15:38:42 (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
Mar-04-2021 15:38:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1223

Subject No: 12231058

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

Mar-04-2021 15:38:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry
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8. Actual Dose:

Date	Location	User	Value	Reason
Mar-04-2021 15:38:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Mar-04-2021 15:38:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Mar-04-2021 15:38:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Mar-04-2021 15:38:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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I. Date of Visit

Date	Location	User	Value	Reason
Mar-23-2021 13:52:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> Mar/23/2021	Initial Entry

Header Text: C4591001

Visit: V102_VAX4

Form Version: 20-Feb-2021 02:14

Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Mar-23-2021 13:53:17 (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
Mar-23-2021 13:53:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Mar-23-2021 13:53:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Mar/23/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Mar-23-2021 13:53:17 (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
Mar-23-2021 13:53:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Mar-23-2021 13:53:17 (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

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 20-Feb-2021 02:14

Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

6.a Sponsor ID:

Date	Location	User	Value	Reason
Mar-23-2021 13:53:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Mar-23-2021 13:53:17 (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
Mar-23-2021 13:53:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NOT DONE	Initial Entry

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Header Text: C4591001**Visit:** V102_VAX4**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1223**Site Name:** (1223) Yale New Haven Medical Center**Subject No:** 12231058**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-23-2021 13:53:34 (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-23-2021 13:53:34 (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
Mar-24-2021 15:04:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-23-2021 13:53:34 (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.
Mar-23-2021 13:53:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES Date of Collection: Mar/23/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-24-2021 15:04:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Suzana Mutic (b) (4)	Data Entry: Sample ID: BRJ4FY	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-24-2021 15:04:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Suzana Mutic (b) (4)	Data Entry: BRJ4FY	Initial Entry

Header Text: C4591001**Visit:** V102_VAX4**Form Version:** 10-Dec-2020 02:26**Site No:** 1223**Subject No:** 12231058**Generated By:** (b) (4)**Form:** VACCINATION - eCRF Audit Trail History**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](#)**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Mar-23-2021 13:54:19 (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
Mar-23-2021 13:54:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Mar-23-2021 13:54:19 (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
Mar-23-2021 13:54:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Mar/23/2021 10:46	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Mar-23-2021 13:54:19 (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
Mar-23-2021 13:54:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

Mar-23-2021 13:54:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry
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8. Actual Dose:

Date	Location	User	Value	Reason
Mar-23-2021 13:54:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Mar-23-2021 13:54:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Mar-23-2021 13:54:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Mar-23-2021 13:54:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES	Initial Entry

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231058

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

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Date	Location	User	Value	Reason
Mar-05-2021 13:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231058

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

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Date	Location	User	Value	Reason
Mar-23-2021 13:55:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Form Created	

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231058

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

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Date	Location	User	Value	Reason
Mar-23-2021 13:58:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

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Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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1. Category:

Date	Location	User	Value	Reason
Mar-05-2021 13:22:12 (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
Mar-05-2021 13:22:12 (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
Mar-05-2021 13:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Data Entry: Shortness of breath	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-05-2021 13:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Data Entry: Feb/3/2021 00:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-10-2021 12:51:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Data Entry: NO End Date Time: Feb/12/2021 UNK:UNK	Changed Information
Mar-05-2021 13:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-05-2021 13:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Data Entry: 2	Initial Entry

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Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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
Mar-08-2021 00:13:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-05-2021 13:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Shortness of breath: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Mar-05-2021 13:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event 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.

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Header Text: C4591001

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Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

Date	Location	User	Value	Reason
Mar-05-2021 13:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-05-2021 13:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	<u>Data Entry:</u> NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: Unknown etiology	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-05-2021 13:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-05-2021 13:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	<u>Data Entry:</u> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-05-2021 13:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	<u>Data Entry:</u> YES	Initial Entry

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

Date	Location	User	Value	Reason
Mar-12-2021 10:35:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Clo sed	sdb updated

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Header Text: C4591001

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Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

Mar-11-2021 04:52:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Reissued: Candidate	Pending SDB update
Mar-10-2021 16:28:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_AE001_35
Mar-10-2021 12:52:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Query 1: Answered	Changed data per query
Mar-10-2021 12:50:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Query 2: Answered	yes it was sent.
Mar-10-2021 07:44:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Reissued: Opened	Since you confirmed that End date is 2/12/21, kindly update Item 5 for this AE and please complete the time as well. Thank you.
Mar-10-2021 05:15:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Reissued: Opened	SAE RECON: Please confirm if follow up SAE form was sent to update outcome in Safety database to RECOVERED/RESOLVED WITH SEQUELAE.
Mar-09-2021 13:56:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Query 1: Answered	Updated to resolved with sequelae, end date was 2/12/21, updated in SAE.
Mar-09-2021 13:51:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Query 2: Answered	Changed to Recovered with sequelae.

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Header Text: C4591001

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Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

Mar-08-2021 00:17:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Op ened	SAE RECON:AER#2021156172,outcome was reported as NOT RECOVERED/NOT RESOLVED to Safety DB however, recorded as RECOVERED/RESOLVED WITH SEQUELAE on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Mar-06-2021 00:16:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW7624646;Response to "What was the outcome of this adverse event?" is 'Recovered/Resolved' or 'Recovered/Resolved with Sequelae' but End Date/Time is missing. Please review and update as appropriate.
Mar-05-2021 13:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Data Entry : RECO VERE D/RE SOLV ED W ITH S EQUE LAE	Initial Entry

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

Date	Location	User	Value	Reason
Mar-05-2021 13:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Mar-08-2021 00:13:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: 2021156172	Initial Entry

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Header Text: C4591001

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Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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1. Category:

Date	Location	User	Value	Reason
Mar-23-2021 13:55:43 (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
Mar-23-2021 13:55:43 (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
Mar-23-2021 13:55:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: fatigue	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-23-2021 13:55:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Mar/3/2021 09:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-23-2021 13:55:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO End Date Time: Mar/4/2021 09:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-23-2021 13:55:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

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Header Text: C4591001

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Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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
Mar-23-2021 13:55:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Mar-23-2021 13:55:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-23-2021 13:55:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-23-2021 13:55:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-23-2021 13:55:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-23-2021 13:55:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

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

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Header Text: C4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

Date	Location	User	Value	Reason
Mar-23-2021 13:55:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Mar-23-2021 13:55:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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1. Category:

Date	Location	User	Value	Reason
Mar-23-2021 13:58:42 (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
Mar-23-2021 13:58:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-23-2021 13:58:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: injection site pain	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-23-2021 13:58:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Mar/2/2021 15:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-23-2021 13:58:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO End Date Time: Mar/4/2021 09:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-23-2021 13:58:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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
Mar-23-2021 13:58:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Mar-23-2021 13:58:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-23-2021 13:58:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-23-2021 13:58:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-23-2021 13:58:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-23-2021 13:58:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

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

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

Date	Location	User	Value	Reason
Mar-23-2021 13:58:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Mar-23-2021 13:58:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS -
Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Oct-22-2020 11:30:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - 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: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Oct-22-2020 11:30:57 (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
Oct-22-2020 11:30:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Oct-22-2020 11:30:57 (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
Oct-22-2020 11:30:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<u>Data Entry:</u> Influenza vaccine	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Oct-22-2020 11:30:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<u>Data Entry:</u> Oct/12/2020	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231058

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-23-2021 18:11:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Feb/12/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-23-2021 18:11:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: ASSESS ELIGIBILITY FOR ADDITI ONAL VACCINATION	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: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

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1. Subject Status

Date	Location	User	Value	Reason
Oct-22-2020 11:31:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-01-2020 19:33:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-01-2020 19:25:44 (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-08-2021 01:41:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Closed	Response satisfies query
Mar-05-2021 13:23:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Query 2: Answered	Changed data per query
Mar-03-2021 09:07:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Reissued:Opened	AER#2021156172 shortness of breath(onset date:04Feb2021)was reported as serious in Safety database but missing in AE CRF. Please confirm if event should be added as an SAE in AE CRF log.
Mar-01-2021 04:32:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Reissued:Candidate	Pending data entry
Feb-27-2021 13:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 2: Answered	Medical records are pending. Will update as soon as medical records are received.
Feb-19-2021 06:34:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Closed	Query closed as corresponding illness visit detail are present.
Feb-18-2021 14:13:02 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Query 1: Answered	Changed data per query

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

(US & Canada)				
Feb-18-2021 02:10:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Opened	SAE RECON:AER#2021156172 shortness of breath(onset date:04Feb2021)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
Feb-09-2021 02:29:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Opened	Illness eDiary: Subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 03FEB2021. But there is no COVID Illness visit reported in the database. Please clarify.
Oct-22-2020 11:31:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/22/2020	Initial Entry
Sep-01-2020 19:33:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/1/2020	Initial Entry
Sep-01-2020 19:25:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/1/2020	Initial Entry

090177e196ae3015\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231058

Subject Initials: ---

Generated By: (b) (4)

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

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I. Casebook Signature

Date	Location	User	Value	Reason
Oct-30-2020 14:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Click Here to Enable	Initial Entry