

Header Text: C4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

[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

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231024

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 Aug/28/2020
----	--------------	--

Header Text: C4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[12231024]
2.	Birth Date:	(b) (6) 1985
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231024

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	Aug/28/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1223

Subject No: 12231024

Generated By:

(b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

090177e196ae3016\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: 12231024

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	Aug/28/2020
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: 12231024

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

Form Comments

Medical History Details

1.	Line/MH Number:	Not Applicable _____ []
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	Not Applicable _____ []
	Start Date:	Not Applicable _____ //
	Ongoing:	Not Applicable _____

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/28/2020
2.	Weight:	[66.2]
3.	Unit:	kg
4.	Height:	[177.0]
5.	Unit:	cm
6.	Body Mass Index:	[21.1]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[98.1]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231024

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 :	Aug/28/2020
2.	Randomization Number:	[72425]
3.	Randomization Group:	[]

Header Text: C4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**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:** 12231024**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 13:30

(b) (4)

[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/28/2020
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	[BP0XPW]
5.b	Sample ID	[BP0XR0]
5.c	Sample ID	[BP0XR1]
5.d	Sample ID	[BPHVFZ]
5.e	Sample ID	[BPHVG0]

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/28/2020
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	[BP0XPZ]
-----	-----------	----------

090177e196ae3016\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: 12231024

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:	Aug/28/2020 15:09
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

090177e196ae3016\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: 12231024

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
----	---	--

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231024

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/18/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

[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

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY -
SYMPTOM RESOLVED DATES

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae3016\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: 12231024

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/18/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.5]
	Unit:	F
	Temperature Location:	FOREHEAD

Header Text: C4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/18/2020
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	[BPXXPS]
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090177e196ae3016\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: 12231024

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/18/2020 15:27
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

090177e196ae3016\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: 12231024 **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/19/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 21-Aug-2020 02:52 **Form Status:** Data Complete, Locked, Frozen, Verified

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

Subject No: 12231024 **Subject Initials:** ---

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

[Form Comments](#)
[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?	Not Done	Comments
2.a	Symptom:	FEVER	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done	Comments
2.b	Symptom:	FATIGUE	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done	Comments
2.c	Symptom:	HEADACHE	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done	Comments

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 21-Aug-2020 02:52 **Form Status:** Data Complete, Locked, Frozen, Verified

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

Subject No: 12231024 **Subject Initials:** ---

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

2.d	Symptom:	CHILLS	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done _____	Comments
2.e	Symptom:	VOMITING	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done _____	Comments
2.f	Symptom:	DIARRHEA	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done _____	Comments
2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done _____	Comments
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done _____	Comments

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 21-Aug-2020 02:52 **Form Status:** Data Complete, Locked, Frozen, Verified

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

Subject No: 12231024 **Subject Initials:** ---

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

3.	Injection Site Location:	Not Done _____	Comments
4.	Injection Site Body Side:	Not Done _____	Comments
5.a	Injection Site Reaction:	REDNESS	
	Were injection site reactions present on the last day the Subject Diary was completed?	Not Done _____	Comments
5.b	Injection Site Reaction:	SWELLING	
	Were injection site reactions present on the last day the Subject Diary was completed?	Not Done _____	Comments
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE	
	Were injection site reactions present on the last day the Subject Diary was completed?	Not Done _____	Comments

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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: 12231024 **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	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/19/2020
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	[BR37R1]
5.b	Sample ID	[BR37R2]
5.c	Sample ID	[BR37R3]

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231024

Generated By:

(b) (4)

Form: DATE OF VISIT - ILLNESS ONSET

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	Sep/29/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

Form Version: 15-Sep-2020 21:55

Site No: 1223

Subject No: 12231024

Generated By:

(b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

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](#)

Signs and Symptoms

1.	Date of Assessment:	Sep/29/2020
2.	Date of First Symptom Started:	Sep/28/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Oct/2/2020

Symptoms

4.a	Symptoms:	FEVER
	Was symptom present?	NO
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	NO
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	NO
4.d	Symptoms:	CHILLS
	Was symptom present?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	NO

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	YES
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	NO
Symptoms - Other		
5.a	Symptoms - Other Text:	[post nasal drip]

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

Microbiology Specimen

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

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231024

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

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_SELF
3.	Sample Collected?	YES Date of Collection: Sep/29/2020
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	[CV21094]
-----	-----------	-----------

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231024

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?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[PI did not feel the subject needed an in person visit.]

Aliquot

Please enter barcode for each aliquot.

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

Form: HEALTH CARE UTILIZATION

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Health Care Utilization

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

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

Form: HEALTH CARE UTILIZATION

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

Health Care Utilization Other

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

Health Care Utilization

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

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.						Repeating Pages

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Respiratory Treatment

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

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

[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:	1

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

#	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 Sep/29/2020

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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Illness Details

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

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

#	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 Sep/29/2020

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

[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

090177e196ae3016\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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

#	Category f or Lab Tes t	Vendor Nam e (DERIVED)	Collecti on Date :	Specim en Type	Lab Result			Form Instan ce
1.					Sponsor-Defi ned Identifie r	Te st:	Res ult:	Repeating Pages

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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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

090177e196ae3016\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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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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:	[]

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

#	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 Sep/29/2020

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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Oxygenation Parameters

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

090177e196ae3016\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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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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?	

090177e196ae3016\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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

#	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 Sep/29/2020

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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Imaging

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

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Dec/29/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_B
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Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

Form Version: 14-Jan-2021 02:23

Site No: 1223

Subject No: 12231024

Generated By:

(b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

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](#)

Signs and Symptoms

1.	Date of Assessment:	Dec/29/2020
2.	Date of First Symptom Started:	Dec/25/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Dec/26/2020

Symptoms

4.a	Symptoms:	FEVER
	Was symptom present?	NO
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	NO
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	NO
4.d	Symptoms:	CHILLS
	Was symptom present?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	NO

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Dec/29/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Microbiology Specimen

1.	Actual Date of Collection:	Dec/29/2020
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	OTHER
7.	Test Result:	NEGATIVE
8.	Comments/Findings /Details:	[]
9.	Trade Name Other, Specify:	[CLIA-Certified Lab]

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231024

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

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_SELF
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[SUBJECT WAS INSTRUCTED TO SEND A SELF SWAB BUT DID NOT DO SO]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231024

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?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[SUBJECT WENT TO A LOCAL TESTING CENTER]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

Form Version: 14-Jan-2021 02:24

Site No: 1223

Subject No: 12231024

Generated By:

(b) (4)

Form: HEALTH CARE UTILIZATION

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](#)

Health Care Utilization

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

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

Health Care Utilization Other

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

Health Care Utilization

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

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.						Repeating Pages

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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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?	

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

[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:	2

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Illness Details

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

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

#	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 2 -
Unscheduled Visit on Dec/29/2020

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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Lab Chemistry Details

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

Lab Result

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

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

#	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 2 -
Unscheduled Visit on Dec/29/2020

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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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

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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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:	[]

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

#	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 2 -
Unscheduled Visit on Dec/29/2020

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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Oxygenation Parameters

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

Header Text: C4591001

Visit: POT_COVID_ILL 2

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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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?	

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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Imaging

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

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

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

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Dec/4/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: C4591001

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

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231024

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPW1YV]
5.b	Sample ID	[BPW1YW]
5.c	Sample ID	[BPW1YX]

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 2 -
Unscheduled Visit on Jan/22/2021

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/22/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_B1
----	-------------------------	----------

Header Text: C4591001

Visit: POT_COVID_CONVA 2 -
Unscheduled Visit on Jan/22/2021

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231024

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

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	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/22/2021
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	[BPW95C]
5.b	Sample ID	[BPW95D]
5.c	Sample ID	[BPW95F]

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: Unplanned - New Unscheduled **Form:** DATE OF VISIT
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: 12231024 **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: 12231024 **Subject Initials:** ---

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

Unplanned Assessments

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

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

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: 12231024 **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/19/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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 **Form:** DATE OF VISIT - REPEAT SWAB
- New Unscheduled Visit

Form Version: 10-Oct-2020 15:57 **Form Status:** Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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:** 12231024**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 13:30

(b) (4)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: C4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

Vital Signs

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

Vital Signs Details

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

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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?	

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

Contact Outcome

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

Header Text: C4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: CONTACT OUTCOME - MONTH 6

Form Version: 10-Oct-2020 16:01

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

Contact Outcome

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

Header Text: C4591001

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

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/11/2021
2.	Erroneous Visit	

Header Text: C4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION
Unscheduled

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

[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: 12231024

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	Feb/17/2021
2.	Erroneous Visit	

Header Text: C4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER
VACCINATION

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Feb/17/2021
----	--------------	--

Header Text: C4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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
----	--	----------------

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation /Death :	Feb/17/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/17/2021
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	[BR184J]
5.b	Sample ID	[BR184K]
5.c	Sample ID	[BR184L]
5.d	Sample ID	[BRV2W2]
5.e	Sample ID	[BRV2W3]

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/17/2021
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	[BR184H]
-----	-----------	----------

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1223

Subject No: 12231024

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:	Feb/17/2021 15:30
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

090177e196ae3016\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: 12231024

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/10/2021
2.	Erroneous Visit	

Header Text: C4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Mar/10/2021
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	[BRJ4B7]
-----	-----------	----------

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1223

Subject No: 12231024

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/10/2021 14:14
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

090177e196ae3016\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: 12231024

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: 12231024

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: 12231024

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: 12231024

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: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231024

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: 12231024

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:
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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

Disposition - Treatment

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

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	scratcy throat	Sep/28/2020 UNK:UNK	NO End Date Time: Oct/2/2020 UNK: UNK	Repeating Pages
2.	ADVERSE EVENT	2	Exposure during pregnancy	Nov/7/2020 UNK:UNK	YES	Repeating Pages
3.	ADVERSE EVENT	3	injection site pain	Feb/17/2021 17:00	NO End Date Time: Feb/19/2021 09:00	Repeating Pages

090177e196ae3016\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, Locked, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[scratchy throat]
4.	Start Date Time:	Sep/28/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/2/2020 UNK:UNK
6.	Toxicity Grade:	1

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231024

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

7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [related to sick contacts]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae3016\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, Locked, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231024

Generated By:

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Form: ADVERSE EVENT REPORT

Form Status: Data Complete

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)	[Exposure during pregnancy]	
4.	Start Date Time:	Nov/7/2020 UNK:UNK	
5.	Is the adverse event still ongoing?	YES	
6.	Toxicity Grade:	1	Comments

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Header Text: C4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231024

Generated By:

(b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

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).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Wife became pregnant, not related to investigational product]

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Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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?:	UNKNOWN
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231024

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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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:	Feb/17/2021 17:00
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/19/2021 09:00
6.	Toxicity Grade:	1

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231024

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

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

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Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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

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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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

#	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: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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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	[]

090177e196ae3016\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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	influenza vaccine	Nov/19/2020	Repeating Pages

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

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: 12231024

Subject Initials: ---

Generated By:

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:	Nov/19/2020

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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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

#	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: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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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?	

090177e196ae3016\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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						Repeating Pages

Header Text: C4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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Radiation Treatment

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

090177e196ae3016\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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

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

Header Text: C4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Feb/11/2021
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: 12231024

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 :	//
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090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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: SUBJECT STATUS

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/19/2020

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

[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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Jessica Tuan	Approved	Mar-19-2021 16:46:04 (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.

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-28-2020 20:37:58 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231024

Generated By:

(b) (4)

Form: GENERAL MEDICAL HISTORY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-28-2020 20:38:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

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: 12231024 **Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Oct-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	vaccination diary not issued <hr/> Not Done

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

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: 12231024 **Subject Initials:** ---

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

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Item	Date	User	Comment
1	Oct-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	vaccination diary not issued <hr/> Not Done

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

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: 12231024 **Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
2.a	Oct-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	vaccination diary not issued <hr/> Not Done

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

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: 12231024 **Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
2.b	Oct-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	vaccination diary not issued <hr/> Not Done

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

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: 12231024 **Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
2.c	Oct-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	vaccination diary not issued <hr/> Not Done

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

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: 12231024 **Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
2.d	Oct-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	vaccination diary not issued <hr/> Not Done

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

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: 12231024 **Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
2.e	Oct-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	vaccination diary not issued <hr/> Not Done

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

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: 12231024 **Subject Initials:** ---

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

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Item	Date	User	Comment
2.f	Oct-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	vaccination diary not issued <hr/> Not Done

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

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: 12231024 **Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
2.g	Oct-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	vaccination diary not issued <hr/> Not Done

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

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: 12231024 **Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
2.h	Oct-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	vaccination diary not issued <hr/> Not Done

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

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: 12231024 **Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
3	Oct-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	vaccination diary not issued <hr/> Not Done

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

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: 12231024 **Subject Initials:** ---

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

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Item	Date	User	Comment
4	Oct-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	vaccination diary not issued <hr/> Not Done

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

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: 12231024 **Subject Initials:** ---

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

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Item	Date	User	Comment
5.a	Oct-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	vaccination diary not issued <hr/> Not Done

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

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: 12231024 **Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
5.b	Oct-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	vaccination diary not issued <hr/> Not Done

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

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: 12231024 **Subject Initials:** ---

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

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Item	Date	User	Comment
5.c	Oct-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	vaccination diary not issued <hr/> Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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Item	Date	User	Comment
Form	Oct-08-2020 13:43:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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Item	Date	User	Comment
1	Oct-08-2020 13:43:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Item	Date	User	Comment
2	Oct-08-2020 13:43:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Item	Date	User	Comment
3	Oct-08-2020 13:43:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Item	Date	User	Comment
4	Oct-08-2020 13:43:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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Item	Date	User	Comment
5	Oct-08-2020 13:43:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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Item	Date	User	Comment
6	Oct-08-2020 13:43:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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Item	Date	User	Comment
7	Oct-08-2020 13:43:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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Item	Date	User	Comment
8	Oct-08-2020 13:43:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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Item	Date	User	Comment
9	Oct-08-2020 13:43:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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Item	Date	User	Comment
Form	Feb-17-2021 16:36:39 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231024

Generated By:

(b) (4)

Form: ADVERSE EVENT REPORT - Comments

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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Item	Date	User	Comment
6	Feb-18-2021 14:24:33 (UTC-05:00) Eastern Time (US & Canada)	Jessica Tuan (b) (4)	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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Jessica Tuan	Approved	Mar-19-2021 16:46:04 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

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

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

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

(b) (6)	N/A	Jan-22-2021 15:42:14 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Jessica Tuan	Approved	Jan-21-2021 13:52:13 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae3016\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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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) [Redacted]	N/A	Dec-04-2020 15:14:06 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Onyema Ogbuagu	Approved	Oct-26-2020 19:11:09 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1223

Subject No: 12231024

Generated By:

(b) (4)

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Status: Data Complete, Signed, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

Affidavit:

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

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

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

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-28-2020 20:36:50 (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
Aug-28-2020 20:36:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORT S	Initial Entry

Header Text: C4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - 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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Consent Was:

Date	Location	User	Value	Reason
Aug-28-2020 20:37:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Aug/28/2020	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1223

Subject No: 12231024

Generated By:

(b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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1. Subject ID

Date	Location	User	Value	Reason
Aug-28-2020 20:36:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12231024	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-28-2020 20:36:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1985	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-28-2020 20:37:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
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090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

Aug-28-2020 20:37:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC O R LATINO(A) OR OF SPANISH ORIG IN	Initial Entry
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5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Aug-28-2020 20:37:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae3016\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: 12231024

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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1. Date of Visit

Date	Location	User	Value	Reason
Aug-28-2020 20:37:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/28/2020	Initial Entry

090177e196ae3016\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: 12231024

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
Aug-28-2020 20:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/28/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-28-2020 20:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-28-2020 20:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Date:

Date	Location	User	Value	Reason
Aug-28-2020 20:44:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/28/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-28-2020 20:44:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 66.2	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-28-2020 20:44:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Aug-28-2020 20:44:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 177.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-28-2020 20:44:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-28-2020 20:44:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 21.1	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-28-2020 20:44:08 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Id 1	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

Eastern Time (US & Canada)			entifier:: Temperat 98.1 ure: Temperat F ure Unit: Temperat ORAL ure Locati CAVIT on:: Y	
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7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-28-2020 20:44:08 (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
Aug-28-2020 20:44:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.1	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
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090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

Aug-28-2020 20:44:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry
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7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-28-2020 20:44:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3016\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: 12231024

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
Aug-28-2020 20:44:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/28/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-28-2020 20:44:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 72425	Initial Entry

090177e196ae3016\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: 12231024

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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. Data Origin

Date	Location	User	Value	Reason
Aug-28-2020 20:45:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-28-2020 20:45:00 (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-01-2020 15:18:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-31-2020 04:10:23	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is

090177e196ae3016\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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-28-2020 20:45:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-28-2020 20:45:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/28/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-01-2020 15:18:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPOXP D: W	Initial Entry

5.a Sample ID

090177e196ae3016\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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Sep-01-2020 15:18:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPOXPW	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-01-2020 15:18:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BPOXR D: 0	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-01-2020 15:18:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPOXR0	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-01-2020 15:19:08 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BPOXR	Initial Entry

090177e196ae3016\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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

Eastern Time (US & Canada)			D:	1	
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5.c Sample ID

Date	Location	User	Value	Reason
Sep-01-2020 15:19:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPOXR1	Initial Entry

5.d

Date	Location	User	Value	Reason
Mar-01-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Suzana Mutic (b) (4)	Data Entry: Sample ID BPHVF : Z	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Mar-01-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Suzana Mutic (b) (4)	Data Entry: BPHVZF	Initial Entry

5.e

090177e196ae3016\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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Mar-01-2021 11:48:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Suzana Mutic (b) (4)	Data Entry: Sample ID BPHVG : 0	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Mar-01-2021 11:48:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Suzana Mutic (b) (4)	Data Entry: BPHVG0	Initial Entry

090177e196ae3016\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: 12231024

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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. Data Origin

Date	Location	User	Value	Reason
Aug-28-2020 20:45:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-28-2020 20:45:19 (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-01-2020 14:36:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-31-2020 04:10:23	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is

090177e196ae3016\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: 12231024
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 13:30

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-28-2020 20:45:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-28-2020 20:45:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/28/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-01-2020 14:36:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BPOXP D: Z	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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Sep-01-2020 14:36:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPOXPZ	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1223

Subject No: 12231024

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
Aug-28-2020 20:45:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-28-2020 20:45:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-28-2020 20:45:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
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090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

Aug-28-2020 20:45:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/28/2020 15:09	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-28-2020 20:45:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-28-2020 20:45:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-28-2020 20:45:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-28-2020 20:45:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 20:45:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-09-2020 03:40:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Per site confirmation
Sep-02-2020 13:17:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Sep-02-2020 13:17:36 (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-02-2020 05:50:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	eDiary: REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT is 'No' however VAX 1 eDiary records are available for the

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

				subject. Please verify and update. Else, confirm in query response appropriately.
Aug-28-2020 20:47:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231024

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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1. Date of Visit

Date	Location	User	Value	Reason
Oct-26-2020 02:02:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Data updated per query
Oct-24-2020 11:46:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	covid illness visit in inform
Oct-01-2020 10:11:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	As per Illness edinary records, subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 29SEP2020. But there is no COVID Illness

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231024

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

				visit reported in the database. Please clarify.
Sep-18-2020 16:28:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/18/2020	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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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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 13:11:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-29-2020 13:11:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: F E V E R Were fever or s N ystemic sympto O ms present on t he last day the Subject Diary was completed ?:	Initial Entry

2.a Symptom:

090177e196ae3016\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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Sep-29-2020 13:11:50 (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
Sep-29-2020 13:11:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-29-2020 13:11:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI G U E	Initial Entry

090177e196ae3016\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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
--	--	--	---	--

2.b Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 13:11:50 (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
Sep-29-2020 13:11:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-29-2020	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

090177e196ae3016\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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

13:11:50 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	Symptom:: HE A D AC HE Were fever or N systemic symp O toms present o n the last day t he Subject Dia ry was comple ted?:
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2.c Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 13:11:50 (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
Sep-29-2020 13:11:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3016\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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

2.d

Date	Location	User	Value	Reason
Sep-29-2020 13:11:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Symptom:: C HI L L S</p> <p>Were fever or s N ystemic sympt O oms present on the last day the Subject Diary was completed ?:</p>	Initial Entry

090177e196ae3016\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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

2.d Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 13:11:50 (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
Sep-29-2020 13:11:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Sep-29-2020 13:11:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MI TI NG	Initial Entry

090177e196ae3016\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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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

Date	Location	User	Value	Reason
Sep-29-2020 13:11:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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 13:11:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Sep-29-2020	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

090177e196ae3016\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

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

13:11:50 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Symptom:: DI A RR HE A Were fever or systemic symp toms present o n the last day t he Subject Dia ry was comple ted?: N O
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2.f Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 13:11:50 (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 13:11:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3016\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
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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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

2.g

Date	Location	User	Value	Reason
Sep-29-2020 13:11:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR W ORSE NED MUS CLE P AIN Were fever or systemic symptoms present on t he last day the Subject Diary was c ompleted?: NO	Initial Entry

090177e196ae3016\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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

2.g Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 13:11:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSE NED MUSCLE PAI N	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 13:11:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Sep-29-2020 13:11:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WOR SENE D JOI NT P AIN	Initial Entry

090177e196ae3016\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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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

Date	Location	User	Value	Reason
Sep-29-2020 13:11:50 (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 13:11:50 (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
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090177e196ae3016\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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

Sep-29-2020 13:11:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry
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4. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-29-2020 13:11:50 (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 13:11:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site RE Reaction:: D N ES S Were injection N site reactions p O resent on the l<p>ast day the Su bject Diary wa s completed?:</p>	Initial Entry

090177e196ae3016\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
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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

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Generated By:

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

(b) (4)

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-29-2020 13:11:50 (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?

Date	Location	User	Value	Reason
Sep-29-2020 13:11:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-29-2020 13:11:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site SW Reaction:: EL LI NG	Initial Entry

090177e196ae3016\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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

			Were injection site reactions present on the last day the Subject Diary was completed?:	NO
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5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-29-2020 13:11:50 (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
Sep-29-2020 13:11:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-29-2020	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

090177e196ae3016\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
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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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

<p>13:11:50 (UTC-05:00) Eastern Time (US & Canada)</p>		<p>(b) (4), (b) (6)</p>	<p>Injection Site PAI Reaction: N A T IN JEC TIO N SI TE Were injections present on the last day the Subject Diary was completed?: NO</p>	
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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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-29-2020 13:11:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTI ON 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 13:11:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3016\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: 12231024

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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1. Date:

Date	Location	User	Value	Reason
Sep-18-2020 16:29:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/18/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-18-2020 16:29:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Temperature: 97.5 Temperature Unit: Temperature Location: HEAD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-18-2020 16:29:29 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

Eastern Time (US & Canada)				
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2.a Temperature:

Date	Location	User	Value	Reason
Sep-18-2020 16:29:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 97.5	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-18-2020 16:29:29 (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-18-2020 16:29:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry

090177e196ae3016\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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Data Origin

Date	Location	User	Value	Reason
Sep-18-2020 16:29:48 (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-18-2020 16:29:48 (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-21-2020 09:28:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-20-2020 02:58:56	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is

090177e196ae3016\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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-18-2020 16:29:48 (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-18-2020 16:29:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collectio n: Sep/18/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-21-2020 09:28:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BPXXP D: S	Initial Entry

5.a Sample ID

090177e196ae3016\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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Sep-21-2020 09:28:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPXXPS	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1223

Subject No: 12231024

Generated By:

(b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-18-2020 16:32:44 (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-18-2020 16:32:44 (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-18-2020 16:32:44 (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
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090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

Sep-18-2020 16:32:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/18/2020 15:27	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-18-2020 16:32:44 (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-18-2020 16:32:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-18-2020 16:32:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-18-2020 16:32:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N 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-18-2020 16:32:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

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

Subject No: 12231024 **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
Oct-19-2020 13:15:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/19/2020	Initial Entry

090177e196ae3016\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: 12231024 **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-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: N ot D on e Were fever or s N ystemic sympt ot oms present on D the last day the on Subject Diary e was completed ?:	Initial Entry

2.a Symptom:

090177e196ae3016\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: 12231024 Subject Initials: ---

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

Date	Location	User	Value	Reason
Oct-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	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-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.b

Date	Location	User	Value	Reason
Oct-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: N ot D on e	Initial Entry

090177e196ae3016\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: 12231024 Subject Initials: ---

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

(b) (4)

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

Date	Location	User	Value	Reason
Oct-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	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-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.c

Date	Location	User	Value	Reason
Oct-20-2020	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

090177e196ae3016\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: 12231024 Subject Initials: ---

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

(b) (4)

12:20:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Symptom:: N ot D on e Were fever or s N ystemic sympt ot oms present on D the last day the on Subject Diary e was completed ?:
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2.c Symptom:

Date	Location	User	Value	Reason
Oct-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	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-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3016\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: 12231024 **Subject Initials:** ---

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

(b) (4)

2.d

Date	Location	User	Value	Reason
Oct-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: N ot D on e Were fever or s N ystemic sympt ot oms present on D the last day the on Subject Diary e was completed ?:	Initial Entry

090177e196ae3016\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: 12231024 **Subject Initials:** ---

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

(b) (4)

2.d Symptom:

Date	Location	User	Value	Reason
Oct-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	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-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.e

Date	Location	User	Value	Reason
Oct-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: N ot D on e	Initial Entry

090177e196ae3016\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: 12231024 Subject Initials: ---

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

(b) (4)

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

Date	Location	User	Value	Reason
Oct-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	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-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

2.f

Date	Location	User	Value	Reason
Oct-20-2020	ACV0PFEINFP6000	(b) (6)	<u>Data Entry:</u>	Initial Entry

090177e196ae3016\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: 12231024 Subject Initials: ---

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

(b) (4)

12:20:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Symptom:: N ot D on e Were fever or s N ystemic sympt ot oms present on D the last day the on Subject Diary e was completed ?:
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2.f Symptom:

Date	Location	User	Value	Reason
Oct-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	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-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3016\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: 12231024 **Subject Initials:** ---

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

(b) (4)

2.g

Date	Location	User	Value	Reason
Oct-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Symptom:: N ot D on e</p> <p>Were fever or s N ystemic sympt ot oms present on D the last day the on Subject Diary e was completed ?:</p>	Initial Entry

090177e196ae3016\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: 12231024 **Subject Initials:** ---

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

(b) (4)

2.g Symptom:

Date	Location	User	Value	Reason
Oct-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	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-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.h

Date	Location	User	Value	Reason
Oct-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: N ot D on e	Initial Entry

090177e196ae3016\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: 12231024 Subject Initials: ---

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

(b) (4)

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

Date	Location	User	Value	Reason
Oct-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	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-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Oct-20-2020	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

090177e196ae3016\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: 12231024 **Subject Initials:** ---

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

(b) (4)

12:20:59 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	Not Done	
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4. Injection Site Body Side:

Date	Location	User	Value	Reason
Oct-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: N ot D on e Were injection site reactions present on the last day the Subject Diary was completed?: N ot D on e	Initial Entry

090177e196ae3016\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: 12231024 **Subject Initials:** ---

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

(b) (4)

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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

Date	Location	User	Value	Reason
Oct-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: N ot D on e	Initial Entry

090177e196ae3016\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: 12231024 Subject Initials: ---

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

(b) (4)

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

Date	Location	User	Value	Reason
Oct-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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

Date	Location	User	Value	Reason
Oct-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-20-2020 12:20:59	ACV0PFEINFP6000	(b) (6)	Data Entry: Injection Site N	Initial Entry

090177e196ae3016\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: 12231024 Subject Initials: ---

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

(UTC-05:00) Eastern Time (US & Canada)	(b) (4)	Reaction:: ot D on e Were injection N site reactions p resent on the l D ast day the Su on bject Diary wa e s completed?:
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5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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

Date	Location	User	Value	Reason
Oct-20-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

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

Subject No: 12231024 **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
Oct-19-2020 13:16:01 (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-19-2020 13:16:01 (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-20-2020 14:13:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-20-2020 09:45:16	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001
Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1223 **Site Name:** (1223) Yale New Haven Medical Center
Subject No: 12231024 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:30

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-19-2020 13:16:01 (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-19-2020 13:16:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/19/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-20-2020 14:13:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BR37R : 1	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: 12231024 **Subject Initials:** ---

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

Date	Location	User	Value	Reason
Oct-20-2020 14:13:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR37R1	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-20-2020 14:14:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BR37R : 2	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 14:14:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR37R2	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-20-2020 14:16:17 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BR37R	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

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

Subject No: 12231024 **Subject Initials:** ---

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

Eastern Time (US & Canada)			:	3	
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5.c Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 14:16:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR37R3	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

Form: DATE OF VISIT - ILLNESS ONSET - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-08-2020 13:32:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-08-2020 13:25:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Oct-08-2020 13:22:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Oct-08-2020 13:22:07 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

Form: DATE OF VISIT - ILLNESS ONSET - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

& Canada)				both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Oct-08-2020 13:22:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/29/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Oct-08-2020 13:22:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

Form Version: 15-Sep-2020 21:55

Site No: 1223

Subject No: 12231024

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

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1. Date of Assessment:

Date	Location	User	Value	Reason
Oct-08-2020 13:25:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/29/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Oct-08-2020 13:25:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/28/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Dec-07-2020 08:10:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-04-2020 14:57:26	ACV0PFEINFP6000	(b) (6)	Query 1: Answered	convalescent visit done

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

Form Version: 15-Sep-2020 21:55

Site No: 1223

Subject No: 12231024

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

(UTC-05:00) Eastern Time (US & Canada)		(b) (4)		04DEC2020. Data will be entered
Nov-30-2020 05:45:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued :Opened	DM: Please confirm whether or not convalescent visit has been scheduled. If yes please provide date the visit will occur or enter visit data if it has occurred.
Nov-16-2020 15:57:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued :Candidate	Convalescent Visit not done yet. Will schedule.
Nov-16-2020 13:32:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Convalescent Visit not done yet. Will schedule.
Nov-15-2020 10:27:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued :Opened	DM: Please confirm whether or not convalescent visit has been

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

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

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

				scheduled. If yes please provide date the visit will occur or enter visit data if it has occurred.
Nov-07-2020 11:09:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued :Candidate	keep in candidate state until visit is entered
Nov-06-2020 17:11:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	subject has not come in yet for convalescent visit. Will schedule
Nov-04-2020 22:01:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Subject has completed illness Visit and symptoms are resolved, however corresponding Convalescent Visit not yet initiated. Please review and update as appropriate. Thank you.

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

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

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

Oct-08-2020 17:01:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Sy mptom Resolved : Oct/2/2020	Transcription Error
Oct-08-2020 13:25:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Oct-08-2020 13:25:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEV ER Symptom Pr NO esent:	Initial Entry
Oct-08-2020 13:23:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEV ER Symptom Pr esent:	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
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090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

Form Version: 15-Sep-2020 21:55

Site No: 1223

Subject No: 12231024

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

Oct-08-2020 13:23:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry
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4.a Was symptom present?

Date	Location	User	Value	Reason
Oct-08-2020 13:25:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Oct-08-2020 13:25:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sympt NEW OR I oms: NCREASE D COUGH Sympt NO om Pr esent:	Initial Entry
Oct-08-2020 13:23:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sympt NEW OR I oms: NCREASE D COUGH	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

Form Version: 15-Sep-2020 21:55

Site No: 1223

Subject No: 12231024

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

			Symptom Present:	
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4.b Symptoms:

Date	Location	User	Value	Reason
Oct-08-2020 13:23:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Oct-08-2020 13:25:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Oct-08-2020 13:25:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

Form Version: 15-Sep-2020 21:55

Site No: 1223

Subject No: 12231024

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

			Symptom Present:	
Oct-08-2020 13:23:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom Present: NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Oct-08-2020 13:23:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Oct-08-2020 13:25:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

Form Version: 15-Sep-2020 21:55

Site No: 1223

Subject No: 12231024

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

4.d

Date	Location	User	Value	Reason
Oct-08-2020 13:25:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHIL LS Symptom P NO resent:	Initial Entry
Oct-08-2020 13:23:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHIL LS Symptom P resent:	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

Form Version: 15-Sep-2020 21:55

Site No: 1223

Subject No: 12231024

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

4.d Symptoms:

Date	Location	User	Value	Reason
Oct-08-2020 13:23:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Oct-08-2020 13:25:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Oct-08-2020 13:25:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symp NEW OR I toms: NCREASE D MUSCLE PAIN Symp NO tom P resent :	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

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

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

Oct-08-2020 13:23:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symp NEW OR I toms: NCREASE D MUSCLE PAIN Symp tom P resent :	Initial Entry
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4.e Symptoms:

Date	Location	User	Value	Reason
Oct-08-2020 13:23:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREAS ED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Oct-08-2020 13:25:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
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090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

Form Version: 15-Sep-2020 21:55

Site No: 1223

Subject No: 12231024

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

Oct-08-2020 13:25:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sympt NEW LOSS oms: OF TASTE OR SMELL Sympt NO om Pr esent:	Initial Entry
Oct-08-2020 13:23:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sympt NEW LOSS oms: OF TASTE OR SMELL Sympt om Pr esent:	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

Form Version: 15-Sep-2020 21:55

Site No: 1223

Subject No: 12231024

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

4.f Symptoms:

Date	Location	User	Value	Reason
Oct-08-2020 13:23:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TA STE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Oct-08-2020 13:25:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Oct-08-2020 13:23:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symp NEW OR I toms: NCREASE D SORE TH ROAT Symp YES tom P resent :	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

Form Version: 15-Sep-2020 21:55

Site No: 1223

Subject No: 12231024

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

4.g Symptoms:

Date	Location	User	Value	Reason
Oct-08-2020 13:23:52 (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
Oct-08-2020 13:23:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.h

Date	Location	User	Value	Reason
Oct-08-2020 13:25:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms DIARR : HEA Symptom NO Present:	Initial Entry
Oct-08-2020 13:23:52 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms DIARR : HEA	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

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

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

& Canada)			Symptom Present:	
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4.h Symptoms:

Date	Location	User	Value	Reason
Oct-08-2020 13:23:52 (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
Oct-08-2020 13:25:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Oct-08-2020 13:25:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms VOMI : TING Symptom NO Present:	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

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

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

Oct-08-2020 13:23:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms VOMI : TING Symptom Present:	Initial Entry
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4.i Symptoms:

Date	Location	User	Value	Reason
Oct-08-2020 13:23:52 (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
Oct-08-2020 13:25:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-08-2020 13:24:07 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms post na - Other: sal drip	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

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

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

& Canada)

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Oct-08-2020 13:24:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: post nasal drip	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

Form Version: 06-Jul-2020 21:54

Site No: 1223

Subject No: 12231024

Generated By:

(b) (4)

Form: MICROBIOLOGY SPECIMEN - 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. Actual Date of Collection:

Date	Location	User	Value	Reason
Oct-08-2020 13:43:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Oct-08-2020 13:43:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Oct-08-2020 13:43:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Assay Code and Description:

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Oct-08-2020 13:43:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Oct-08-2020 13:43:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Oct-08-2020 13:43:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Oct-08-2020 13:43:43 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

Eastern Time (US & Canada)				
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8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Oct-08-2020 13:43:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Oct-08-2020 13:43:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231024

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

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1. Data Origin

Date	Location	User	Value	Reason
Oct-08-2020 13:32:25 (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-08-2020 13:32:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-12-2020 13:44:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-09-2020 03:27:03	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1223**Subject No:** 12231024**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

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-08-2020 13:32:25 (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-08-2020 13:32:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection : Sep/29/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-12-2020 13:44:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I CV2109 D: 4	Initial Entry

5.a Sample ID

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231024

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
Oct-12-2020 13:44:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CV21094	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231024

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB - 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. Data Origin

Date	Location	User	Value	Reason
Oct-08-2020 13:27:00 (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-08-2020 13:27:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-08-2020 13:29:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-08-2020 13:27:00	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Sample Collected?' is

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001
Visit: POT_COVID_ILL 1 -
 Unscheduled Visit on Sep/29/2020
Form Version: 22-Apr-2020 21:03
Site No: 1223
Subject No: 12231024
Generated By:
 (b) (4)
Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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

(UTC-05:00) Eastern Time (US & Canada)				marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Oct-08-2020 13:27:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-08-2020 13:29:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PI did not feel the subject needed an in person visit.	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

Form Version: 15-Sep-2020 21:53

Site No: 1223

Subject No: 12231024

Generated By:

(b) (4)

Form: HEALTH CARE UTILIZATION - 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.a

Date	Location	User	Value	Reason
Oct-08-2020 13:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Prac SPEC itioner: IALI ST Occurrence NO of Visits or Contacts:	Initial Entry

1.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-08-2020 13:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

1.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-08-2020 13:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

1.b

Date	Location	User	Value	Reason
Oct-08-2020 13:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Pr EMER actitioner: GENC Y ROO M Occurenc NO e of Visits or Contac ts:	Initial Entry

1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-08-2020 13:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY RO OM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-08-2020 13:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

I.c

Date	Location	User	Value	Reason
Oct-08-2020 13:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of P PRIMAR ractition Y CARE er: PHYSIC IAN Occurre NO nce of Vi sits or C ontacts:	Initial Entry

I.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-08-2020 13:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE P HYSICIAN	Initial Entry

I.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-08-2020 13:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

1.d

Date	Location	User	Value	Reason
Oct-08-2020 13:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: URGE NT C ARE Occurrence of Visits or Contacts: NO	Initial Entry

1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-08-2020 13:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-08-2020 13:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.e

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Oct-08-2020 13:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of P TELEPH ractition ONE CO er: NSULTA TION Occurre NO nce of Vi sits or C ontacts:	Initial Entry

I.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-08-2020 13:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CON SULTATION	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-08-2020 13:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.f

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Oct-08-2020 13:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OT HE R Occurrence of Visits or Contacts: NO	Initial Entry

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-08-2020 13:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-08-2020 13:34:38 (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
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090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

Form Version: 15-Sep-2020 21:53

Site No: 1223

Subject No: 12231024

Generated By:

(b) (4)

Form: HEALTH CARE UTILIZATION - 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

Oct-08-2020 13:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/29/2020

Form Version: 06-Jul-2020 21:52

Site No: 1223

Subject No: 12231024

Generated By:

(b) (4)

Form: ILLNESS DETAILS - 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. Category of Clinical Event:

Date	Location	User	Value	Reason
Oct-08-2020 13:46:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID- 19 ILLNESS	Initial Entry

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

Date	Location	User	Value	Reason
Oct-08-2020 13:46:06 (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
Oct-08-2020 13:46:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231024

Generated By:

(b) (4)

Form: DATE OF VISIT - ILLNESS ONSET - 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 of Visit

Date	Location	User	Value	Reason
Jan-27-2021 02:07:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed as per comment on Swab, updated PD tracker for clinical review
Jan-26-2021 16:47:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Jan-21-2021 04:29:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	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.
Jan-20-2021 15:58:50 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/29/2020	Transcription Error

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

Form: DATE OF VISIT - ILLNESS ONSET - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

& Canada)				
Jan-20-2021 15:55:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Jan-20-2021 15:54:22 (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.
Jan-20-2021 15:54:22 (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.
Jan-20-2021 15:54:22	ACV0PFEINFP6000	(b) (6) [Redacted]	Data Entry: Dec/25/2020	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231024

Generated By:

(b) (4)

Form: DATE OF VISIT - ILLNESS ONSET - 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

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

(b) (4)

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Jan-20-2021 15:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_B	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

Form Version: 14-Jan-2021 02:23

Site No: 1223

Subject No: 12231024

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
Jan-20-2021 15:58:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-20-2021 15:55:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of assessment is not same as Date Visit. Please check and correct.
Jan-20-2021 15:55:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/29/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Jan-20-2021 15:55:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/25/2020	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Jan-20-2021 15:55:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved: Dec/26/2020	Initial Entry

4.a

Date	Location	User	Value	Reason
Jan-20-2021 15:55:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEV ER Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Jan-20-2021 15:55:37 (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
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090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

Form Version: 14-Jan-2021 02:23

Site No: 1223

Subject No: 12231024

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

Jan-20-2021 15:55:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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4.b

Date	Location	User	Value	Reason
Jan-20-2021 15:55:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sympt NEW OR I oms: NCREASE D COUGH Sympt NO om Pr esent:	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

Form Version: 14-Jan-2021 02:23

Site No: 1223

Subject No: 12231024

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

4.b Symptoms:

Date	Location	User	Value	Reason
Jan-20-2021 15:55:37 (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
Jan-20-2021 15:55:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Jan-20-2021 15:55:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: NO	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

Form Version: 14-Jan-2021 02:23

Site No: 1223

Subject No: 12231024

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

4.c Symptoms:

Date	Location	User	Value	Reason
Jan-20-2021 15:55:37 (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
Jan-20-2021 15:55:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Jan-20-2021 15:55:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

4.d Symptoms:

Date	Location	User	Value	Reason
Jan-20-2021 15:55:37 (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
Jan-20-2021 15:55:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Jan-20-2021 15:55:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symp NEW OR I toms: NCREASE D MUSCLE PAIN Symp NO tom P resent :	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

Form Version: 14-Jan-2021 02:23

Site No: 1223

Subject No: 12231024

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

4.e Symptoms:

Date	Location	User	Value	Reason
Jan-20-2021 15:55:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Jan-20-2021 15:55:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Jan-20-2021 15:55:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: NEW LOSS OF TASTE OR SMELL Symptom Present: NO	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

Form Version: 14-Jan-2021 02:23

Site No: 1223

Subject No: 12231024

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

4.f Symptoms:

Date	Location	User	Value	Reason
Jan-20-2021 15:55:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TA STE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Jan-20-2021 15:55:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Jan-20-2021 15:55:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symp NEW OR I toms: NCREASE D SORE TH ROAT Symp NO tom P resent :	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

4.g Symptoms:

Date	Location	User	Value	Reason
Jan-20-2021 15:55:37 (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
Jan-20-2021 15:55:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Jan-20-2021 15:55:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms DIARR : HEA Symptom Present: YES	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

4.h Symptoms:

Date	Location	User	Value	Reason
Jan-20-2021 15:55:37 (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
Jan-20-2021 15:55:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.i

Date	Location	User	Value	Reason
Jan-20-2021 15:55:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms VOMI : TING Symptom NO Present:	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

Form Version: 14-Jan-2021 02:23

Site No: 1223

Subject No: 12231024

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

4.i Symptoms:

Date	Location	User	Value	Reason
Jan-20-2021 15:55:37 (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
Jan-20-2021 15:55:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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Date	Location	User	Value	Reason
Jan-20-2021 16:03:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Jan-20-2021 16:03:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/29/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jan-20-2021 16:03:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWABBED MATER IAL	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Jan-20-2021 16:03:58 (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
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090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

Jan-20-2021 16:03:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RES P SYNDROME CORO NAVIRUS 2	Initial Entry
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5. Device Type:

Date	Location	User	Value	Reason
Jan-20-2021 16:03:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGN OSTIC TEST	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Jan-27-2021 10:24:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-27-2021 10:23:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Trade Name is Other, however Trade Name Other, Specify is not completed. Please update.

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

Jan-27-2021 10:23:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	New Information
Jan-20-2021 16:03:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ABBOTT MOLEC ULAR REALTIME SARS-COV-2 ASS AY	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Jan-20-2021 16:03:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Feb-04-2021 02:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-03-2021 13:15:55 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CLIA-Certified Lab	Transcription Error

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

Eastern Time (US & Canada)				
Feb-03-2021 13:13:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Answered	Changed data per query
Feb-03-2021 03:56:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Opened	DM: Manufacturer/test kit name provided does not uniquely match with the FDA List. Kindly update data as requested else please confirm and add text "CLIA-certified lab", Thank you.
Jan-27-2021 10:24:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: MAG MAX 96 THERMO FISHER	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231024

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

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1. Data Origin

Date	Location	User	Value	Reason
Jan-20-2021 16:05:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-20-2021 16:05:40 (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
Jan-20-2021 16:05:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231024

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
Jan-20-2021 16:05:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SUBJECT WAS INS TRUCTED TO SEN D A SELF SWAB B UT DID NOT DO S O	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231024

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB - 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. Data Origin

Date	Location	User	Value	Reason
Jan-26-2021 16:45:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-26-2021 16:45:38 (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
Jan-26-2021 16:45:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231024

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB - 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
Jan-26-2021 16:45:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SUBJECT WENT T O A LOCAL TESTI NG CENTER	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

Form Version: 14-Jan-2021 02:24

Site No: 1223

Subject No: 12231024

Generated By:

(b) (4)

Form: HEALTH CARE UTILIZATION - 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.a

Date	Location	User	Value	Reason
Jan-26-2021 16:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Prac SPEC itioner: IALI ST Occurrence NO of Visits or Contacts:	Initial Entry

1.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-26-2021 16:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

1.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-26-2021 16:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

1.b

Date	Location	User	Value	Reason
Jan-26-2021 16:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Pr EMER actitioner: GENC Y ROO M Occurenc NO e of Visits or Contac ts:	Initial Entry

1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-26-2021 16:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY RO OM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-26-2021 16:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

I.c

Date	Location	User	Value	Reason
Jan-26-2021 16:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of P PRIMAR ractition Y CARE er: PHYSIC IAN Occurre NO nce of Vi sits or C ontacts:	Initial Entry

I.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-26-2021 16:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE P HYSICIAN	Initial Entry

I.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-26-2021 16:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

1.d

Date	Location	User	Value	Reason
Jan-26-2021 16:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: URGE NT C ARE Occurrence of Visits or Contacts: NO	Initial Entry

1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-26-2021 16:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-26-2021 16:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.e

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Jan-26-2021 16:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of P TELEPH ractition ONE CO er: NSULTA TION Occurre NO nce of Vi sits or C ontacts:	Initial Entry

I.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-26-2021 16:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CON SULTATION	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-26-2021 16:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.f

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

Form Version: 14-Jan-2021 02:24

Site No: 1223

Subject No: 12231024

Generated By:

(b) (4)

Form: HEALTH CARE UTILIZATION - 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
Jan-26-2021 16:46:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OT HE R Occurrence of Visits or Cont acts: NO	Initial Entry
Jan-26-2021 16:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OT HE R Occurrence of Visits or Cont acts:	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-26-2021 16:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-26-2021 16:46:05 (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
Jan-26-2021 16:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

Form Version: 06-Jul-2020 21:52

Site No: 1223

Subject No: 12231024

Generated By:

(b) (4)

Form: ILLNESS DETAILS - 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. Category of Clinical Event:

Date	Location	User	Value	Reason
Jan-26-2021 16:46:19 (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
Jan-27-2021 08:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-26-2021 16:46:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Jan-26-2021 16:46:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Dec/29/2020

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

Jan-25-2021 08:02:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLIQUEY: Please complete the required CRF.
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3. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-26-2021 16:46:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

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

Form Version: 22-Apr-2020 21:04

Site No: 1223

Subject No: 12231024

Generated By:

(b) (4)

Form: DATE OF VISIT - ILLNESS CONVALESCENT -
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 of Visit

Date	Location	User	Value	Reason
Dec-04-2020 15:14:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/4/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Dec-04-2020 15:14:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID_A1	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

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

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231024

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - 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. Data Origin

Date	Location	User	Value	Reason
Dec-04-2020 15:14:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-04-2020 15:14:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-07-2020 14:15:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-07-2020 00:07:50	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	'Sample Collected?' is

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

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

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-04-2020 15:14:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-04-2020 15:14:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collectio n: Dec/4/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-07-2020 14:15:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Suzana Mutic (b) (4)	Data Entry: Sample ID BPW1Y : V	Initial Entry

5.a Sample ID

Header Text: C4591001

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

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231024

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - 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
Dec-07-2020 14:15:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Suzana Mutic (b) (4)	Data Entry: BPW1YV	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-07-2020 14:15:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Suzana Mutic (b) (4)	Data Entry: Sample I BPW1Y D: W	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-07-2020 14:15:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Suzana Mutic (b) (4)	Data Entry: BPW1YW	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-07-2020 14:15:58 (UTC-05:00)	ACV0PFEINFP6000	Suzana Mutic (b) (4)	Data Entry: Sample ID BPW1Y	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

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

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231024

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - 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

Eastern Time (US
& Canada)

: X

5.c Sample ID

Date	Location	User	Value	Reason
Dec-07-2020 14:15:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Suzana Mutic (b) (4)	Data Entry: BPW1YX	Initial Entry

Header Text: C4591001

Visit: POT_COVID_CONVA 2 -
Unscheduled Visit on Jan/22/2021

Form Version: 22-Apr-2020 21:04

Site No: 1223

Subject No: 12231024

Generated By:

(b) (4)

Form: DATE OF VISIT - ILLNESS CONVALESCENT -
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 of Visit

Date	Location	User	Value	Reason
Jan-22-2021 15:42:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/22/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Jan-22-2021 15:42:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID_B1	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 2 -
Unscheduled Visit on Jan/22/2021

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231024

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - 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. Data Origin

Date	Location	User	Value	Reason
Jan-22-2021 15:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-22-2021 15:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-27-2021 15:10:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-25-2021 07:39:20	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001**Visit:** POT_COVID_CONVA 2 -
Unscheduled Visit on Jan/22/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1223**Subject No:** 12231024**Generated By:**

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - 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

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-22-2021 15:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-22-2021 15:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collectio n: Jan/22/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-27-2021 15:11:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BPW95 D: C	Transcription Error
Jan-27-2021 15:10:54	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

Header Text: C4591001

Visit: POT_COVID_CONVA 2 -
Unscheduled Visit on Jan/22/2021

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231024

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - 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

(UTC-05:00) Eastern Time (US & Canada)		(b) (4)	Sample ID: BPW95 C8	
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5.a Sample ID

Date	Location	User	Value	Reason
Jan-27-2021 15:11:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-27-2021 15:11:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPW95C	Transcription Error
Jan-27-2021 15:10:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Barcode is not 6 characters in length. Please review and correct as appropriate.
Jan-27-2021 15:10:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPW95C8	Initial Entry

5.b

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 2 -
Unscheduled Visit on Jan/22/2021

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231024

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - 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
Jan-27-2021 15:11:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BPW95 D: D	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-27-2021 15:11:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPW95D	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-27-2021 15:12:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BPW95 D: F	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 2 -
Unscheduled Visit on Jan/22/2021

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231024

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - 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

5.c Sample ID

Date	Location	User	Value	Reason
Jan-27-2021 15:12:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPW95F	Initial Entry

Header Text: C4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

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

Subject No: 12231024 **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-19-2020 13:16:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/19/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-19-2020 13:16:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-19-2020 13:16:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT - eCRF Audit Trail History
Unscheduled

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-17-2021 16:35:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/11/2021	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled 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: 12231024 **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-17-2021 16:35:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-17-2021 16:35:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidat e	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-17-2021 16:35:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willi ng to return for Va ccination 3 Participant is: eligible per oth er protocol allo wance(s) and c	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled 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: 12231024 **Subject Initials:** ---

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

(b) (4)

			onfirmed to ha ve received onl y placebo at Va ccination 1/2	
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Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231024

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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1. Date of Visit

Date	Location	User	Value	Reason
Feb-17-2021 16:36:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/17/2021	Initial Entry

090177e196ae3016\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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Consent Was:

Date	Location	User	Value	Reason
Feb-17-2021 16:36:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Feb/17/2021	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Feb-18-2021 15:10:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rivkah Rosen (b) (4)	Query 1: Closed	Response satisfies query
Feb-18-2021 08:44:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-18-2021 08:44:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/17/2021	Transcription Error
Feb-18-2021 03:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	Date is reported as 11Feb2021, but subject received vaccination on 17Feb2021. Please confirm the date is correct as

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

				entered or update if necessary. Otherwise clarify. Thank you.
Feb-17-2021 16:36:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/11/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-17-2021 16:36:59 (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
Feb-17-2021 16:36:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3016\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: 12231024

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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. Data Origin

Date	Location	User	Value	Reason
Feb-17-2021 16:37:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-17-2021 16:37:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-22-2021 12:19:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-19-2021 06:19:45	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is

090177e196ae3016\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:** 12231024**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 13:30

(b) (4)

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-17-2021 16:37:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-17-2021 16:37:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collectio n: Feb/17/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-22-2021 12:19:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BR184 : J	Initial Entry

5.a Sample ID

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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Feb-22-2021 12:19:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR184J	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-22-2021 12:19:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BR184 : K	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-22-2021 12:19:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR184K	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-22-2021 12:20:07 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BR184	Initial Entry

090177e196ae3016\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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

Eastern Time (US & Canada)			:	L	
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5.c Sample ID

Date	Location	User	Value	Reason
Feb-22-2021 12:20:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR184L	Initial Entry

5.d

Date	Location	User	Value	Reason
Feb-22-2021 12:20:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BRV2W D: 2	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Feb-22-2021 12:20:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRV2W2	Initial Entry

5.e

090177e196ae3016\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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Feb-22-2021 12:21:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BRV2W D: 3	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Feb-22-2021 12:21:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRV2W3	Initial Entry

090177e196ae3016\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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Data Origin

Date	Location	User	Value	Reason
Feb-17-2021 16:37:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-17-2021 16:37:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-22-2021 12:18:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-19-2021 06:19:45	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is

090177e196ae3016\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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-17-2021 16:37:38 (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-17-2021 16:37:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collectio n: Feb/17/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-22-2021 12:18:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BR184 : H	Initial Entry

5.a Sample ID

090177e196ae3016\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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Feb-22-2021 12:18:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR184H	Initial Entry

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1223

Subject No: 12231024

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
Feb-17-2021 16:39:35 (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
Feb-17-2021 16:39:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-17-2021 16:39:35 (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
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090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

Feb-17-2021 16:39:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/17/2021 15:30	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-17-2021 16:39:35 (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
Feb-17-2021 16:39:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Feb-17-2021 16:39:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-17-2021 16:39:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-17-2021 16:39:35 (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
Feb-17-2021 16:39:35 (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
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090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1223

Subject No: 12231024

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

Feb-17-2021 16:39:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry
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Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231024

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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1. Date of Visit

Date	Location	User	Value	Reason
Mar-10-2021 16:09:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/10/2021	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Data Origin

Date	Location	User	Value	Reason
Mar-10-2021 16:09:37 (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-10-2021 16:09:37 (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-11-2021 14:10:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-11-2021 05:21:16	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001
Visit: V102_VAX4
Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1223
Site Name: (1223) Yale New Haven Medical Center
Subject No: 12231024
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 13:30

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-10-2021 16:09:37 (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-10-2021 16:09:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/10/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-11-2021 14:10:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BRJ4B : 7	Initial Entry

5.a Sample ID

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, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

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Generated By:

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(b) (4)

Date	Location	User	Value	Reason
Mar-11-2021 14:10:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: BRJ4B7	Initial Entry

Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1223

Subject No: 12231024

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
Mar-10-2021 16:11:01 (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-10-2021 16:11:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Mar-10-2021 16:11:01 (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
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090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

Mar-10-2021 16:11:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/10/2021 14:14	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Mar-10-2021 16:11:01 (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-10-2021 16:11:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Mar-10-2021 16:11:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

8. Actual Dose:

Date	Location	User	Value	Reason
Mar-10-2021 16:11:01 (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-10-2021 16:11:01 (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-10-2021 16:11:01 (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
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Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1223

Subject No: 12231024

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: ---

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Mar-10-2021 16:11:01 (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

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Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1223

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Subject Initials: ---

Generated By:

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(b) (4)

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Date	Location	User	Value	Reason
Oct-19-2020 13:21:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

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Subject Initials: ---

Generated By:

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(b) (4)

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Date	Location	User	Value	Reason
Feb-18-2021 14:23:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

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Form Status:

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

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Subject Initials: ---

Generated By:

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(b) (4)

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Date	Location	User	Value	Reason
Mar-10-2021 16:55:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

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Form Status: Data Complete, Locked, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

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Subject Initials: ---

Generated By:

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(b) (4)

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1. Category:

Date	Location	User	Value	Reason
Oct-19-2020 13:21:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-19-2020 13:21:08 (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
Oct-20-2020 13:16:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Clin: issued in error as Covid Visit was completed
Oct-20-2020 13:13:01	ACV0PFEINFP6000	(b) (6)	Query 1: Opened	ClinQuery: Per protocol

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Site No: 1223
Site Name: (1223) Yale New Haven Medical Center
Subject No: 12231024
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 13:30

(UTC-05:00) Eastern Time (US & Canada)		(b) (4)		section 8.1., COVID-19 listed symptom scratchy THROAT, should have please triggered a COVID Illness Visit irrespective of perceived etiology or clinical significance. Please complete the COVID Illness CRF forms.
Oct-19-2020 13:21:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: scratcy throat	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-19-2020 13:21:08 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/28/2020 UNK: UNK	Initial Entry

Header Text: C4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Locked, Frozen**Site No:** 1223**Site Name:** (1223) Yale New Haven Medical Center**Subject No:** 12231024**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 13:30

(b) (4)

Eastern Time (US
& Canada)**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Oct-19-2020 13:21:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/2/2020 UNK :UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-19-2020 13:21:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?**If Yes, NOTIFY PFIZER IMMEDIATELY.**

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

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Generated By:

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

(b) (4)

Oct-19-2020 13:21:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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8. Is this adverse event the result of a study Medication Error?

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

Date	Location	User	Value	Reason
Oct-19-2020 13:21:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-25-2020 06:54:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-24-2020 11:43:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Oct-24-2020 11:43:38	ACV0PFEINFP6000	(b) (6)	Data Entry: NOT RELATED	New Information

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Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen

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Subject Initials: ---

Generated By:

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(b) (4)

(UTC-05:00) Eastern Time (US & Canada)		(b) (4)	If Not Related to study treatment(s) , this event is due to: OTHER <i>If Other, specif y:</i> related to sic k contacts	
Oct-21-2020 05:09:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: If other is selected then please complete specify field. Thank you.
Oct-19-2020 13:21:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s) , this event is due to: OTHER	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-19-2020	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

Header Text: C4591001

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Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

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Generated By:

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(b) (4)

13:21:08 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	NOT APPLICABLE	
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-19-2020 13:21:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-19-2020 13:21:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-19-2020 13:21:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen

Site No: 1223

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Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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

Date	Location	User	Value	Reason
Oct-19-2020 13:21:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete

Site No: 1223

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Generated By:

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1. Category:

Date	Location	User	Value	Reason
Feb-18-2021 14:23:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-18-2021 14:23:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-19-2021 05:00:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Cl osed	update query text

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Header Text: C4591001

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Generated By:

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(b) (4)

Feb-19-2021 03:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2021036854, the term in safety database was recorded as 'pregnancy'. Per 3 Nov EDP guidance, term should be recorded as Exposure during pregnancy. Please confirm and submit a follow up AEM form to update term in SDB.
Feb-18-2021 14:23:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Data Entry : Exposure during pregnancy	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-10-2021 11:18:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Response satisfies query
Mar-09-2021 13:50:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Query 1: Answered	Yes SAE already updated in safety database.

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Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

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Subject Initials: ---

Generated By:

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(b) (4)

Mar-08-2021 05:24:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Per query response changed data per query. Please confirm if follow up SAE form was sent to update onset date in Safety database
Mar-04-2021 16:51:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Mar-04-2021 06:00:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Per latest SDAE listing onset date is still recorded as 21nOV2020. If correct onset date is 07Nov2020. Please submit a follow up SAE form to update onset date in Safety database
Feb-27-2021 12:07:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	determined by ultrasound
Feb-25-2021	ACV0PFEINFP6000	Giselle	Query 1: Reissue	was the date

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Header Text: C4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete**Site No:** 1223**Site Name:** (1223) Yale New Haven Medical Center**Subject No:** 12231024**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 13:30

(b) (4)

18:59:59 (UTC-05:00) Eastern Time (US & Canada)		Castillo (b) (4)	d:Opened	determined by ultrasound or date of last menstrual period?
Feb-23-2021 14:45:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Query 1: Answered	Original value is correct
Feb-22-2021 12:32:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	As per V12 CRF CG 8.50.2.5, Date of onset is determined by ultrasound results or date of last menstrual period. Please revise/update accordingly. Thank you
Feb-18-2021 14:23:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Data Entry: Nov/7/2020 UN K:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-18-2021 14:23:23	ACV0PFEINFP6000	Jessica Tuan	Data Entry: YES	Initial Entry

Header Text: C4591001

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Form Status: Data Complete

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Generated By:

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

(b) (4)

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

(b) (4)

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-18-2021 14:23:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Feb-21-2021 08:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Feb-19-2021 15:45:20	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Changed Information

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

(UTC-05:00) Eastern Time (US & Canada)			d	
Feb-19-2021 15:45:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Data Entry: NO	Changed Information
Feb-19-2021 05:00:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	SAE RECON: AER#2021036870,'EXPOSURE DURING PREGNANCY' event was appropriately reported to safety; however, seriousness criteria is met there is an abnormal pregnancy outcome/protocol section 8.3.5.1. Please update seriousness criteria accordingly.
Feb-19-2021 04:59:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	update query text
Feb-19-2021 03:43:34 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON: AER#2021036854,'EXPOSURE DURING PREGNANCY' event was appropriately reported to

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

(US & Canada)				safety; however, seriousness criteria is met there is an abnormal pregnancy outcome/protocol section 8.3.5.1. Please update seriousness criteria accordingly.
Feb-19-2021 03:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query can be addressed internally
Feb-18-2021 14:23:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Exposure during pregnancy: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-18-2021 14:23:23 (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?	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

NO

Did this serious event result in death?

NO

Did this serious event require or prolong hospitalization?

NO

Did this serious event result in persistent or significant disability/incapac

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Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

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Subject Initials: ---

Generated By:

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

(b) (4)

			ity?	
			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.

Date	Location	User	Value	Reason
Feb-18-2021 14:23:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Feb-18-2021 14:23:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Data Entry: NOT RELATED If Not Related to stud y treatment(s), this ev ent is due to: OTHER <i>If Other, specify:</i> Wife became pre gnant, not related to investigational product	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-18-2021 14:23:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-18-2021 14:23:23 (UTC-05:00)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Data Entry: NO	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

Eastern Time (US & Canada)

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-18-2021 14:23:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-19-2021 00:24:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-18-2021 14:25:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Query 1: Answered	Original value is correct
Feb-18-2021 14:23:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Exposure during pregnancy: Response to "What was

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Header Text: C4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete**Site No:** 1223**Site Name:** (1223) Yale New Haven Medical Center**Subject No:** 12231024**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 13:30

(b) (4)

				the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Feb-18-2021 14:23:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Data Entry: UNKNOWN	Initial Entry

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

Date	Location	User	Value	Reason
Feb-18-2021 14:23:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Data Entry: NO	Initial Entry

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Category:

Date	Location	User	Value	Reason
Mar-10-2021 16:55:23 (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-10-2021 16:55:23 (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-10-2021 16:55:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: injection site pain	Initial Entry

4. Start Date Time:

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Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Mar-10-2021 16:55:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/17/2021 17:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-10-2021 16:55:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Feb/19/2021 09:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-10-2021 16:55:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization;

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Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1223

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Subject Initials: ---

Generated By:

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(b) (4)

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-10-2021 16:55:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Mar-10-2021 16:55:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-10-2021 16:55:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

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Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Mar-10-2021 16:55:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-10-2021 16:55:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-10-2021 16:55:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Mar-10-2021 16:55:23 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

Eastern Time (US & Canada)

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

Date	Location	User	Value	Reason
Mar-10-2021 16:55:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3016\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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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Date	Location	User	Value	Reason
Dec-04-2020 15:17:55 (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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Dec-04-2020 15:17:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Dec-04-2020 15:17:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Dec-04-2020 15:17:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic

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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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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
Dec-04-2020 15:17:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: influenza vaccine	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Dec-04-2020 15:18:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/19/2020	Transcription Error
Dec-04-2020 15:17:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/19/2020	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - 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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-17-2021 16:35:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/11/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-17-2021 16:35:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBIL ITY FOR ADDITIO NAL VACCINATIO N	Initial Entry

090177e196ae3016\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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Subject Status

Date	Location	User	Value	Reason
Jan-22-2021 17:26:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Response satisfies query
Jan-19-2021 16:13:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	that was reported in error. The SAE report has been corrected and re faxed.
Jan-19-2021 10:26:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	CLINICAL_ An SAE of Hypertensive urgency was reported to safety. Please revise an update AE log accordingly. Thank you.
Oct-19-2020 13:16:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry

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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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

Aug-28-2020 20:44:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RAN DOMIZED	Initial Entry
Aug-28-2020 20:38:21 (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
Feb-19-2021 03:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-18-2021 14:25:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Query 2: Answered	Changed data per query
Feb-17-2021 20:14:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2021036870 Non serious AE of WIFE BECAME PREGNANT was reported in Safety database but missing in AE

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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: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

				CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Jan-21-2021 03:52:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Added data per query
Jan-20-2021 16:09:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Dec-29-2020 07:48:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Illness eduary: As per Illness eduary records, subject reported "Yes" for the COVID-19 symptoms or diagnosis on 25DEC2020. But no corresponding COVID Illness visit indicate symptoms present at this date. Pls update Covid illness visit or clarify.
Oct-19-2020 13:16:26 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/19/20 20	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

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Form Status: Data Complete, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231024

Subject Initials: ---

Generated By:

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

(b) (4)

(US & Canada)				
Aug-28-2020 20:44:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/28/2020	Initial Entry
Aug-28-2020 20:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/28/2020	Initial Entry

090177e196ae3016\Final\Final On: 01-Apr-2021 03:59 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1223

Subject No: 12231024

Generated By:

(b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit
Trail History

Form Status: Data Complete, Signed, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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1. Casebook Signature

Date	Location	User	Value	Reason
Oct-26-2020 17:48:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry

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