

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[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	01 DEC 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/9/2021
----	--------------	---

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[12231273]
2.	Birth Date:	(b) (6) /2005
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:	

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231273

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): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/9/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1223

Subject No: 12231273

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): 10-Nov-2021 20:44

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1223

Subject No: 12231273

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): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation/Death	Jan/9/2021
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: 12231273

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): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[seasonal allergies]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1223

Subject No: 12231273

Generated By: (b) (4)

Form: HIV STATUS

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

HIV Status

1.	Select appropriate response - What is the subject HIV status?	The subject is NOT known to be HIV POSITIVE
----	--	---

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Jan/9/2021
2.	Weight:	[66.4]
3.	Unit:	kg
4.	Height:	[169.0]
5.	Unit:	cm
6.	Body Mass Index:	[23.2]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.9]
	Unit:	F
	Temperature Location:	FOREHEAD

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231273

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): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Jan/9/2021
2.	Randomization Number:	[26295]
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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/9/2021
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	[BPW91R]
5.b	Sample ID	[BPW91S]
5.c	Sample ID	[BPW91T]
5.d	Sample ID	[BRV2NJ]
5.e	Sample ID	[BRV2NK]

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/9/2021
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	[BPW914]
-----	-----------	----------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:26

Site No: 1223

Subject No: 12231273

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): 10-Nov-2021 20:44

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:	Jan/9/2021 10:25
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1223

Subject No: 12231273

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): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
----	---	--

Header Text: c4591001

Visit: V2_VAX2_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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[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

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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
3.	Injection Site Location:	DELTOID MUSCLE

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

4.	Injection Site Body Side:	RIGHT
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

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 14-Jan-2021 02:22

Site No: 1223

Subject No: 12231273

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): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Jan/29/2021
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.4]
	Unit:	F
	Temperature Location:	FOREHEAD

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/29/2021
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	[BR1817]
-----	-----------	----------

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[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:	Jan/29/2021 15:36
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (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: 12231273 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Mar/3/2021
2.	Erroneous Visit	

Header Text: c4591001

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

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: 12231273 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[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

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

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

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: 12231273 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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
3.	Injection Site Location:	DELTOID MUSCLE

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

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

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: 12231273 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

4.	Injection Site Body Side:	RIGHT
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

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (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: 12231273 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Mar/3/2021
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	[BR1883]
5.b	Sample ID	[BR1884]

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Jun/13/2021
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	COVID_A

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form Version: 30-Apr-2021 01:47

Site No: 1223

Subject No: 12231273

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Data Complete

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Jun/13/2021
2.	Date of First Symptom Started:	Jun/5/2021
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Jun/9/2021

Symptoms

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

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Version: 30-Apr-2021 01:47

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Jun/13/2021	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

Microbiology Specimen

1.	Actual Date of Collection:	Jun/13/2021
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	YALE NEW HAVEN HOSPITAL SARS-COV-2 PCR TEST
7.	Test Result:	NEGATIVE
8.	Comments/Findings /Details:	[]
9.	Trade Name Other, Specify:	[]

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231273

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): 10-Nov-2021 20:44

[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 in the emergency room and the hospital did the test.]

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[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:	[This test was done by hospital staff and they do not have access to study sample barcodes.]

Aliquot

Please enter barcode for each aliquot.

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

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form: HEALTH CARE UTILIZATION

Form Version: 30-Apr-2021 01:37

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Health Care Utilization

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

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form: HEALTH CARE UTILIZATION

Form Version: 30-Apr-2021 01:37

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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
----	--	----

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[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?	

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form Version: 06-Jul-2020 21:52

Site No: 1223

Subject No: 12231273

Generated By: (b) (4)

Form: ILLNESS DETAILS

Form Status: Data Complete

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	YES Respiratory Illness Diagnosis: [Rhinovirus Infection] Date of Diagnosis: Jun/13/2021
3.	Toxicity Grade:	2

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	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 Jun/13/2021

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Illness Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 10-Dec-2020 02:24

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 10-Dec-2020 02:24

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[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

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 10-Dec-2020 02:28

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	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

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 10-Dec-2020 02:28

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Laboratory Data Hematology

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

Lab Result

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

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 10-Dec-2020 02:25

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	Date:	Vital Signs Details			Form Instance
1.	Jun/13/2021	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		1	112	60	

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form: VITAL SIGNS - COVID

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

Vital Signs

1.	Date:	Jun/13/2021
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Systolic:	[112]
	Diastolic:	[60]
	Respiratory Rate in respirations/minute:	[17]
	Heart Rate in beats/minute:	[63]

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 10-Dec-2020 02:31

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	Date:	Vital Signs Details		Form Instance
1.	Jun/13/2021	Record Identifier:	Oxygen Saturation	Repeating Pages
		1	99.0	

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

Vital Signs

1.	Date:	Jun/13/2021
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	SPO2 Pulse Oximetry %	[99.0]

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	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 Jun/13/2021

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Oxygenation Parameters

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	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 Jun/13/2021

Form Version: 06-Jul-2020 21:55

Site No: 1223

Subject No: 12231273

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

Form Status: Not Started

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Concomitant Medications

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

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Jun/14/2021	CHEST	MRI	NORMAL	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Imaging

1.	Date of Assessment:	Jun/14/2021
2.	Location of Assessment:	CHEST
3.	Type of Imaging Exam:	MRI
4.	Assessment:	NORMAL

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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: 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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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: 12231273 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Unplanned - New Unscheduled **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: 12231273 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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: 12231273 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

Unplanned Assessments

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

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VITAL SIGNS - TEMP

Form Version: 30-Apr-2021 01:41

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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?	

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Contact Outcome

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - **Form:** DATE OF VISIT
Unscheduled

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

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

Subject No: 12231273 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[Form Comments](#)

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Apr/7/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Form Comments](#)

[eCRF Audit Trail History](#)

Informed Consent - Asymptomatic Surveillance

			Comments
1.	Consent Was:	OBTAINED Date Written Consent Obtained Apr/7/2021	

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001**Visit:** V201_SURVEIL_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING -
Unscheduled IMMUNOGENICITY**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:** 12231273**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44[Form Comments](#)[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE	Comments
2.	Sample Type	SERUM	Comments
3.	Sample Collected?	YES Date of Collection: Apr/7/2021	Comments
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]	Comments

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BNKYPC]
5.b	Sample ID	[BTFRZZ]
5.c	Sample ID	[BTFS00]

Header Text: c4591001**Visit:** V201_SURVEIL_CONSENT -
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING - NASAL
SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1223**Site Name:** (1223) Yale New Haven Medical Center**Subject No:** 12231273**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44[Form Comments](#)[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE	Comments
2.	Sample Type	NASAL_SWAB	Comments
3.	Sample Collected?	YES Date of Collection: Apr/7/2021	Comments
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]	Comments

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRJ4N0]
-----	-----------	----------

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Disposition - Treatment

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

Header Text: c4591001

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

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

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

Subject No: 12231273 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	May/20/2021
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, Frozen

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

Subject No: 12231273 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[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: 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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Disposition - Follow-Up

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

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Myopericarditis	Jun/12/2021 19:00	NO End Date Time: Jun/13/2021 UNK:UNK	Repeating Pages

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Myopericarditis]
4.	Start Date Time:	Jun/12/2021 19:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jun/13/2021 UNK:UNK
6.	Toxicity Grade:	3

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

7.	<p>Is the adverse event serious?</p> <p>If Yes, NOTIFY PFIZER IMMEDIATELY.</p> <p>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).</p>	<p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect? NO</p> <p>Did this serious event result in death? NO</p> <p>Did this serious event require or prolong hospitalization? YES</p> <p>Did this serious event result in persistent or significant disability/incapacity? NO</p> <p>Is this serious event life threatening? NO</p> <p>Other medically important serious event NO</p>
8.	<p>Is this adverse event the result of a study Medication Error?</p> <p>If Yes, record the type of medication error on the Medication Error Log.</p>	NO
9.	<p>Is this event related to study treatment:</p>	<p>NOT RELATED</p> <p>If Not Related to study treatment(s), this event is due to: OTHER</p> <p>If Other, specify: [Rhinovirus infection]</p>
10.	<p>Latest Action Taken with Study Treatment:</p>	NOT APPLICABLE

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021699328]

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Medication Error

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

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages
2.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages
3.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages
4.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages
5.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages
6.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages
7.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Concomitant Medications

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

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Concomitant Medications

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

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Concomitant Medications

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

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Concomitant Medications

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

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Concomitant Medications

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

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Concomitant Medications

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

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Concomitant Medications

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

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages
2.	2	CORTICOSTEROIDS	NO	prednisone	30	Repeating Pages
3.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages
4.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages
5.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages
6.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

Concomitant Medications

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

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

7.	Dose Frequency:	Not Applicable _____	Comments
8.	Route:	Not Applicable _____	Comments
9.	Start Date:	Not Applicable _____ //	Comments
10.	Ongoing?	Not Applicable _____	Comments

Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** CONCOMITANT MEDICATIONS - PROHIBITED**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:** 12231273**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44[Back to Form](#)[eCRF Audit Trail History](#)[Form Audit Trail](#)**Concomitant Medications**

1.	What is the medication identifier?	[2]
2.	Category:	CORTICOSTEROIDS
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).	[prednisone]
5.	Dose:	[30]
6.	Dose Unit:	mg
7.	Dose Frequency:	BID
8.	Route:	ORAL
9.	Start Date:	Jun/13/2021

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

10.	Ongoing?	YES
-----	----------	-----

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Concomitant Medications

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

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

7.	Dose Frequency:	Not Applicable _____	Comments
8.	Route:	Not Applicable _____	Comments
9.	Start Date:	Not Applicable _____ //	Comments
10.	Ongoing?	Not Applicable _____	Comments

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Concomitant Medications

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

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

7.	Dose Frequency:	Not Applicable _____	Comments
8.	Route:	Not Applicable _____	Comments
9.	Start Date:	Not Applicable _____ //	Comments
10.	Ongoing?	Not Applicable _____	Comments

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Concomitant Medications

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

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

7.	Dose Frequency:	Not Applicable _____	Comments
8.	Route:	Not Applicable _____	Comments
9.	Start Date:	Not Applicable _____ //	Comments
10.	Ongoing?	Not Applicable _____	Comments

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Concomitant Medications

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

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

7.	Dose Frequency:	Not Applicable _____	Comments
8.	Route:	Not Applicable _____	Comments
9.	Start Date:	Not Applicable _____ //	Comments
10.	Ongoing?	Not Applicable _____	Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Radiation Treatment

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

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

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

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 -
Unscheduled Visit on Apr/21/2021

Form: DATE OF VISIT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Apr/21/2021
2.	Erroneous Visit	

COVID-19 Surveillance Visit

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK2
----	------------------------------	-------------

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 -
Unscheduled Visit on Apr/21/2021

Form: ELECTRONIC SAMPLE TRACKING - REPEAT
SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Apr/21/2021
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	[AA01556]
-----	-----------	-----------

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 2 -
Unscheduled Visit on May/05/2021

Form: DATE OF VISIT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	May/5/2021
2.	Erroneous Visit	

COVID-19 Surveillance Visit

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK4
----	------------------------------	-------------

Header Text: c4591001**Visit:** V202_SURVEIL_SWAB 2 -
Unscheduled Visit on May/05/2021**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT
SWAB**Form Version:** 10-Oct-2020 15:57**Form Status:** Data Complete, Frozen, Verified**Site No:** 1223**Site Name:** (1223) Yale New Haven Medical Center**Subject No:** 12231273**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: May/5/2021
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	[AA06954]
-----	-----------	-----------

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 3 -
Unscheduled Visit on May/19/2021

Form: DATE OF VISIT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	May/19/2021
2.	Erroneous Visit	

COVID-19 Surveillance Visit

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK6
----	---------------------------------	-------------

Header Text: c4591001**Visit:** V202_SURVEIL_SWAB 3 -
Unscheduled Visit on May/19/2021**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT
SWAB**Form Version:** 10-Oct-2020 15:57**Form Status:** Data Complete, Frozen, Verified**Site No:** 1223**Site Name:** (1223) Yale New Haven Medical Center**Subject No:** 12231273**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: May/19/2021
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	[AA01055]
-----	-----------	-----------

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 10-Dec-2020 02:27

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	May/20/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: V101_VAX3

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	May/21/2021
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, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained May/21/2021
----	--------------	--

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 28-Mar-2021 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation/Death :	May/21/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: May/21/2021
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	[BTFS6C]
5.b	Sample ID	[BTFS6D]
5.c	Sample ID	[BTFS6F]
5.d	Sample ID	[]
5.e	Sample ID	[]

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: May/21/2021
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	[BN1PSL]
-----	-----------	----------

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[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:	May/21/2021 13:12
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jun/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, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jun/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	[BN1PT0]
-----	-----------	----------

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[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:	Jun/10/2021 09:58
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231273

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jul/9/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1223

Subject No: 12231273

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Data Complete, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Jul/9/2021
3.	Comments:	[]

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231273

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): 10-Nov-2021 20:44

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: 12231273

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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: 12231273

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): 10-Nov-2021 20:44

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: 12231273

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

Contact Outcome

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

Header Text: c4591001

Visit:
FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Jul/9/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
4.	Specify Status:	[]

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Mar/3/2021

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Audit Trail](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
------	----------------------	------	------	--------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Version: 10-Oct-2020 16:00

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-09-2021 11:52:46 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - **Form:** DATE OF VISIT - Comments
Unscheduled

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

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

Subject No: 12231273 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-31-2021 18:20:49 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	put in wrong patient

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC
SURVEILLANCE - Comments

Form Version: 14-Jan-2021 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
Form	Apr-12-2021 13:36:39 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
Form	Mar-31-2021 18:21:38 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT

Form: INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE - Comments

Form Version: 14-Jan-2021 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
1	Apr-12-2021 13:36:39 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
1	Mar-31-2021 18:21:38 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

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

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: 12231273 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
Form	Apr-12-2021 13:37:14 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
Form	Mar-31-2021 18:22:14 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
1	Apr-12-2021 13:37:14 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
1	Mar-31-2021 18:22:14 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
2	Apr-12-2021 13:37:14 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
2	Mar-31-2021 18:22:14 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
3	Apr-12-2021 13:37:14 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
3	Mar-31-2021 18:22:14 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
4	Apr-12-2021 13:37:14 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
4	Mar-31-2021 18:22:14 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
Form	Apr-12-2021 13:37:49 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
Form	Mar-31-2021 18:22:55 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
1	Apr-12-2021 13:37:49 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
1	Mar-31-2021 18:22:55 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
2	Apr-12-2021 13:37:49 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
2	Mar-31-2021 18:22:55 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
3	Apr-12-2021 13:37:49 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
3	Mar-31-2021 18:22:55 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
4	Apr-12-2021 13:37:49 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
4	Mar-31-2021 18:22:55 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
Form	Jun-21-2021 12:20:51 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
1	Jun-21-2021 12:20:51 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
2	Jun-21-2021 12:20:51 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
3	Jun-21-2021 12:20:51 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
4	Jun-21-2021 12:20:51 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
5	Jun-21-2021 12:20:51 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
Form	Jun-21-2021 12:22:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
1	Jun-21-2021 12:22:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
2	Jun-21-2021 12:22:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
3	Jun-21-2021 12:22:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
4	Jun-21-2021 12:22:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
5	Jun-21-2021 12:22:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
Form	Jun-21-2021 12:23:28 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
1	Jun-21-2021 12:23:28 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
2	Jun-21-2021 12:23:28 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
3	Jun-21-2021 12:23:28 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
4	Jun-21-2021 12:23:28 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
5	Jun-21-2021 12:23:28 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
Form	Jun-21-2021 12:24:32 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
1	Jun-21-2021 12:24:32 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
2	Jun-21-2021 12:24:32 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
3	Jun-21-2021 12:24:32 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
4	Jun-21-2021 12:24:32 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
5	Jun-21-2021 12:24:32 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
Form	Jun-21-2021 12:25:27 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
1	Jun-21-2021 12:25:27 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
2	Jun-21-2021 12:25:27 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
3	Jun-21-2021 12:25:27 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
4	Jun-21-2021 12:25:27 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
5	Jun-21-2021 12:25:27 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
Form	Jun-21-2021 12:26:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
1	Jun-21-2021 12:26:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
2	Jun-21-2021 12:26:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
3	Jun-21-2021 12:26:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
4	Jun-21-2021 12:26:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
5	Jun-21-2021 12:26:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
Form	Jun-21-2021 12:27:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
1	Jun-21-2021 12:27:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
2	Jun-21-2021 12:27:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
3	Jun-21-2021 12:27:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
4	Jun-21-2021 12:27:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
5	Jun-21-2021 12:27:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
Form	Jun-25-2021 11:32:23 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
1	Jun-25-2021 11:32:23 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
2	Jun-25-2021 11:32:23 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
3	Jun-25-2021 11:32:23 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
4	Jun-25-2021 11:32:23 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
5	Jun-25-2021 11:32:23 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
6	Jun-25-2021 11:32:23 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
7	Jun-25-2021 11:32:23 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
8	Jun-25-2021 11:32:23 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
9	Jun-25-2021 11:32:23 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
10	Jun-25-2021 11:32:23 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
Form	Jun-25-2021 11:34:52 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
1	Jun-25-2021 11:34:52 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
2	Jun-25-2021 11:34:52 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
3	Jun-25-2021 11:34:52 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
4	Jun-25-2021 11:34:52 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
5	Jun-25-2021 11:34:52 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
6	Jun-25-2021 11:34:52 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
7	Jun-25-2021 11:34:52 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
8	Jun-25-2021 11:34:52 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
9	Jun-25-2021 11:34:52 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
10	Jun-25-2021 11:34:52 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
Form	Jun-25-2021 11:37:33 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
1	Jun-25-2021 11:37:33 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
2	Jun-25-2021 11:37:33 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
3	Jun-25-2021 11:37:33 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
4	Jun-25-2021 11:37:33 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
5	Jun-25-2021 11:37:33 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
6	Jun-25-2021 11:37:33 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
7	Jun-25-2021 11:37:33 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
8	Jun-25-2021 11:37:33 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
9	Jun-25-2021 11:37:33 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
10	Jun-25-2021 11:37:33 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
Form	Jun-25-2021 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
1	Jun-25-2021 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
2	Jun-25-2021 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
3	Jun-25-2021 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
4	Jun-25-2021 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
5	Jun-25-2021 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
6	Jun-25-2021 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
7	Jun-25-2021 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
8	Jun-25-2021 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
9	Jun-25-2021 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
10	Jun-25-2021 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
Form	Jun-25-2021 11:42:01 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
1	Jun-25-2021 11:42:01 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
2	Jun-25-2021 11:42:01 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
3	Jun-25-2021 11:42:01 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
4	Jun-25-2021 11:42:01 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
5	Jun-25-2021 11:42:01 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
6	Jun-25-2021 11:42:01 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
7	Jun-25-2021 11:42:01 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
8	Jun-25-2021 11:42:01 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
9	Jun-25-2021 11:42:01 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
10	Jun-25-2021 11:42:01 (UTC-05:00) Eastern Time (US & Canada)	Anousheh Behnegar (b) (4)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

Form Version: 28-Mar-2021 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
Form	May-21-2021 14:15:41 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Mar-31-2021 17:52:07 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

Jessica Tuan	Approved	Mar-19-2021 21:55:54 (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.

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - 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: 12231273

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Jan-09-2021 11:51:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) [redacted] (4), [redacted] (b) (6) [redacted]	Data Entry: 01 DEC 2020	Initial Entry

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

Date	Location	User	Value	Reason
Jan-09-2021 11:51:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) [redacted] (4), [redacted] (b) (6) [redacted]	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Jan-09-2021 11:53:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-09-2021 11:52:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Opened	Date Informed Consent Obtained is not the same as the Date of Visit. Please correct as necessary.
Jan-09-2021 11:51:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Jan/9/2021	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 10-Dec-2020 02:26

Site No: 1223

Subject No: 12231273

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): 10-Nov-2021 20:44

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Jan-09-2021 11:50:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 12231273	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Jan-09-2021 11:50:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: (b) (6) 2005	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Jan-09-2021 11:51:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Jan-09-2021 11:51:56 (UTC-05:00) Eastern Time (US &	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATI NO(A) OR OF SPANISH ORIGIN	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - 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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Canada)				
---------	--	--	--	--

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

Date	Location	User	Value	Reason
Jan-09-2021 11:51:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231273

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): 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Jan-09-2021 11:53:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-09-2021 11:53:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jan/9/2021	Transcription Error
Jan-09-2021 11:52:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Opened	Date of Visit, 09/Feb/2021 is a future date relative to when it was entered on 09/Jan/2021. Please correct.
Jan-09-2021 11:52:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Feb/9/2021	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Jan-09-2021 11:53:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jan/9/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-09-2021 11:53:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-09-2021 11:53:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - 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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1.a

Date	Location	User	Value	Reason
Jan-09-2021 11:54:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Line/MH Num 1 ber: Medical Histor seasonal all y Term: ergies Start Date: UNK/UNK/ 2005 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Jan-09-2021 11:54:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Jan-09-2021 11:54:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: seasonal allergies	Initial Entry

1.a Start Date:

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - 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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Jan-09-2021 11:54:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: UNK/UNK/2005	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Jan-09-2021 11:54:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1223

Subject No: 12231273

Generated By: (b) (4)

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Select appropriate response - What is the subject HIV status?

Date	Location	User	Value	Reason
Jan-09-2021 11:54:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: The subject is NOT known to be HIV POSITIVE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Jan-09-2021 11:56:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jan/9/2021	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Jan-09-2021 11:56:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 66.4	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Jan-09-2021 11:56:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

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

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Jan-09-2021 11:56:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 169.0	Initial Entry
--	-------------------------	---------------------	-----------------------------	---------------

5. Unit:

Date	Location	User	Value	Reason
Jan-09-2021 11:56:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Jan-09-2021 11:56:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 23.2	Initial Entry

7.a

Date	Location	User	Value	Reason
Jan-09-2021 11:56:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Record Identifier:: Temperature: 97.9 Temperature Unit:	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

			Temperature Location:	FOREH EAD
--	--	--	------------------------------	--------------

7.a Record Identifier:

Date	Location	User	Value	Reason
Jan-09-2021 11:56:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Jan-09-2021 11:56:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 97.9	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Jan-09-2021 11:56:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: F	Initial Entry

7.a Temperature Location:

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Jan-09-2021 11:56:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231273

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): 10-Nov-2021 20:44

[Back to Form](#)

1. Randomization Date :

Date	Location	User	Value	Reason
Jan-09-2021 11:56:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jan/9/2021	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Jan-09-2021 11:56:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 26295	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jan-09-2021 11:57:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-09-2021 11:57:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-09-2021 12:55:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-09-2021 11:57:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

				appropriate.
Jan-09-2021 11:57:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/9/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-09-2021 12:55:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Suzana Mutic (b) (4)	Data Entry: Sample ID: BPW91R	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-09-2021 12:55:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Suzana Mutic (b) (4)	Data Entry: BPW91R	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-09-2021 12:55:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Suzana Mutic (b) (4)	Data Entry: Sample ID: BPW91S	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

5.b Sample ID

Date	Location	User	Value	Reason
Jan-09-2021 12:55:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Suzana Mutic (b) (4)	Data Entry: BPW91S	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-09-2021 12:56:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Suzana Mutic (b) (4)	Data Entry: Sample ID: BPW91T	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-09-2021 12:56:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Suzana Mutic (b) (4)	Data Entry: BPW91T	Initial Entry

5.d

Date	Location	User	Value	Reason
Jan-11-2021 15:10:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Suzana Mutic (b) (4)	Data Entry: Sample ID: BRV2NJ	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

5.d Sample ID

Date	Location	User	Value	Reason
Jan-11-2021 15:10:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Suzana Mutic (b) (4)	Data Entry: BRV2NJ	Initial Entry

5.e

Date	Location	User	Value	Reason
Jan-11-2021 15:10:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Suzana Mutic (b) (4)	Data Entry: Sample ID: BRV2NK	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Jan-11-2021 15:10:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Suzana Mutic (b) (4)	Data Entry: BRV2NK	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jan-09-2021 11:57:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-09-2021 11:57:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-11-2021 14:10:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-11-2021 06:28:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

				appropriate.
Jan-09-2021 11:57:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-09-2021 11:57:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/9/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-11-2021 14:13:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Suzana Mutic (b) (4)	Data Entry: Sample ID: BPW914	Transcription Error
Jan-11-2021 14:11:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Suzana Mutic (b) (4)	Data Entry: Sample ID: BPW91F	Transcription Error
Jan-11-2021 14:10:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Suzana Mutic (b) (4)	Data Entry: Sample ID: BPW92N	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

5.a Sample ID

Date	Location	User	Value	Reason
Jan-11-2021 14:13:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Suzana Mutic (b) (4)	Data Entry: BPW914	Transcription Error
Jan-11-2021 14:11:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Suzana Mutic (b) (4)	Data Entry: BPW91F	Transcription Error
Jan-11-2021 14:10:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Suzana Mutic (b) (4)	Data Entry: BPW92N	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:26

Site No: 1223

Subject No: 12231273

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): 10-Nov-2021 20:44

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-09-2021 11:58:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-09-2021 11:58:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-09-2021 11:58:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Jan-09-2021 11:58:35 (UTC-05:00) Eastern Time (US &	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jan/9/2021 10:25	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Canada)

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-09-2021 11:58:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jan-09-2021 11:58:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jan-09-2021 11:58:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-09-2021 11:58:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIE D OBSERVATION PERIOD	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

Date	Location	User	Value	Reason
Jan-09-2021 11:58:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1223

Subject No: 12231273

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Mar-03-2021 01:50:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	As per site confirmation - updated PD tracker
Mar-02-2021 15:04:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Jessica Tuan (b) (4)	Query 1: Answered	Diary was not activated for vaccination 2
Mar-02-2021 05:17:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	PDQ : Subject is between 12 to 15 years old, however e-Diary data is missing in trail max report for Vaccination 2 , Please review and update as appropriate else clarify.
Jan-11-2021 12:16:36 (UTC-05:00) Eastern Time (US &	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT	Transcription Error

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Canada)				
Jan-09-2021 11:58:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO - REACTOGENICIT Y E-DIARY NOT COLLE CTED FOR THIS SUBJE CT	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231273

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): 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Jan-29-2021 17:46:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jan/29/2021	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[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
Jan-29-2021 17:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-29-2021 17:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: FE V E R Were fever or systemi N c symptoms present o O n the last day the Sub ject Diary was compl eted?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Jan-29-2021 17:47:33	ACV0PF EINFP60	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

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

Date	Location	User	Value	Reason
Jan-29-2021 17:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Jan-29-2021 17:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI G UE Were fever or system N ic symptoms present O on the last day the S ubject Diary was co mpleted?:	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.b Symptom:

Date	Location	User	Value	Reason
Jan-29-2021 17:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(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
Jan-29-2021 17:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Jan-29-2021 17:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.c Symptom:

Date	Location	User	Value	Reason
Jan-29-2021 17:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(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
Jan-29-2021 17:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Jan-29-2021 17:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: C HI LL S Were fever or system N ic symptoms present O on the last day the Su bject Diary was com pleted?:	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.d Symptom:

Date	Location	User	Value	Reason
Jan-29-2021 17:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(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
Jan-29-2021 17:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Jan-29-2021 17:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: VO MI TIN G Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.e Symptom:

Date	Location	User	Value	Reason
Jan-29-2021 17:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(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
Jan-29-2021 17:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Jan-29-2021 17:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: DI AR RH EA Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.f Symptom:

Date	Location	User	Value	Reason
Jan-29-2021 17:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(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
Jan-29-2021 17:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Jan-29-2021 17:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSENERED MUSCLE PAIN	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

2.g Symptom:

Date	Location	User	Value	Reason
Jan-29-2021 17:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR WORSENER MUSCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Jan-29-2021 17:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Jan-29-2021 17:47:33 (UTC-05:00)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: NEW OR WORSENER	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Eastern Time (US & Canada)			SENE JOINT PAIN Were fever or sy NO stemic symptom s present on the l ast day the Subj ect Diary was co mpleted?:	
----------------------------	--	--	---	--

2.h Symptom:

Date	Location	User	Value	Reason
Jan-29-2021 17:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR WORSENE D 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
Jan-29-2021 17:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

3. Injection Site Location:

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

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Jan-29-2021 17:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry
--	-------------------------	-------------------------	--------------------------------------	---------------

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Jan-29-2021 17:49:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-29-2021 17:49:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: RIGHT	Transcription Error
Jan-29-2021 17:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Opened	Injection Site Body Side entered on this page is not matching with Body Side entered on Vaccination page of VID1VX1L. Please review and update as appropriate.

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Jan-29-2021 17:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry
--	-------------------------	---------------------	----------------------------	---------------

5.a

Date	Location	User	Value	Reason
Jan-29-2021 17:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: RE DN ES S Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Jan-29-2021 17:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(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
------	----------	------	-------	--------

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Jan-29-2021 17:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
--	-------------------------	---------------------	--------------------------	---------------

5.b

Date	Location	User	Value	Reason
Jan-29-2021 17:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: SW ELLING Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Jan-29-2021 17:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(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
Jan-29-2021 17:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-29-2021 17:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: PAIN AT IN JECTI ON SI TE	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Jan-29-2021 17:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Jan-29-2021 17:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 14-Jan-2021 02:22

Site No: 1223

Subject No: 12231273

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): 10-Nov-2021 20:44

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Jan-29-2021 17:48:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jan/29/2021	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-29-2021 17:48:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 97.4 Temperature Unit: F Temperature Location: FOREHEAD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jan-29-2021 17:48:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:22

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.a Temperature:

Date	Location	User	Value	Reason
Jan-29-2021 17:48:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 97.4	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Jan-29-2021 17:48:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Jan-29-2021 17:48:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jan-29-2021 17:48:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-29-2021 17:48:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-02-2021 16:47:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-31-2021 21:59:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

				appropriate.
Jan-29-2021 17:48:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-29-2021 17:48:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/29/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-02-2021 16:48:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Suzana Mutic (b) (4)	Data Entry: Sample ID: BR1817	Transcription Error
Feb-02-2021 16:47:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Suzana Mutic (b) (4)	Data Entry: Sample ID: BR1817C	Initial Entry

5.a Sample ID

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

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Feb-02-2021 16:48:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-02-2021 16:48:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Suzana Mutic (b) (4)	Data Entry: BR1817	Transcription Error
Feb-02-2021 16:47:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Opened	Barcode is not 6 characters in length. Please review and correct as appropriate.
Feb-02-2021 16:47:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Suzana Mutic (b) (4)	Data Entry: BR1817C	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1223

Subject No: 12231273

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): 10-Nov-2021 20:44

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-29-2021 17:49:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-29-2021 17:49:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-29-2021 17:49:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Jan-29-2021 17:49:13 (UTC-05:00) Eastern Time (US &	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jan/29/2021 15:36	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Canada)

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-29-2021 17:49:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jan-29-2021 17:49:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jan-29-2021 17:49:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-29-2021 17:49:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIE D OBSERVATION PERIOD	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

Date	Location	User	Value	Reason
Jan-29-2021 17:49:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (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: 12231273 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Mar-03-2021 16:48:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Mar/3/2021	Transcription Error
Mar-02-2021 11:55:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Mar/2/2021	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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: 12231273 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[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
Mar-02-2021 11:56:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Mar-02-2021 11:56:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: FE V E R Were fever or systemi N c symptoms present o O n the last day the Sub ject Diary was compl eted?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Mar-02-2021 11:56:13	ACV0PF EINFP60	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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: 12231273 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

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

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

Date	Location	User	Value	Reason
Mar-02-2021 11:56:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Mar-02-2021 11:56:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI G UE Were fever or system N ic symptoms present O on the last day the S ubject Diary was co mpleted?:	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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: 12231273 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

2.b Symptom:

Date	Location	User	Value	Reason
Mar-02-2021 11:56:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Mar-02-2021 11:56:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Mar-02-2021 11:56:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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: 12231273 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

2.c Symptom:

Date	Location	User	Value	Reason
Mar-02-2021 11:56:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(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
Mar-02-2021 11:56:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Mar-02-2021 11:56:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: C HI LL S Were fever or system N ic symptoms present O on the last day the Su bject Diary was com pleted?:	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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: 12231273 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

2.d Symptom:

Date	Location	User	Value	Reason
Mar-02-2021 11:56:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(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
Mar-02-2021 11:56:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Mar-02-2021 11:56:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: VO MI TIN G Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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: 12231273 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

2.e Symptom:

Date	Location	User	Value	Reason
Mar-02-2021 11:56:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(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
Mar-02-2021 11:56:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Mar-02-2021 11:56:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: DI AR RH EA Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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: 12231273 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

2.f Symptom:

Date	Location	User	Value	Reason
Mar-02-2021 11:56:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Mar-02-2021 11:56:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Mar-02-2021 11:56:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: NEW O R WOR SENED MUSCL E PAIN	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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: 12231273 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

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

2.g Symptom:

Date	Location	User	Value	Reason
Mar-02-2021 11:56:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR WORSENER MUSCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Mar-02-2021 11:56:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Mar-02-2021 11:56:13 (UTC-05:00)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSENER MUSCLE PAIN	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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: 12231273 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

Eastern Time (US & Canada)			SENE JOINT PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	
----------------------------	--	--	---	--

2.h Symptom:

Date	Location	User	Value	Reason
Mar-02-2021 11:56:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENE 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
Mar-02-2021 11:56:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

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

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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: 12231273 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

Mar-02-2021 11:56:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry
--	-------------------------	-------------------------	--------------------------------------	---------------

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Mar-02-2021 14:40:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-02-2021 14:40:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Jessica Tuan (b) (4)	Data Entry: RIGHT	Changed Information
Mar-02-2021 11:56:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Opened	Injection Site Body Side entered on this page is not matching with Body Side entered on Vaccination page of V2VX2L. Please review and update as appropriate.

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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: 12231273 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

Mar-02-2021 11:56:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry
--	-------------------------	---------------------	----------------------------	---------------

5.a

Date	Location	User	Value	Reason
Mar-02-2021 11:56:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: RE DN ES S Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Mar-02-2021 11:56:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(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
------	----------	------	-------	--------

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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: 12231273 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

Mar-02-2021 11:56:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
--	-------------------------	---------------------	--------------------------	---------------

5.b

Date	Location	User	Value	Reason
Mar-02-2021 11:56:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: SW ELL ING Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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: 12231273 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Mar-02-2021 11:56:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(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
Mar-02-2021 11:56:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-02-2021 11:56:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: PAIN AT INJECTION SITE	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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: 12231273 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

			Were injection site reactions present on the last day the Subject Diary was completed?:	
--	--	--	--	--

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Mar-02-2021 11:56:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Mar-02-2021 11:56:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (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: 12231273 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Mar-02-2021 11:56:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-02-2021 11:56:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-04-2021 15:03:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-03-2021 16:48:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/3/2021	Transcription Error

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (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:** 12231273**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44

Mar-03-2021 06:31:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-02-2021 11:56:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-02-2021 11:56:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/2/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-04-2021 15:03:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BR1883	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: 12231273 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Mar-04-2021 15:03:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: BR1883	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-04-2021 15:05:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Sample ID: BR1884	Transcription Error
Mar-04-2021 15:04:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Sample ID: BR1883	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (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: 12231273 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

5.b Sample ID

Date	Location	User	Value	Reason
Mar-04-2021 15:05:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: BR1884	Transcription Error
Mar-04-2021 15:04:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: BR1883	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231273

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): 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Jun-18-2021 05:54:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 3: Deleted	as per comments updated on swab forms
Jun-17-2021 11:06:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 3: 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.
Jun-17-2021 11:06:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jun-17-2021 10:06:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 2: Deleted	Close Auto Query

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1223**Site Name:** (1223) Yale New Haven Medical Center**Subject No:** 12231273**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44

Jun-17-2021 09:27:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	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.
Jun-17-2021 09:27:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	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.
Jun-17-2021 09:27:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: Jun/13/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Jun-17-2021 09:27:56 (UTC-05:00) Eastern	ACV0PF EINFP60	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231273

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): 10-Nov-2021 20:44

Time (US & Canada)	00			
--------------------	----	--	--	--

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

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

Form Version: 30-Apr-2021 01:47

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Assessment:

Date	Location	User	Value	Reason
Jun-17-2021 10:06:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jun/13/2021	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Jun-17-2021 10:06:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jun/5/2021	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Jun-17-2021 10:06:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Re solved: Jun/9/2021	Initial Entry

4.a

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

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

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

Form Version: 30-Apr-2021 01:47

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Jun-17-2021 10:06:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms: FEVE R Symptom Present YES :	Initial Entry
--	-------------------------	---------------------	---	---------------

4.a Symptoms:

Date	Location	User	Value	Reason
Jun-17-2021 10:06:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Jun-17-2021 10:06:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.b

Date	Location	User	Value	Reason
Jun-17-2021 10:06:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCR EASED COUGH H	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

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

Form Version: 30-Apr-2021 01:47

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

4.b Symptoms:

Date	Location	User	Value	Reason
Jun-17-2021 10:06:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED CO UGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Jun-17-2021 10:06:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Jun-17-2021 10:06:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCRE ASED SHORTNE SS OF BREATH Symptom Present: NO	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

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

Form Version: 30-Apr-2021 01:47

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

4.c Symptoms:

Date	Location	User	Value	Reason
Jun-17-2021 10:06:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SH ORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Jun-17-2021 10:06:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Jun-17-2021 10:06:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms: CHILL S Symptom Present: NO	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

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

Form Version: 30-Apr-2021 01:47

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

4.d Symptoms:

Date	Location	User	Value	Reason
Jun-17-2021 10:06:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Jun-17-2021 10:06:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Jun-17-2021 10:06:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom: NEW OR INCREASED MUSCLE PAIN Symptom Present: NO	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

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

Form Version: 30-Apr-2021 01:47

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

4.e Symptoms:

Date	Location	User	Value	Reason
Jun-17-2021 10:06:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED M USCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Jun-17-2021 10:06:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Jun-17-2021 10:06:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom: NEW LOSS OF TASTE OR SM ELL Symptom Present: NO	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form Version: 30-Apr-2021 01:47

Site No: 1223

Subject No: 12231273

Generated By: (b) (4)

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

Form Status: Data Complete

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

4.f Symptoms:

Date	Location	User	Value	Reason
Jun-17-2021 10:06:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Jun-17-2021 10:06:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Jun-17-2021 10:06:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom: NEW OR INCRE ASED SORE TH ROAT Symptom Present: NO	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form Version: 30-Apr-2021 01:47

Site No: 1223

Subject No: 12231273

Generated By: (b) (4)

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

Form Status: Data Complete

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

4.g Symptoms:

Date	Location	User	Value	Reason
Jun-17-2021 10:06:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SO RE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Jun-17-2021 10:06:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Jun-17-2021 10:06:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRH EA Symptom Present: NO	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

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

Form Version: 30-Apr-2021 01:47

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

4.h Symptoms:

Date	Location	User	Value	Reason
Jun-17-2021 10:06:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Jun-17-2021 10:06:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Jun-17-2021 10:06:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms: VOMITI NG Symptom Present: NO	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

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

Form Version: 30-Apr-2021 01:47

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

4.i Symptoms:

Date	Location	User	Value	Reason
Jun-17-2021 10:06:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Jun-17-2021 10:06:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Jun-17-2021 11:48:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms - Other: rhinorrhea	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Jun-17-2021 11:48:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: rhinorrhea	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form: MICROBIOLOGY SPECIMEN - Audit Trail

Form Version: 06-Jul-2020 21:54

Form Status:

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Date	Location	User	Value	Reason
Jun-17-2021 10:20:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Actual Date of Collection:

Date	Location	User	Value	Reason
Jun-17-2021 10:20:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jun/13/2021	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jun-17-2021 10:20:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: SWABBED MATERIAL	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Jun-17-2021 10:20:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NASOPHARYNX	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Jun-17-2021 10:20:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYN DROME CORONAVIRUS 2	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form Version: 06-Jul-2020 21:54

Site No: 1223

Subject No: 12231273

Generated By: (b) (4)

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Status: Data Complete, Frozen

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

5. Device Type:

Date	Location	User	Value	Reason
Jun-17-2021 10:20:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC TEST	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Jun-17-2021 10:20:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YALE NEW HAVEN HOS PITAL SARS-COV-2 PCR TEST	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Jun-17-2021 10:20:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231273

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): 10-Nov-2021 20:44

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jun-17-2021 10:20:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jun-17-2021 10:20:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jun-17-2021 11:04:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jun-17-2021 10:20:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231273

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): 10-Nov-2021 20:44

				collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Jun-17-2021 10:20:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	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
Jun-17-2021 11:04:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Subject was in the emergency room and the hospital did the test.	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231273

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): 10-Nov-2021 20:44

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jun-17-2021 10:20:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jun-17-2021 10:20:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jun-17-2021 11:08:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 3: Closed	Close Auto Query
Jun-17-2021 11:06:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 3: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231273

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): 10-Nov-2021 20:44

				collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Jun-17-2021 11:06:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Jun-17-2021 11:06:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: NO	Transcription Error
Jun-17-2021 11:06:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jun-17-2021 11:06:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Jun-17-2021 11:06:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: YES Date of Collection: Jun/13/2021	Transcription Error
Jun-17-2021 10:20:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Jun-17-2021 10:20:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(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
Jun-17-2021 11:08:04	ACV0PF EINFP60	Anousheh Behnegar	Data Entry: This test was done by hosp	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231273

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): 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00	(b) (4)	ital staff and they do not ha ve access to study sample b arcodes.	
--	----	---------	--	--

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 30-Apr-2021 01:37

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1.a

Date	Location	User	Value	Reason
Jun-17-2021 10:22:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Type of Pra SPECIALIS ctitioner: T Occurrence YES of Visits or <i>Number of</i> Contacts: <i>Visits or Co</i> <i>ntacts:</i> 1	Initial Entry

1.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jun-17-2021 10:22:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

1.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jun-17-2021 10:22:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES <i>Number of Visits or Conta</i> <i>cts:</i>	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 30-Apr-2021 01:37

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

			1	
--	--	--	---	--

1.b

Date	Location	User	Value	Reason
Jun-17-2021 10:22:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Type of Pra EMERGEN ctitioner: CY ROOM Occurrence YES of Visits or <i>Number of</i> Contacts: <i>Visits or Co</i> <i>ntacts:</i> 1	Initial Entry

1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jun-17-2021 10:22:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: EMERGENCY ROOM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jun-17-2021 10:22:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES <i>Number of Visits or Conta</i> <i>cts:</i> 1	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 30-Apr-2021 01:37

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

I.c

Date	Location	User	Value	Reason
Jun-17-2021 10:22:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Type of Prac PRIMARY titioner: CARE PHY SICIAN Occurrence NO of Visits or Contacts:	Initial Entry

I.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jun-17-2021 10:22:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PHYSIC IAN	Initial Entry

I.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jun-17-2021 10:22:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.d

Date	Location	User	Value	Reason
Jun-17-2021	ACV0PF	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 30-Apr-2021 01:37

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

10:22:06 (UTC-05:00) Eastern Time (US & Canada)	EINFP60 00	(b) (4), (b) (6)	Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: NO
---	---------------	---------------------	---

1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jun-17-2021 10:22:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jun-17-2021 10:22:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Jun-17-2021 10:22:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 30-Apr-2021 01:37

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

			Occurrence NO of Visits or Contacts:	
--	--	--	--	--

I.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jun-17-2021 10:22:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTA TION	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jun-17-2021 10:22:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.f

Date	Location	User	Value	Reason
Jun-17-2021 10:22:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Type of Practitione OTH r: ER Occurrence of Visit NO s or Contacts:	Initial Entry
Jun-17-2021 10:22:06 (UTC-05:00) Eastern	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Type of Practitione OTH r: ER	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 30-Apr-2021 01:37

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Time (US & Canada)		(b) (4), (b) (6)	Occurrence of Visits or Contacts:	
--------------------	--	------------------	--	--

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jun-17-2021 10:22:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jun-17-2021 10:22:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Other Type of Practitioner Specify:

Date	Location	User	Value	Reason
Jun-17-2021 11:50:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry:	Transcription Error
Jun-17-2021 10:22:06 (UTC-05:00) Eastern Time (US &	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Pediatric Infectious Disease Consult	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 30-Apr-2021 01:37

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Canada)				
---------	--	--	--	--

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

Date	Location	User	Value	Reason
Jun-17-2021 10:22:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: NO	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Category of Clinical Event:

Date	Location	User	Value	Reason
Jun-18-2021 08:42:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILL NESS	Initial Entry
Jun-17-2021 10:25:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry:	Transcription Error
Jun-17-2021 10:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILL NESS	Initial Entry

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

Date	Location	User	Value	Reason
Jun-18-2021 13:58:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00.InFor mAdapte r.Discrep ancy	PFETMS Oracle (b) (4)	Query 2: Closed	Discrepancy has been closed.
Jun-18-2021 10:19:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Jun-18-2021 10:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 2: Answered	Changed Information
Jun-18-2021 10:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: YES <i>Respiratory Illness Dia gnosis:</i> Rhinovirus Infection Date of Diagnosis: Jun/13/2021	Changed Information
Jun-18-2021 10:04:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00.InFor mAdapte r.Discrep ancy	PFETMS Oracle (b) (4)	Query 2: Opened	Clarify RHINOVIRUS as follows...Organism only. Please update the verbatim term to clarify whether reporting RHINOVIRUS TEST or RHINOVIRUS TEST POSITIVE or RHINOVIRUS INFECTION or other. Thank you.
Jun-18-2021 08:42:43	ACV0PF EINFP60	auto query (autoquery)	Query 1: Answered	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021**Form:** ILLNESS DETAILS - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:52**Form Status:** Data Complete**Site No:** 1223**Site Name:** (1223) Yale New Haven Medical Center**Subject No:** 12231273**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00			
Jun-18-2021 08:42:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: YES <i>Respiratory Illness Dia gnosis:</i> Rhinovirus Date of Diagnosis: Jun/13/2021	Initial Entry
Jun-18-2021 07:46:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly review the form and update the missing data.
Jun-17-2021 10:25:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry:	Transcription Error
Jun-17-2021 10:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Jun-18-2021 08:42:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: 2	Initial Entry
---	-------------------------	---------------------------------	-------------------------	---------------

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form: VITAL SIGNS - COVID - Audit Trail

Form Version: 10-Dec-2020 02:25

Form Status:

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Date	Location	User	Value	Reason
Jun-17-2021 10:47:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form: VITAL SIGNS - COVID - eCRF Audit Trail
History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Jun-17-2021 10:47:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jun/13/2021	Initial Entry

2.a

Date	Location	User	Value	Reason
Jun-17-2021 10:47:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Systolic:: 11 2 Diastolic:: 60 Respiratory Rate in re 17 spirations/minute: Heart Rate in beats/mi 63 nute:	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jun-17-2021 10:47:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Systolic:

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form: VITAL SIGNS - COVID - eCRF Audit Trail
History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Jun-17-2021 10:47:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 112	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Jun-17-2021 10:47:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 60	Initial Entry

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Jun-17-2021 10:47:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 17	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Jun-17-2021 10:47:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 63	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form: VITAL SIGNS - PULSE OX ROOM AIR - Audit
Trail

Form Version: 10-Dec-2020 02:31

Form Status:

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Date	Location	User	Value	Reason
Jun-17-2021 10:48:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF
Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Jun-17-2021 10:48:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jun/13/2021	Initial Entry

2.a

Date	Location	User	Value	Reason
Jun-17-2021 10:48:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Oxygen Saturation: 99.0	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jun-17-2021 10:48:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Jun-17-2021 10:48:43 (UTC-05:00) Eastern	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 99.0	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF
Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Time (US & Canada)	(b) (4), (b) (6)
--------------------	------------------

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form: IMAGING - Audit Trail

Form Version: 06-Jul-2020 21:53

Form Status:

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Date	Location	User	Value	Reason
Jun-17-2021 10:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form: IMAGING - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Assessment:

Date	Location	User	Value	Reason
Jun-17-2021 10:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jun/14/2021	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Jun-17-2021 10:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: CHEST	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Jun-17-2021 10:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: MRI	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Jun-17-2021 10:52:30 (UTC-05:00) Eastern	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NORMAL	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jun/13/2021

Form: IMAGING - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Time (US & Canada)	(b) (4), (b) (6)		
--------------------	------------------	--	--

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - **Form:** DATE OF VISIT - eCRF Audit Trail History
Unscheduled

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

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

Subject No: 12231273 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Apr-12-2021 13:36:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Apr/7/2021	Transcription Error
Apr-09-2021 14:18:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Deleted	Query is invalid or does not apply
Mar-31-2021 18:21:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark any forms containing data within this visit as Not Done/Not Applicable at the form level.
Mar-31-2021 17:52:07	ACV0PF EINFP60	(b) (4), (b) (6)	Data Entry: Mar/31/2021	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - **Form:** DATE OF VISIT - eCRF Audit Trail History
Unscheduled

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

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

Subject No: 12231273 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 10-Nov-2021 20:44

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

2. Erroneous Visit

Date	Location	User	Value	Reason
Apr-12-2021 13:36:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry:	Transcription Error
Mar-31-2021 18:21:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: ERRONEOUS VISIT	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC
SURVEILLANCE - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Apr-12-2021 13:36:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Ob tained Apr/7/2021	Initial Entry
Apr-12-2021 13:36:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry:	Initial Entry
Mar-31-2021 18:21:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Mar-31-2021 18:21:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry:	Transcription Error
Mar-31-2021 17:52:24 (UTC-05:00) Eastern Time (US &	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Ob tained	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC
SURVEILLANCE - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Canada)			Mar/31/2021	
---------	--	--	-------------	--

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Apr-12-2021 13:37:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry
Apr-12-2021 13:37:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry:	Initial Entry
Mar-31-2021 18:22:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Mar-31-2021 18:22:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry:	Transcription Error
Mar-31-2021 17:52:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

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

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History
Unscheduled

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: 12231273 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

Apr-12-2021 13:37:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SERUM	Initial Entry
Apr-12-2021 13:37:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry:	Initial Entry
Mar-31-2021 18:22:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Mar-31-2021 18:22:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry:	Transcription Error
Mar-31-2021 17:52:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
May-07-2021 15:35:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	Query 4: Closed	Response satisfies query
May-06-2021	ACV0PF	(b) (4), (b) (6) [Redacted]	Query 4: Answered	Barcodes entered

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History
Unscheduled

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: 12231273 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

12:39:47 (UTC-05:00) Eastern Time (US & Canada)	EINFP60 00	(b) (4), (b) (6)		
May-06-2021 10:57:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 4: Opened	HOLDS: For Visit 201, the lab received serum sample barcodes BTFRZZ,BTFS00; however, the barcodes have not been recorded. Please review and update as appropriate. Otherwise please clarify.
Apr-22-2021 11:33:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 3: Closed	Close Auto Query
Apr-15-2021 05:32:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 3: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Apr-14-2021 09:29:50	ACV0PF EINFP60	auto query (autoquery)	Query 3: Candidate	'Sample Collected?' is Yes,

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History
Unscheduled

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: 12231273 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00			however no barcodes are entered. Please review and correct as appropriate.
Apr-14-2021 09:29:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 2: Closed	Close Auto Query
Apr-14-2021 06:11:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Apr-12-2021 13:37:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Apr-12-2021 13:37:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Apr/7/2021	Initial Entry
Apr-12-2021 13:37:14	ACV0PF EINFP60	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00			
Mar-31-2021 18:22:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Mar-31-2021 18:22:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-31-2021 18:22:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry:	Transcription Error
Mar-31-2021 17:52:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-31-2021 17:52:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/31/2021	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History
Unscheduled

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: 12231273 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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

Date	Location	User	Value	Reason
Apr-12-2021 13:37:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry:	Initial Entry
Mar-31-2021 18:22:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Apr-22-2021 11:33:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BNKYPC	Initial Entry
Apr-14-2021 09:29:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Sample ID:	Transcription Error
Apr-14-2021 09:29:19 (UTC-05:00)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Sample ID: BRJ4N0	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History
Unscheduled

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: 12231273 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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

5.a Sample ID

Date	Location	User	Value	Reason
Apr-22-2021 11:33:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: BNKYPC	Initial Entry
Apr-14-2021 09:29:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry:	Transcription Error
Apr-14-2021 09:29:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: BRJ4N0	Initial Entry

5.b

Date	Location	User	Value	Reason
May-06-2021 12:38:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Sample ID: BTFRZZ	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History
Unscheduled

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: 12231273 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

5.b Sample ID

Date	Location	User	Value	Reason
May-06-2021 12:38:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BTFRZZ	Initial Entry

5.c

Date	Location	User	Value	Reason
May-06-2021 12:39:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BTFS00	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
May-06-2021 12:39:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BTFS00	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Apr-12-2021 13:38:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry
Apr-12-2021 13:37:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry:	Initial Entry
Mar-31-2021 18:22:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Mar-31-2021 18:22:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry:	Transcription Error
Mar-31-2021 17:53:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

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

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History
Unscheduled

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: 12231273 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

Apr-12-2021 13:38:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry
Apr-12-2021 13:37:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry:	Initial Entry
Mar-31-2021 18:22:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Mar-31-2021 18:22:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry:	Transcription Error
Mar-31-2021 17:53:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Apr-14-2021 09:30:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 2: Closed	Close Auto Query
Apr-14-2021	ACV0PF	(b) (4), (b) (6)	Query 2: Opened	'Sample

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History
Unscheduled

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: 12231273 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

06:11:37 (UTC-05:00) Eastern Time (US & Canada)	EINFP60 00	(b) (4), (b) (6)		Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Apr-12-2021 13:38:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Apr-12-2021 13:38:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Apr/7/2021	Initial Entry
Apr-12-2021 13:37:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry:	Initial Entry
Mar-31-2021 18:22:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001**Visit:** V201_SURVEIL_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING - NASAL
Unscheduled SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified**Site No:** 1223**Site Name:** (1223) Yale New Haven Medical Center**Subject No:** 12231273**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44

Mar-31-2021 18:22:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-31-2021 18:22:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry:	Transcription Error
Mar-31-2021 17:53:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-31-2021 17:53:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/31/2021	Initial Entry

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

Date	Location	User	Value	Reason
Apr-12-2021 13:37:49 (UTC-05:00) Eastern Time (US &	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING - NASAL
Unscheduled SWAB - eCRF Audit Trail History

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

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

Subject No: 12231273 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

Canada)				
Mar-31-2021 18:22:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Apr-14-2021 09:30:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Sample ID: BRJ4N0	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Apr-14-2021 09:30:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: BRJ4N0	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:26 **Form Status:** Data Complete, Locked, Frozen, Verified

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

Subject No: 12231273 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Mar-05-2021 14:46:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-05-2021 08:27:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-05-2021 08:27:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Mar/3/2021	Transcription Error
Mar-04-2021 01:51:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00.InFormAdap r.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7592644;Status on the Disposition - Treatment form is COMPLETED, but Date is different than Visit 3 Date. Please review and update as appropriate.
Mar-02-2021 11:56:51	ACV0PF EINFP60	(b) (4), (b) (6)	Data Entry: Mar/2/2021	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:26 **Form Status:** Data Complete, Locked, Frozen, Verified

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

Subject No: 12231273 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-02-2021 11:56:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Mar-02-2021 11:56:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (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, Frozen, Verified

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

Subject No: 12231273 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
May-21-2021 08:51:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: May/20/2021	Initial Entry

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, Frozen

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

Subject No: 12231273 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[Back to Form](#)

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

Date	Location	User	Value	Reason
May-21-2021 08:51:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per other protocol allowance(s) and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (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

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Date	Location	User	Value	Reason
Jun-15-2021 12:08:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Anousheh Behnegar (b) (4)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Jun-15-2021 12:08:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jun-15-2021 12:08:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Aug-11-2021 06:48:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Donald Scott McVinnie (b) (4)	Query 21: Closed	Being tracked separately now
Aug-11-2021 06:48:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Donald Scott McVinnie (b) (4)	Query 20: Closed	Being tracked separately now
Aug-06-2021 06:16:31	ACV0PF EINFP60	Donald Scott McVinnie	Query 21: Reissued:C andidate	Await SAE FUP - Being tracked by MM

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00	(b) (4)		
Aug-05-2021 09:59:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 21: Answered	info added to SAE FUP
Aug-04-2021 07:20:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Donald Scott McVinnie (b) (4)	Query 21: Reissued:O pened	Thanks kindly for all your help with this case. Can I request that this info is also included on an SAE FUP to update the safety database?
Aug-03-2021 11:57:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Query 21: Answered	He was told to limit activity to prevent tachycardia
Aug-03-2021 11:26:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Donald Scott McVinnie (b) (4)	Query 21: Opened	MM: Was any lifestyle advice given to subject by cardiologist as a result of the AE (eg any advice to refrain from strenuous exercise)?
Jul-26-2021 08:43:57 (UTC-05:00)	ACV0PF EINFP60 00	Donald Scott McVinnie (b) (4)	Query 20: Reissued:C andidate	Await SAE FUP

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Eastern Time (US & Canada)				
Jul-26-2021 07:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Query 20: Answered	SAE update has been sent
Jul-22-2021 09:17:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Donald Scott McVinnie (b) (4)	Query 20: Opened	MM: Thanks kindly for confirming that subject remains under cardiology FUP as an O/P. Could the site kindly send updated SAE FUP form to state that this is the case?
Jul-22-2021 07:33:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Donald Scott McVinnie (b) (4)	Query 19: Closed	Response satisfies query
Jul-21-2021 14:46:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Query 19: Answered	Subject has been discharged from the hospital but continues to follow-up with cardiology as an outpatient
Jul-21-2021 12:18:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Donald Scott McVinnie (b) (4)	Query 19: Opened	CLIN: Per SAE FUP the subject had a reassuring ECG and echo on 24Jun2021.

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

& Canada)				Thank you for providing this update. Is any further cardiology follow-up expected or has the subject now been discharged from cardiology?
Jul-21-2021 07:54:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Donald Scott McVinnie (b) (4)	Query 18: Closed	Await further SAE follow-up with MRI
Jul-21-2021 07:51:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Donald Scott McVinnie (b) (4)	Query 16: Closed	Response satisfies query
Jul-21-2021 07:46:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Donald Scott McVinnie (b) (4)	Query 15: Closed	Response satisfies query
Jul-21-2021 07:45:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Donald Scott McVinnie (b) (4)	Query 14: Closed	Response satisfies query
Jul-16-2021 05:47:15 (UTC-05:00)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 13: Closed	SAE term now matched as myopericarditis in

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Eastern Time (US & Canada)				both database
Jul-14-2021 09:32:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Query 16: Answered	residual symptoms of cough and rhinorrhea had resolved prior to chest symptoms. Updated SAE and medical records have been submitted
Jul-14-2021 09:28:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Query 18: Answered	This information has been submitted
Jul-14-2021 09:27:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Query 14: Answered	Chest tightness preceded chest pain
Jul-14-2021 09:26:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Query 15: Answered	This information is in the SAE report!!! The normal range is 0-less than 0.01 ng/ml
Jul-13-2021 12:13:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Donald Scott McVinnie (b) (4)	Query 18: Opened	CLIN: Per previous query response detailing echo, cardiac MRI, Covid PCR results, please submit this information on

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

				updated safety SAE form.
Jul-13-2021 12:08:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Donald Scott McVinnie (b) (4)	Query 17: Closed	Previously answered within another query
Jul-13-2021 12:07:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Donald Scott McVinnie (b) (4)	Query 17: Opened	CLIN: Per previous query please clarify as to why the mother had a nebuliser and albuterol and administered it to the participant if he is not a known asthmatic. Update SAE report accordingly please
Jul-13-2021 12:06:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Donald Scott McVinnie (b) (4)	Query 16: Opened	CLIN: Per previous query please add if there were residual or recurrence of symptoms of cough and rhinorrhoea when the chest symptoms occurred. Update SAE report accordingly please
Jul-13-2021 12:03:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Donald Scott McVinnie (b) (4)	Query 15: Opened	CLIN: Per previous query please clarify the normal range for the initial troponin value provided (0.27)

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

				and the units. Update SAE report accordingly please
Jul-13-2021 12:03:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Donald Scott McVinnie (b) (4)	Query 14: Opened	CLIN: Per previous query please clarify the presenting symptoms "chest tightness pain", was it chest tightness that then became pain, was it alternating chest tightness and chest pain, was it just chest pain? Update SAE report accordingly please
Jul-13-2021 09:11:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 13: Answered	Transcription Error
Jul-13-2021 09:11:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Myopericarditis	Transcription Error
Jul-12-2021 15:30:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 13: Reissued: Opened	SAE RECON: Thanks for the response. Please update databases with the correct SAE term. If safety update is

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

				required, please submit a follow-up form.
Jul-06-2021 10:03:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Query 13: Answered	Chest pain was of cardiac origin
Jul-05-2021 04:54:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 13: Opened	SAE RECON: AER#2021699328, the term was reported as chest pain in Safety database while recorded as Chest pain of cardiac origin Myopericarditis in AE CRF. Please confirm correct term.If safety update is required, please submit a follow-up form.
Jul-01-2021 10:27:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Juleen Gayed (b) (4)	Query 12: Closed	Response satisfies query
Jun-30-2021 10:07:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Query 12: Answered	No test was performed for enterovirus.

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Jun-30-2021 09:21:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Juleen Gayed (b) (4)	Query 12: Opened	Clin: Please confirm if a test was performed to exclude enterovirus
Jun-22-2021 04:34:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Juleen Gayed (b) (4)	Query 11: Closed	Response satisfies query
Jun-22-2021 04:34:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Juleen Gayed (b) (4)	Query 10: Closed	Response satisfies query
Jun-22-2021 04:34:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Juleen Gayed (b) (4)	Query 9: Closed	Response satisfies query
Jun-22-2021 04:34:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Juleen Gayed (b) (4)	Query 7: Closed	Response satisfies query
Jun-22-2021 04:34:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Juleen Gayed (b) (4)	Query 6: Closed	Response satisfies query

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Jun-22-2021 04:34:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Juleen Gayed (b) (4)	Query 5: Closed	Response satisfies query
Jun-22-2021 04:34:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Juleen Gayed (b) (4)	Query 4: Closed	Response satisfies query
Jun-22-2021 04:30:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Juleen Gayed (b) (4)	Query 3: Closed	Response satisfies query
Jun-22-2021 04:29:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Juleen Gayed (b) (4)	Query 8: Closed	Response satisfies query
Jun-18-2021 09:35:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Query 11: Answered	ketorolac, diphenhydramine, prednisone were administered as anti-inflammatory agents. Ibuprofen as an anti-inflammatory, antipyretic and analgesic agent, acetaminophen as an antipyretic and analgesic agent, and

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

				famotidine as a prophylactic for gastritis.
Jun-18-2021 09:24:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Query 10: Answered	Echocardiogram showed normal cardiac anatomy, an no pericardial effusion. Cardiac MRI showed no evidence of acute myocarditis or pericarditis or pericardial effusion. SARS-CoV-2 nucleocapsid antibody was negative. Rhinovirus PCR was positive.
Jun-18-2021 08:50:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Query 9: Answered	ECG showed diffuse ST elevation

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jun-18-2021 08:41:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Juleen Gayed (b) (4)	Query 2: Closed	Response satisfies query
Jun-18-2021 08:40:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Juleen Gayed (b) (4)	Query 11: Opened	Clin: Please include the indication for all the medications administered which were part of the hospital's protocol for managing any paediatric patient presenting with possible myocarditis/pericarditis in an SAE f/u report
Jun-18-2021 08:39:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Juleen Gayed (b) (4)	Query 10: Opened	Clin: Please include all investigation findings, echocardiogram, cardiac MRI, CRP, viral PCR, COVID-19 PCR, and any follow up investigation results in an SAE report f/u

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Jun-18-2021 08:38:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Query 8: Answered	Mother used another child's inhaler. The medical history does not need to be changed.
Jun-18-2021 08:38:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Juleen Gayed (b) (4)	Query 9: Opened	Clin: Please confirm the EKG findings including, which leads had ST elevation and the cardiologist's review and update SAE report accordingly please.
Jun-18-2021 08:37:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Juleen Gayed (b) (4)	Query 8: Opened	Clin: Please update MHx log with any other medical conditions and update SAE report accordingly with any associated medications please.
Jun-18-2021 08:36:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 7: Answered	New Information
Jun-18-2021 08:36:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 6: Answered	New Information

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Jun-18-2021 08:36:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 5: Answered	New Information
Jun-18-2021 08:36:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 4: Answered	New Information
Jun-18-2021 08:36:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 3: Answered	New Information
Jun-18-2021 08:36:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Chest pain of cardiac origin Myopericardit is	New Information
Jun-18-2021 08:32:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Juleen Gayed (b) (4)	Query 7: Opened	Clin: Please clarify as to why the mother had a nebuliser and albuterol and administered it to the participant if he is not a known asthmatic. Update SAE report accordingly please
Jun-18-2021	ACV0PF	Juleen Gayed	Query 6: Opened	Clin: please add if

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

08:31:54 (UTC-05:00) Eastern Time (US & Canada)	EINFP60 00	(b) (4)		there were residual or recurrence of symptoms of cough and rhinorrhoea when the chest symptoms occurred. Update SAE report accordingly please
Jun-18-2021 08:31:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Juleen Gayed (b) (4)	Query 5: Opened	Clin: Please clarify the normal range for the initial troponin value provided (0.27) and the units. Update SAE report accordingly please
Jun-18-2021 08:29:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Juleen Gayed (b) (4)	Query 4: Opened	Clin: Please clarify the presenting symptoms "chest tightness pain", was it chest tightness that then became pain, was it alternating chest tightness and chest pain, was it just chest pain? Update SAE report accordingly please
Jun-18-2021 07:54:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Juleen Gayed (b) (4)	Query 3: Opened	Clin: Please confirm AE term as SAE report states chest pain and d/w PI the hospital diagnosis was acute myopericarditis, please

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

				harmonise diagnosis between InForm and SAE report.
Jun-18-2021 07:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Juleen Gayed (b) (4)	Query 1: Closed	Response satisfies query
Jun-17-2021 11:00:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Query 2: Answered	Changed data per query
Jun-17-2021 10:19:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Query 1: Answered	diagnosis was made based on ECG findings (ST elevation) and increased troponin levels
Jun-16-2021 12:27:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Juleen Gayed (b) (4)	Query 2: Opened	Clin: As per SAE report the participant had symptoms of fever, rhinorrhoea and cough please add these to a potential covid illness visit and follow section 8.13 of the clinical protocol
Jun-16-2021 12:20:06 (UTC-05:00)	ACV0PF EINFP60 00	Juleen Gayed (b) (4)	Query 1: Reissued: Opened	Clin: Please provide details as to how the diagnosis of

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Eastern Time (US & Canada)				pericarditis was made,e.g. clinically, ECG, Echo, MRI etc... and please submit SAE f/u report with this information accordingly
Jun-16-2021 10:56:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Answered	New Information
Jun-16-2021 10:56:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Chest pain of cardiac origin Pericarditis	New Information
Jun-16-2021 10:30:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Please Specify if this CHEST PAIN was Cardiac or Non-Cardiac and update the AE Term accordingly.
Jun-15-2021 12:08:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Chest pain	Initial Entry

4. Start Date Time:

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Jun-15-2021 12:08:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Jun/12/2021 19:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jun-15-2021 12:08:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: NO End Date Time: Jun/13/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jun-18-2021 08:41:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Juleen Gayed (b) (4)	Query 1: Closed	Response satisfies query
Jun-18-2021 08:35:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Answered	Transcription Error

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Jun-18-2021 08:35:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: 3	Transcription Error
Jun-18-2021 08:15:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Juleen Gayed (b) (4)	Query 1: Opened	Clin: Toxicity Grade 4 is life-threatening, please confirm if this correct as life-threatening was not one of the seriousness criteria selected
Jun-15-2021 12:08:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: 4	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
Jun-17-2021 04:37:52	ACV0PF EINFP60	auto query (autoquery)	Query 1: Deleted	Close Auto Query

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00			
Jun-16-2021 10:56:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	For AE Chest pain of cardiac origin Pericarditis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jun-15-2021 12:08:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	For AE Chest pain: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jun-15-2021 12:08:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

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

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Jun-15-2021 12:08:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: NO	Initial Entry
--	-------------------------	------------------------------	--------------------------	---------------

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jul-12-2021 15:21:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Gary Steven Friedman (b) (4)	Query 1: Closed	Query response noted and no further queries indicated
Jun-18-2021 08:46:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Juleen Gayed (b) (4)	Query 2: Closed	Response satisfies query
Jun-18-2021 08:37:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 2: Answered	New Information
Jun-18-2021 08:37:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER	New Information

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

			<i>If Other, specify:</i> Rhinovirus infection	
Jun-18-2021 08:35:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Juleen Gayed (b) (4)	Query 2: Opened	Clin: Please update as SAE f/u report has been submitted with causality of not related
Jun-17-2021 10:14:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Query 1: Answered	Chest X-ray or Chest CT were not done.
Jun-16-2021 11:18:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Gary Steven Friedman (b) (4)	Query 1: Opened	Please confirm that a Chest X-Ray or Chest CT did or did not show evidence of pneumonia or pulmonary embolism
Jun-15-2021 12:08:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Jun-15-2021 12:08:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: NOT APPLICABLE	Initial Entry

II. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jul-12-2021 15:23:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Gary Steven Friedman (b) (4)	Query 1: Closed	Query response accepted. No further queries
Jun-17-2021 10:15:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Query 1: Answered	Anticoagulation treatment was not administered
Jun-16-2021 11:19:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Gary Steven Friedman (b) (4)	Query 1: Opened	Please confirm that oral or parenteral anticoagulation treatment was or was not administered for thromboembolism

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jun-15-2021 12:08:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jul-12-2021 15:22:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Gary Steven Friedman (b) (4)	Query 1: Closed	Query response accepted
Jun-17-2021 10:17:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Query 1: Answered	pericardial effusion was not detected neither on echocardiographic nor MRI examinations of the heart
Jun-16-2021 11:22:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Gary Steven Friedman (b) (4)	Query 1: Opened	Please confirm that pericardial effusion was or was not visualized on

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

				radiographic or echocardiographic examination of the heart/lungs
Jun-15-2021 12:08:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jun-15-2021 12:08:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: RECOVERED/RESOLVE D	Initial Entry

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

Date	Location	User	Value	Reason
Jun-15-2021 12:08:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

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

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Jun-17-2021 04:37:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 2021699328	Initial Entry
--	-------------------------	---------------------	----------------------------------	---------------

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Date	Location	User	Value	Reason
Jun-15-2021 12:11:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Anousheh Behnegar (b) (4)	Form Created	

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Date	Location	User	Value	Reason
Jun-15-2021 12:12:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Anousheh Behnegar (b) (4)	Form Created	

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Date	Location	User	Value	Reason
Jun-15-2021 12:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Anousheh Behnegar (b) (4)	Form Created	

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Date	Location	User	Value	Reason
Jun-15-2021 12:14:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Anousheh Behnegar (b) (4)	Form Created	

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Date	Location	User	Value	Reason
Jun-15-2021 12:15:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Anousheh Behnegar (b) (4)	Form Created	

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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Date	Location	User	Value	Reason
Jun-15-2021 12:15:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Anousheh Behnegar (b) (4)	Form Created	

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Date	Location	User	Value	Reason
Jun-18-2021 09:42:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Anousheh Behnegar (b) (4)	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, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. What is the medication identifier?

Date	Location	User	Value	Reason
Jun-21-2021 12:20:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jun-21-2021 12:18:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry:	Changed Information
Jun-15-2021 12:11:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jun-21-2021 12:20:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jun-21-2021 12:18:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry:	Changed Information
Jun-15-2021 12:11:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

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

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

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, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Jun-21-2021 12:20:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jun-21-2021 12:18:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry:	Changed Information
Jun-15-2021 12:11:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Jun-21-2021 12:20:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jun-21-2021 12:18:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry:	Changed Information
Jun-15-2021 12:11:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: ketorolac 30mg IM	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

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, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Canada)

5. Date:

Date	Location	User	Value	Reason
Jun-21-2021 12:20:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jun-21-2021 12:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry:	Changed Information
Jun-15-2021 12:11:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Jun/12/2021	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

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, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. What is the medication identifier?

Date	Location	User	Value	Reason
Jun-21-2021 12:22:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jun-21-2021 12:21:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry:	New Information
Jun-15-2021 12:12:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 2	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jun-21-2021 12:22:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jun-21-2021 12:21:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry:	New Information
Jun-15-2021 12:12:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

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, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Jun-21-2021 12:22:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jun-21-2021 12:21:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry:	New Information
Jun-15-2021 12:12:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Jun-21-2021 12:22:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jun-21-2021 12:21:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry:	New Information
Jun-15-2021 12:12:48	ACV0PF EINFP60	Anousheh Behnegar	Data Entry: Tylenol 650 mg PO	Transcription Error

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

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, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00	(b) (4)		
Jun-15-2021 12:12:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Tyleno 650 mg PO	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Jun-21-2021 12:22:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jun-21-2021 12:22:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry:	New Information
Jun-15-2021 12:12:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Jun/13/2021	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

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, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. What is the medication identifier?

Date	Location	User	Value	Reason
Jun-21-2021 12:23:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jun-21-2021 12:22:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry:	New Information
Jun-15-2021 12:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 3	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jun-21-2021 12:23:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jun-21-2021 12:22:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry:	New Information
Jun-15-2021 12:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

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, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Jun-21-2021 12:23:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jun-21-2021 12:22:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry:	New Information
Jun-15-2021 12:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Jun-21-2021 12:23:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jun-21-2021 12:22:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry:	New Information
Jun-16-2021 11:02:52	ACV0PF EINFP60	PFETMS Oracle	Query 1: Closed	Discrepancy has been closed.

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

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, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00.InFor mAdapte r.Discrep ancy	(b) (4)		
Jun-16-2021 09:53:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Answered	Transcription Error
Jun-16-2021 09:53:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: diphenhydramine 25 mg PO	Transcription Error
Jun-15-2021 15:48:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00.InFor mAdapte r.Discrep ancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify DYPHENHYDRAMINE 25 MG PO as follows...Should the spelling be DIPHENHYDRAMINE 25 MG PO? If so, update the verbatim term as such. Otherwise clarify and update the term as appropriate or provide reference/label. Thank you.
Jun-15-2021 12:13:40 (UTC-05:00) Eastern Time (US	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: dyphenhydramine 2 5 mg PO	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

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, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

& Canada)

5. Date:

Date	Location	User	Value	Reason
Jun-21-2021 12:23:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jun-21-2021 12:23:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry:	New Information
Jun-15-2021 12:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Jun/13/2021	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

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, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. What is the medication identifier?

Date	Location	User	Value	Reason
Jun-21-2021 12:24:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jun-21-2021 12:23:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry:	New Information
Jun-15-2021 12:14:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 4	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jun-21-2021 12:24:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jun-21-2021 12:23:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry:	New Information
Jun-15-2021 12:14:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

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, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Jun-21-2021 12:24:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jun-21-2021 12:23:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry:	New Information
Jun-15-2021 12:14:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Jun-21-2021 12:24:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jun-21-2021 12:23:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry:	New Information
Jun-15-2021 12:14:22	ACV0PF EINFP60	Anousheh Behnegar	Data Entry: prednisone 30 mg PO BID	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

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, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00	(b) (4)		
--	----	---------	--	--

5. Date:

Date	Location	User	Value	Reason
Jun-21-2021 12:24:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jun-21-2021 12:24:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry:	New Information
Jun-15-2021 12:14:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Jun/13/2021	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

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, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. What is the medication identifier?

Date	Location	User	Value	Reason
Jun-21-2021 12:25:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jun-21-2021 12:24:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry:	New Information
Jun-15-2021 12:15:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 5	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jun-21-2021 12:25:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jun-21-2021 12:24:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry:	New Information
Jun-15-2021 12:15:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

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, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Jun-21-2021 12:25:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jun-21-2021 12:24:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry:	New Information
Jun-15-2021 12:15:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Jun-21-2021 12:25:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jun-21-2021 12:24:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry:	New Information
Jun-15-2021 12:15:26	ACV0PF EINFP60	Anousheh Behnegar	Data Entry: ibuprofen 600 mg PO	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

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, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00	(b) (4)		
---	----	---------	--	--

5. Date:

Date	Location	User	Value	Reason
Jun-21-2021 12:25:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jun-21-2021 12:25:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry:	New Information
Jun-15-2021 12:15:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Jun/13/2021	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

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, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. What is the medication identifier?

Date	Location	User	Value	Reason
Jun-21-2021 12:26:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jun-21-2021 12:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry:	New Information
Jun-15-2021 12:15:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 6	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jun-21-2021 12:26:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jun-21-2021 12:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry:	New Information
Jun-15-2021 12:15:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

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, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Jun-21-2021 12:26:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jun-21-2021 12:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry:	New Information
Jun-15-2021 12:15:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Jun-21-2021 12:26:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jun-21-2021 12:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry:	New Information
Jun-16-2021 11:03:30	ACV0PF EINFP60	PFETMS Oracle	Query 1: Closed	Discrepancy has been closed.

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

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, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00.InFor mAdapte r.Discrep ancy	(b) (4)		
Jun-16-2021 09:50:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Answered	Transcription Error
Jun-16-2021 09:50:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: famotidine 20 mg PO	Transcription Error
Jun-15-2021 15:48:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00.InFor mAdapte r.Discrep ancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify FAMOTADINE 20 MG PO as follows...Should the spelling be FAMOTIDINE 20 MG PO? If so, update the verbatim term as such. Otherwise clarify and update the term as appropriate or provide reference/label. Thank you.
Jun-15-2021	ACV0PF	Anousheh	Data Entry:	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

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, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

12:15:56 (UTC-05:00) Eastern Time (US & Canada)	EINFP60 00	Behnegar (b) (4)	famotadine 20 mg PO	
---	---------------	---------------------	---------------------	--

5. Date:

Date	Location	User	Value	Reason
Jun-21-2021 12:26:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jun-21-2021 12:26:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry:	New Information
Jun-15-2021 12:15:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Jun/13/2021	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

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, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. What is the medication identifier?

Date	Location	User	Value	Reason
Jun-21-2021 12:27:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jun-21-2021 12:27:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry:	New Information
Jun-18-2021 09:42:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 7	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jun-21-2021 12:27:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jun-21-2021 12:27:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry:	New Information
Jun-18-2021 09:42:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

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, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Jun-21-2021 12:27:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jun-21-2021 12:27:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry:	New Information
Jun-18-2021 09:42:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Jun-21-2021 12:27:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jun-21-2021 12:27:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry:	New Information
Jun-18-2021 09:42:24	ACV0PF EINFP60	Anousheh Behnegar	Data Entry: IVIG	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

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, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00	(b) (4)		
--	----	---------	--	--

5. Date:

Date	Location	User	Value	Reason
Jun-21-2021 12:27:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jun-21-2021 12:27:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry:	New Information
Jun-18-2021 09:42:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Jun/13/2021	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Date	Location	User	Value	Reason
Jun-21-2021 12:08:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS -
PROHIBITED - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Date	Location	User	Value	Reason
Jun-21-2021 12:11:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Date	Location	User	Value	Reason
Jun-21-2021 12:13:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Date	Location	User	Value	Reason
Jun-21-2021 12:14:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Date	Location	User	Value	Reason
Jun-21-2021 12:15:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Date	Location	User	Value	Reason
Jun-21-2021 12:16:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. What is the medication identifier?

Date	Location	User	Value	Reason
Jun-25-2021 11:32:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jun-25-2021 11:30:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry:	Deleting data per query
Jun-21-2021 12:08:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jun-25-2021 11:32:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Not Applicable	Initial Entry
Jun-25-2021 11:30:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry:	Deleting data per query
Jun-21-2021 12:09:18 (UTC-05:00)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: CORTICOSTEROIDS	Transcription Error

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Eastern Time (US & Canada)				
Jun-21-2021 12:08:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: CONCOMITANT IMMU NOSUPPRESSIVE THER APY	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Jun-25-2021 11:32:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jun-25-2021 11:30:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry:	Deleting data per query
Jun-21-2021 12:08:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Jun-25-2021 15:23:14 (UTC-05:00)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Eastern Time (US & Canada)				
Jun-25-2021 11:32:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Not Applicable	Initial Entry
Jun-25-2021 11:30:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Answered	Deleting data per query
Jun-25-2021 11:30:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry:	Deleting data per query
Jun-25-2021 10:52:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Reissued:Opened	CLINQUERY2- Thank you for your response. Per CRF Completion Guidelines Section 8.54, details of prohibited medications ONLY should be documented. Please update accordingly.

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

<p>Jun-24-2021 11:11:16 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PF EINFP60 00</p>	<p>Anousheh Behnegar (b) (4)</p>	<p>Query 1: Answered</p>	<p>We are aware this is not a prohibited drug. However, this site does not allow for regular Con. Med. entry. If the sponsor does not want regular Con Meds. to be recorded, we can delete them. Please Advise.</p>
<p>Jun-22-2021 13:10:11 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PF EINFP60 00</p>	<p>(b) (4), (b) (6)</p>	<p>Query 1: Opened</p>	<p>CLINQUERY- Ketorolac is reported, yet medication is not a corticosteroid and does not meet prohibited definition per section 6.5.1 of the protocol. Therefore, please verify it was entered in error.</p>
<p>Jun-21-2021 12:08:14 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PF EINFP60 00</p>	<p>(b) (4), (b) (6)</p>	<p>Data Entry: ketorolac</p>	<p>Initial Entry</p>

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

5. Dose:

Date	Location	User	Value	Reason
Jun-25-2021 11:32:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Not Applicable	Initial Entry
Jun-25-2021 11:30:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry:	Deleting data per query
Jun-21-2021 12:08:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 30	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
Jun-25-2021 11:32:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Not Applicable	Initial Entry
Jun-25-2021 11:31:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry:	Deleting data per query

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Canada)				
Jun-21-2021 12:08:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: mg	Initial Entry

7. Dose Frequency:

Date	Location	User	Value	Reason
Jun-25-2021 11:32:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Not Applicable	Initial Entry
Jun-25-2021 11:31:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry:	Deleting data per query
Jun-21-2021 12:08:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: UNKNOWN	Initial Entry

8. Route:

Date	Location	User	Value	Reason
Jun-25-2021 11:32:23	ACV0PF EINFP60	Anousheh Behnegar	Data Entry: Not Applicable	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00	(b) (4)		
Jun-25-2021 11:31:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry:	Deleting data per query
Jun-21-2021 12:08:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: INTRAMUSCULAR	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Jun-25-2021 11:32:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Not Applicable	Initial Entry
Jun-25-2021 11:31:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry:	Deleting data per query
Jun-21-2021 12:09:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jun/12/2021	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Canada)

10. Ongoing?

Date	Location	User	Value	Reason
Jun-25-2021 11:32:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Not Applicable	Initial Entry
Jun-25-2021 11:32:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry:	Deleting data per query
Jun-21-2021 12:08:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. What is the medication identifier?

Date	Location	User	Value	Reason
Jun-21-2021 12:11:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 2	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jun-21-2021 12:11:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: CORTICOSTEROIDS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Jun-21-2021 12:11:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

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

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Jun-21-2021 12:11:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: prednisone	Initial Entry
--	-------------------------	---------------------	----------------------------------	---------------

5. Dose:

Date	Location	User	Value	Reason
Jun-21-2021 12:11:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 30	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
Jun-21-2021 12:11:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: mg	Initial Entry

7. Dose Frequency:

Date	Location	User	Value	Reason
Jun-21-2021 12:11:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BID	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

8. Route:

Date	Location	User	Value	Reason
Jun-21-2021 12:11:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: ORAL	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Jun-21-2021 12:11:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jun/13/2021	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
Jun-21-2021 12:11:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. What is the medication identifier?

Date	Location	User	Value	Reason
Jun-25-2021 11:34:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jun-25-2021 11:33:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry:	Deleting data per query
Jun-21-2021 12:13:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 3	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jun-25-2021 11:34:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Not Applicable	Initial Entry
Jun-25-2021 11:33:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry:	Deleting data per query
Jun-21-2021 12:13:01	ACV0PF EINFP60	(b) (4), (b) (6)	Data Entry: CONCOMITANT IMMU	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Jun-25-2021 11:34:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jun-25-2021 11:33:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry:	Deleting data per query
Jun-21-2021 12:13:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Jun-25-2021 15:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jun-25-2021 11:34:52	ACV0PF EINFP60	Anousheh Behnegar	Data Entry: Not Applicable	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00	(b) (4)		
Jun-25-2021 11:33:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Answered	Deleting data per query
Jun-25-2021 11:33:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry:	Deleting data per query
Jun-25-2021 10:52:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Reissued:Opened	CLINQUERY2- Thank you for your response. Per CRF Completion Guidelines Section 8.54, details of prohibited medications ONLY should be documented. Please update accordingly.
Jun-24-2021 11:11:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Query 1: Answered	We are aware this is not a prohibited drug. However, this site does not allow for regular Con. Med. entry. If the sponsor does not

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

				want regular Con Meds. to be recorded, we can delete them. Please Advise.
Jun-22-2021 13:33:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY- Ibuprofen is reported on the PROHIBITED CON MED CRF. Please note this medication is not an immunosuppressant and is not required to be listed. Please verify it was entered in error and update CRF accordingly.
Jun-21-2021 12:13:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: ibuprofen	Initial Entry

5. Dose:

Date	Location	User	Value	Reason
Jun-25-2021 11:34:52 (UTC-05:00)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Not Applicable	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Eastern Time (US & Canada)				
Jun-25-2021 11:33:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry:	Deleting data per query
Jun-21-2021 12:13:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 600	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
Jun-25-2021 11:34:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Not Applicable	Initial Entry
Jun-25-2021 11:33:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry:	Deleting data per query
Jun-21-2021 12:13:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: mg	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

7. Dose Frequency:

Date	Location	User	Value	Reason
Jun-25-2021 11:34:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Not Applicable	Initial Entry
Jun-25-2021 11:34:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry:	Deleting data per query
Jun-21-2021 12:13:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: UNKNOWN	Initial Entry

8. Route:

Date	Location	User	Value	Reason
Jun-25-2021 11:34:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Not Applicable	Initial Entry
Jun-25-2021 11:34:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry:	Deleting data per query

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Canada)				
Jun-21-2021 12:13:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: ORAL	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Jun-25-2021 11:34:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Not Applicable	Initial Entry
Jun-25-2021 11:34:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry:	Deleting data per query
Jun-21-2021 12:13:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jun/13/2021	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
Jun-25-2021 11:34:52	ACV0PF EINFP60	Anousheh Behnegar	Data Entry: Not Applicable	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00	(b) (4)		
Jun-25-2021 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry:	Deleting data per query
Jun-21-2021 12:13:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. What is the medication identifier?

Date	Location	User	Value	Reason
Jun-25-2021 11:37:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jun-25-2021 11:36:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry:	Deleting data per query
Jun-21-2021 12:14:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 4	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jun-25-2021 11:37:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Not Applicable	Initial Entry
Jun-25-2021 11:35:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry:	Deleting data per query
Jun-21-2021 12:14:12	ACV0PF EINFP60	(b) (4), (b) (6)	Data Entry: CONCOMITANT IMMU	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Jun-25-2021 11:37:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jun-25-2021 11:36:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry:	Deleting data per query
Jun-21-2021 12:14:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Jun-25-2021 15:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jun-25-2021 11:37:33	ACV0PF EINFP60	Anousheh Behnegar	Data Entry: Not Applicable	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00	(b) (4)		
Jun-25-2021 11:36:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Answered	Deleting data per query
Jun-25-2021 11:36:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry:	Deleting data per query
Jun-25-2021 10:52:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Reissued:Opened	CLINQUERY2- Thank you for your response. Per CRF Completion Guidelines Section 8.54, details of prohibited medications ONLY should be documented. Please update accordingly.
Jun-24-2021 11:12:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Query 1: Answered	We are aware this is not a prohibited drug. However, this site does not allow for regular Con. Med. entry. If the sponsor does not

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

				want regular Con Meds. to be recorded, we can delete them. Please Advise.
Jun-22-2021 13:33:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY- Famotidine is reported on the PROHIBITED CON MED CRF. Please note this medication is not an immunosuppressant and is not required to be listed. Please verify it was entered in error and update CRF accordingly.
Jun-21-2021 12:14:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: FAMOTIDINE	Initial Entry

5. Dose:

Date	Location	User	Value	Reason
Jun-25-2021 11:37:33 (UTC-05:00)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Not Applicable	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Eastern Time (US & Canada)				
Jun-25-2021 11:36:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry:	Deleting data per query
Jun-21-2021 12:14:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 20	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
Jun-25-2021 11:37:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Not Applicable	Initial Entry
Jun-25-2021 11:36:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry:	Deleting data per query
Jun-21-2021 12:14:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: mg	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

7. Dose Frequency:

Date	Location	User	Value	Reason
Jun-25-2021 11:37:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Not Applicable	Initial Entry
Jun-25-2021 11:36:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry:	Deleting data per query
Jun-21-2021 12:14:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: UNKNOWN	Initial Entry

8. Route:

Date	Location	User	Value	Reason
Jun-25-2021 11:37:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Not Applicable	Initial Entry
Jun-25-2021 11:36:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry:	Deleting data per query

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Canada)				
Jun-21-2021 12:14:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: ORAL	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Jun-25-2021 11:37:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Not Applicable	Initial Entry
Jun-25-2021 11:37:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry:	Deleting data per query
Jun-21-2021 12:14:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jun/13/2021	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
Jun-25-2021 11:37:33	ACV0PF EINFP60	Anousheh Behnegar	Data Entry: Not Applicable	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00	(b) (4)		
Jun-25-2021 11:37:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry:	Deleting data per query
Jun-21-2021 12:14:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. What is the medication identifier?

Date	Location	User	Value	Reason
Jun-25-2021 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jun-25-2021 11:38:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry:	Deleting data per query
Jun-21-2021 12:15:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 5	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jun-25-2021 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Not Applicable	Initial Entry
Jun-25-2021 11:38:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry:	Deleting data per query
Jun-21-2021 12:15:33	ACV0PF EINFP60	(b) (4), (b) (6)	Data Entry: CONCOMITANT IMMU	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Jun-25-2021 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jun-25-2021 11:38:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry:	Deleting data per query
Jun-21-2021 12:15:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Jun-25-2021 15:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jun-25-2021 11:39:53	ACV0PF EINFP60	Anousheh Behnegar	Data Entry: Not Applicable	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00	(b) (4)		
Jun-25-2021 11:38:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Answered	Deleting data per query
Jun-25-2021 11:38:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry:	Deleting data per query
Jun-25-2021 10:52:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Reissued:Opened	CLINQUERY2- Thank you for your response. Per CRF Completion Guidelines Section 8.54, details of prohibited medications ONLY should be documented. Please update accordingly.
Jun-24-2021 11:12:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Query 1: Answered	We are aware this is not a prohibited drug. However, this site does not allow for regular Con. Med. entry. If the sponsor does not

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

				want regular Con Meds. to be recorded, we can delete them. Please Advise.
Jun-22-2021 13:35:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY- Diphenhydramine is reported on the PROHIBITED CON MED CRF. Please note this medication is not an immunosuppressant and is not required to be listed. Please verify it was entered in error and update CRF accordingly.
Jun-21-2021 12:15:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: DIPHENHYDRAMIN E	Initial Entry

5. Dose:

Date	Location	User	Value	Reason
Jun-25-2021 11:39:53 (UTC-05:00)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Not Applicable	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Eastern Time (US & Canada)				
Jun-25-2021 11:38:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry:	Deleting data per query
Jun-21-2021 12:15:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 25	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
Jun-25-2021 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Not Applicable	Initial Entry
Jun-25-2021 11:38:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry:	Deleting data per query
Jun-21-2021 12:15:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: mg	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS -
PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

7. Dose Frequency:

Date	Location	User	Value	Reason
Jun-25-2021 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Not Applicable	Initial Entry
Jun-25-2021 11:39:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry:	Deleting data per query
Jun-21-2021 12:15:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: UNKNOWN	Initial Entry

8. Route:

Date	Location	User	Value	Reason
Jun-25-2021 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Not Applicable	Initial Entry
Jun-25-2021 11:39:19 (UTC-05:00) Eastern Time (US &	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry:	Deleting data per query

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Canada)				
Jun-21-2021 12:15:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: ORAL	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Jun-25-2021 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Not Applicable	Initial Entry
Jun-25-2021 11:39:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry:	Deleting data per query
Jun-21-2021 12:15:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jun/13/2021	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
Jun-25-2021 11:39:53	ACV0PF EINFP60	Anousheh Behnegar	Data Entry: Not Applicable	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00	(b) (4)		
Jun-25-2021 11:39:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry:	Deleting data per query
Jun-21-2021 12:15:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. What is the medication identifier?

Date	Location	User	Value	Reason
Jun-25-2021 11:42:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jun-25-2021 11:40:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry:	Deleting data per query
Jun-21-2021 12:16:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 6	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jun-25-2021 11:42:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Not Applicable	Initial Entry
Jun-25-2021 11:40:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry:	Deleting data per query
Jun-21-2021 12:16:24	ACV0PF EINFP60	(b) (4), (b) (6)	Data Entry: CONCOMITANT IMMU	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Jun-25-2021 11:42:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jun-25-2021 11:40:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry:	Deleting data per query
Jun-21-2021 12:16:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Jun-25-2021 15:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jun-25-2021 11:42:01	ACV0PF EINFP60	Anousheh Behnegar	Data Entry: Not Applicable	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00	(b) (4)		
Jun-25-2021 11:40:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Answered	Deleting data per query
Jun-25-2021 11:40:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry:	Deleting data per query
Jun-25-2021 10:52:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Reissued:Ope ned	CLINQUERY2- Thank you for your response. Per CRF Completion Guidelines Section 8.54, details of prohibited medications ONLY should be documented. Please update accordingly.
Jun-24-2021 11:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Query 1: Answered	We are aware this is not a prohibited drug. However, this site does not allow for regular Con. Med. entry. If the sponsor does not

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

				want regular Con Meds. to be recorded, we can delete them. Please Advise.
Jun-22-2021 13:36:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY-Paracetamol is reported on the PROHIBITED CON MED CRF. Please note this medication is not an immunosuppressant and is not required to be listed. Please verify it was entered in error and update CRF accordingly.
Jun-21-2021 12:16:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: PARACETAMOL	Initial Entry

5. Dose:

Date	Location	User	Value	Reason
Jun-25-2021 11:42:01 (UTC-05:00)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Not Applicable	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Eastern Time (US & Canada)				
Jun-25-2021 11:40:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry:	Deleting data per query
Jun-21-2021 12:16:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 650	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
Jun-25-2021 11:42:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Not Applicable	Initial Entry
Jun-25-2021 11:41:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry:	Deleting data per query
Jun-21-2021 12:16:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: mg	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

7. Dose Frequency:

Date	Location	User	Value	Reason
Jun-25-2021 11:42:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Not Applicable	Initial Entry
Jun-25-2021 11:41:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry:	Deleting data per query
Jun-21-2021 12:16:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: UNKNOWN	Initial Entry

8. Route:

Date	Location	User	Value	Reason
Jun-25-2021 11:42:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Not Applicable	Initial Entry
Jun-25-2021 11:41:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry:	Deleting data per query

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Canada)				
Jun-21-2021 12:16:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: ORAL	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Jun-25-2021 11:42:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Not Applicable	Initial Entry
Jun-25-2021 11:41:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry:	Deleting data per query
Jun-21-2021 12:16:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jun/13/2021	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
Jun-25-2021 11:42:01	ACV0PF EINFP60	Anousheh Behnegar	Data Entry: Not Applicable	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00	(b) (4)		
Jun-25-2021 11:41:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry:	Deleting data per query
Jun-21-2021 12:16:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 -
Unscheduled Visit on Apr/21/2021

Form Version: 14-Jan-2021 02:22

Site No: 1223

Subject No: 12231273

Generated By: (b) (4)

Form: DATE OF VISIT - ASYMPTOMATIC
SURVEILLANCE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Apr-26-2021 10:09:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Suzana Mutic (b) (4)	Data Entry: Apr/21/2021	Initial Entry

3. COVID-19 Surveillance Visit:

Date	Location	User	Value	Reason
Apr-26-2021 10:09:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Suzana Mutic (b) (4)	Data Entry: SSWAB_WEEK2	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 -
Unscheduled Visit on Apr/21/2021

Form Version: 10-Oct-2020 15:57

Site No: 1223

Subject No: 12231273

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Apr-26-2021 10:10:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Apr-26-2021 10:10:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Suzana Mutic (b) (4)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Apr-26-2021 10:10:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Apr-26-2021 10:10:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 -
Unscheduled Visit on Apr/21/2021

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

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

				correct as appropriate.
Apr-26-2021 10:10:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Suzana Mutic (b) (4)	Data Entry: YES Date of Collection: Apr/21/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Apr-26-2021 10:10:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Suzana Mutic (b) (4)	Data Entry: Sample ID: AA01556	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Apr-26-2021 10:10:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Suzana Mutic (b) (4)	Data Entry: AA01556	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 2 -
Unscheduled Visit on May/05/2021

Form: DATE OF VISIT - ASYMPTOMATIC
SURVEILLANCE - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
May-06-2021 10:53:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: May/5/2021	Initial Entry

3. COVID-19 Surveillance Visit:

Date	Location	User	Value	Reason
May-06-2021 10:53:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: SSWAB_WEEK4	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 2 -
Unscheduled Visit on May/05/2021

Form Version: 10-Oct-2020 15:57

Site No: 1223

Subject No: 12231273

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
May-06-2021 10:54:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
May-06-2021 10:54:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
May-06-2021 10:54:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
May-06-2021 10:54:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 2 -
Unscheduled Visit on May/05/2021

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

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

				review and correct as appropriate.
May-06-2021 10:54:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: May/5/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
May-06-2021 10:54:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: AA06954	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
May-06-2021 10:54:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: AA06954	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 3 -
Unscheduled Visit on May/19/2021

Form Version: 14-Jan-2021 02:22

Site No: 1223

Subject No: 12231273

Generated By: (b) (4)

Form: DATE OF VISIT - ASYMPTOMATIC
SURVEILLANCE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
May-20-2021 12:35:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: May/19/2021	Initial Entry

3. COVID-19 Surveillance Visit:

Date	Location	User	Value	Reason
May-20-2021 12:35:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: SSWAB_WEEK6	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 3 -
Unscheduled Visit on May/19/2021

Form Version: 10-Oct-2020 15:57

Site No: 1223

Subject No: 12231273

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
May-20-2021 12:37:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
May-20-2021 12:37:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
May-20-2021 12:37:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
May-20-2021 12:37:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 3 -
Unscheduled Visit on May/19/2021

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

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

				review and correct as appropriate.
May-20-2021 12:37:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: May/19/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
May-20-2021 12:37:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: AA01055	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
May-20-2021 12:37:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: AA01055	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:27

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
May-21-2021 08:50:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: May/20/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
May-21-2021 08:50:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FO R ADDITIONAL VACCIN ATION	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231273

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
May-21-2021 14:15:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: May/21/2021	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1223

Subject No: 12231273

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
May-21-2021 14:15:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained May/21/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
May-21-2021 14:16:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: May/21/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
May-21-2021 14:16:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
May-21-2021 14:16:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
May-21-2021 14:18:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
May-21-2021 14:18:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
May-24-2021 10:10:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query
May-24-2021 07:39:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

				review and correct as appropriate.
May-21-2021 14:18:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
May-21-2021 14:18:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: May/21/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
May-24-2021 10:10:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Sample ID: BTFS6C	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
May-24-2021 10:10:18 (UTC-05:00)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: BTFS6C	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

5.b

Date	Location	User	Value	Reason
May-24-2021 10:10:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Sample ID: BTFS6D	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
May-24-2021 10:10:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: BTFS6D	Initial Entry

5.c

Date	Location	User	Value	Reason
May-24-2021 10:10:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Sample ID: BTFS6F	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

5.c Sample ID

Date	Location	User	Value	Reason
May-24-2021 10:10:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: BTFS6F	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
May-21-2021 14:18:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
May-21-2021 14:18:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
May-24-2021 10:08:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query
May-24-2021 07:39:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

				review and correct as appropriate.
May-21-2021 14:18:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
May-21-2021 14:18:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: May/21/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
May-24-2021 10:08:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Sample ID: BN1PSL	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
May-24-2021 10:08:41 (UTC-05:00)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: BN1PSL	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
May-21-2021 14:19:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
May-21-2021 14:19:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
May-21-2021 14:19:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
May-21-2021 14:19:36	ACV0PF EINFP60	(b) (4), (b) (6)	Data Entry: May/21/2021 13:12	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

5. Anatomical Location:

Date	Location	User	Value	Reason
May-21-2021 14:19:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
May-21-2021 14:19:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
May-21-2021 14:19:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

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

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

May-21-2021 14:19:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 30.0	Initial Entry
--	-------------------------	-------------------------	----------------------------	---------------

9. Unit:

Date	Location	User	Value	Reason
May-21-2021 14:19:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
May-21-2021 14:19:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	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
May-21-2021 14:19:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231273

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Jun-10-2021 12:54:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jun/10/2021	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jun-10-2021 12:54:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jun-10-2021 12:54:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jun-15-2021 10:15:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jun-11-2021 06:53:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

				appropriate.
Jun-10-2021 12:54:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jun-10-2021 12:54:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jun/10/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jun-15-2021 10:15:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Sample ID: BN1PT0	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jun-15-2021 10:15:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: BN1PT0	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1223

Subject No: 12231273

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jun-10-2021 12:55:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jun-10-2021 12:55:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jun-10-2021 12:55:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Jun-10-2021 12:55:16 (UTC-05:00) Eastern Time (US &	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jun/10/2021 09:58	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Canada)

5. Anatomical Location:

Date	Location	User	Value	Reason
Jun-10-2021 12:55:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jun-10-2021 12:55:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jun-10-2021 12:55:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jun-10-2021 12:55:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

9. Unit:

Date	Location	User	Value	Reason
Jun-10-2021 12:55:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jun-10-2021 12:55:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	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
Jun-10-2021 12:55:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231273

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Jul-09-2021 10:52:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jul/9/2021	Initial Entry

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1223

Subject No: 12231273

Generated By: (b) (4)

Form: CONTACT OUTCOME - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Contact Type:

Date	Location	User	Value	Reason
Jul-09-2021 10:53:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Jul-09-2021 10:53:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Contact: Jul/9/2021	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit:
FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit
Trail History

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Jul-13-2021 15:20:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Query 1: Closed	Response satisfies query
Jul-13-2021 09:20:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Answered	Initial Entry
Jul-13-2021 09:20:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: Jul/9/2021	Initial Entry
Jul-12-2021 11:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	CLINQUERY: Per Guidelines, If the Participant receives all vaccinations and completes the follow-up visit procedures within the 1-month post

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit:
FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit
Trail History

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

				vaccination period, report the status as COMPLETED and with same Date as V103 Month 1.
--	--	--	--	--

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jul-13-2021 09:20:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: OPEN LABEL TREATMENT	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jul-13-2021 09:20:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Data Entry: COMPLETED	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Mar-02-2021 11:56:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Jan-09-2021 11:56:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Jan-09-2021 11:53:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Jun-17-2021 04:39:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jun-15-2021 12:18:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Anousheh Behnegar (b) (4)	Query 1: Answered	Changed data per query
Jun-15-2021	ACV0PF	(b) (4), (b) (6)	Query 1: Opened	SAE

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (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: 12231273

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

07:32:55 (UTC-05:00) Eastern Time (US & Canada)	EINFP60 00	(b) (4), (b) (6)		RECON:AER#2021699328 chest pain (onset date:12Jun2021)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Mar-05-2021 08:27:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Mar/3/2021	Transcription Error
Mar-02-2021 11:56:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Mar/2/2021	Initial Entry
Jan-09-2021 11:56:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Jan/9/2021	Initial Entry
Jan-09-2021 11:53:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Jan/9/2021	Initial Entry

090177e19891a037\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1223

Subject No: 12231273

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit
Trail History

Form Status: Data Complete, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Casebook Signature

Date	Location	User	Value	Reason
Mar-19-2021 21:55:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Jessica Tuan (b) (4)	Data Entry: Click Here to Enable	Initial Entry