

Header Text: C4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Cohort Selection

DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.

1.	Select appropriate response - Protocol version	24 JUL 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

Header Text: C4591001

Visit: COHORT_SELECTION

Form: 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: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/14/2020
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Header Text: C4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[12231166]
2.	Birth Date:	(b) (6) 1978
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	BLACK OR AFRICAN AMERICAN
6.	Racial Designation:	

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/14/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[Form Comments](#)

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Sep/14/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hypertension]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Gout]
	Start Date:	UNK/UNK/2014
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[left frontal stroke]
	Start Date:	Jan/UNK/2019
	Ongoing:	NO End Date: Jan/UNK/2019
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Diabetes Mellitus]
	Start Date:	UNK/UNK/2014
	Ongoing:	YES

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Sleep Apnea]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[glaucoma]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Depression]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Chronic Kidney Disease]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Cerebellar Stroke]
	Start Date:	UNK/UNK/2017
	Ongoing:	NO End Date: UNK/UNK/2017

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/14/2020
2.	Weight:	[125.7]
3.	Unit:	kg
4.	Height:	[180.0]
5.	Unit:	cm
6.	Body Mass Index:	[38.8]

Vital Signs Details

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

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Sep/14/2020
2.	Randomization Number:	[89458]
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: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/14/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPXXKS]
5.b	Sample ID	[BPXXKT]
5.c	Sample ID	[BPXXKV]

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/14/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPXXKR]
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090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/14/2020 12:56
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
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090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Oct/7/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Oct/7/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.1]
	Unit:	F
	Temperature Location:	FOREHEAD

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/7/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR37KP]
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090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/7/2020 15:22
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

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Nov/6/2020
2.	Erroneous Visit	

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: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/6/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPW1RP]
5.b	Sample ID	[BPW1RR]
5.c	Sample ID	[BPW1RS]

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V4_MONTH6_L

Form: 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: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V5_MONTH12_L

Form: 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: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V6_MONTH24_L

Form: 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: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled **Form:** DATE OF VISIT - ILLNESS ONSET
Visit

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 Visit

Form Version: 28-Mar-2021 02:35

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

Signs and Symptoms

1.	Date of Assessment:	//
2.	Date of First Symptom Started:	//
3.	Symptoms Ongoing?	

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

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

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF Visit

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB Visit

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** HEALTH CARE UTILIZATION

Form Version: 28-Mar-2021 02:23

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

Health Care Utilization

1.	Physician or Healthcare Professional:	
	Occurrence of Visits or Contacts:	

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?	
----	----------------------------------------------------------------------	--

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

Illness Details

1.	Category of Clinical Event:	
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	
3.	Toxicity Grade:	

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: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Status: Not Started

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: Unplanned - New Unscheduled Visit

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

Unplanned Assessments

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

Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Nov/6/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

Disposition - Follow-Up

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

Header Text: C4591001

Visit: POT_COVID_REPEAT_SWAB - New **Form:** DATE OF VISIT - REPEAT SWAB
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: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

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

Header Text: C4591001

Visit: POT_COVID_REPEAT_SWAB - New **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB
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: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VITAL SIGNS - TEMP

Form Version: 28-Mar-2021 02:28

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

Vital Signs

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

Vital Signs Details

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

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form: 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: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

Vaccination

1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

Contact Outcome

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

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 6

Form Version: 10-Oct-2020 16:01

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

Contact Outcome

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

Header Text: C4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

Informed Consent - Asymptomatic Surveillance

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

Header Text: C4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Status: Not Started

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2
----	-----------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------

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: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	exacerbation of gout in shoulder	Oct/4/2020 08:00	YES	Repeating Pages
2.	ADVERSE EVENT	2	hypertensive urgency	Oct/28/2020 22:00	NO End Date Time: Nov/5/2020 03:40	Repeating Pages

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[exacerbation of gout in shoulder]
4.	Start Date Time:	Oct/4/2020 08:00
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [food and medical history]

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[hypertensive urgency]
4.	Start Date Time:	Oct/28/2020 22:00
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/5/2020 03:40
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [hypertension]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020437800]

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[Back to Form](#)

Medication Error

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

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Concomitant Medications

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

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[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.	Dose:	[]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
10.	Ongoing?	

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[Back to Form](#)

Radiation Treatment

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

Header Text: C4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[Back to Form](#)

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

Header Text: C4591001

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

- Unscheduled

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

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

Form Version: 20-Feb-2021 02:20

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

Booster Dose Trigger Form

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

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Feb/19/2021
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: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

Withdrawal Of Consent

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

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

Death Details

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

Cause of Death

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

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Nov/6/2020

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Jessica Tuan	Approved	Mar-19-2021 21:07:43 (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.

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-14-2020 14:42:17 (UTC-05:00) Eastern Time (US & Canada)	(b)(4),(b)(6)	Not Applicable

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Jessica Tuan	Approved	Mar-19-2021 21:07:43 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

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

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

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

(b) (6)	N/A	Feb-22-2021 13:24:51 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Jessica Tuan	Approved	Nov-12-2020 16:01:46 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

(b) (6)	N/A	Nov-11-2020 14:02:13 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

Affidavit:

N/A

Jessica Tuan	Approved	Nov-10-2020 15:14:19 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-14-2020 14:40:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-14-2020 14:40:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[Back to Form](#)

I. Consent Was:

Date	Location	User	Value	Reason
Sep-14-2020 14:41:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: OBTAINED Date Written Consent Obtain ed Sep/14/2020	Initial Entry

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Sep-14-2020 14:40:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12231166	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-14-2020 14:40:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1978	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-14-2020 14:41:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-14-2020 14:41:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NOT HISPANIC OR LATINO (A) OR OF SPANISH ORIGI N	Initial Entry

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

Date	Location	User	Value	Reason
Sep-14-2020 14:41:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BLACK OR AFRICAN AME RICAN	Initial Entry

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[Back to Form](#)

1. Date of Visit

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

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

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

2. Phase of Disposition:

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

3. Status:

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

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[Back to Form](#)

1.a

Date	Location	User	Value	Reason
Sep-14-2020 14:44:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: hypertension Start Date: UNK/UNK/ 2015 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-14-2020 14:44:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-14-2020 14:44:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: hypertension	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Sep-14-2020 14:44:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: UNK/UNK/2015	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Sep-14-2020 14:44:01 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (6)	Data Entry: YES	Initial Entry

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

Time (US & Canada)

(b) (4)

1.b

Date	Location	User	Value	Reason
Oct-27-2020 16:38:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History: Gout Term: Start Date: UNK/UNK/ 2014 Ongoing: YES	Initial Entry

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

1.b Line/MH Number:

Date	Location	User	Value	Reason
Oct-27-2020 16:38:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Oct-27-2020 16:38:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Gout	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Nov-11-2020 14:45:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Appreciate the prompt response. Thank you.
Nov-11-2020 14:08:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 1: Answered	Changed data per query
Nov-11-2020 02:45:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Opened	Per case narrative, the subject has additional Med Hx of DM, Sleep apnea, glaucoma, depression and Chronic kidney disease not recorded on CRF. Please verify/update accordingly.
Nov-10-2020 18:58:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Candidate	Per case narrative, the subject has additional Med Hx of DM, Sleep apnea, glaucoma,

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

				depression and Chronic kidney disease not recorded on CRF. Please verify/update accordingly.
Oct-27-2020 16:38:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: UNK/UNK/2014	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Oct-27-2020 16:38:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Nov-11-2020 14:02:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Term: left frontal stroke Start Date: Jan/UNK/2019 Ongoing: NO End Date: Jan/UNK/2019	Initial Entry

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

I.c Line/MH Number:

Date	Location	User	Value	Reason
Nov-11-2020 14:02:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Nov-11-2020 14:02:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: left frontal stroke	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Nov-11-2020 14:02:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Jan/UNK/2019	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Nov-11-2020 14:02:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO End Date: Jan/UNK/2019	Initial Entry

I.d

Date	Location	User	Value	Reason
Nov-11-2020 14:03:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History Diabetes Mel Term: litus Start Date: UNK/UNK/2 014	Initial Entry

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

			Ongoing:	YES
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I.d Line/MH Number:

Date	Location	User	Value	Reason
Nov-11-2020 14:03:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Nov-11-2020 14:03:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Diabetes Mellitus	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Nov-11-2020 14:03:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: UNK/UNK/2014	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Nov-11-2020 14:03:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES	Initial Entry

I.e

Date	Location	User	Value	Reason
Nov-11-2020 14:03:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Term: Sleep Apnea Start Date: UNK/UNK/ 2018	Initial Entry

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

			Ongoing:	YES	
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I.e Line/MH Number:

Date	Location	User	Value	Reason
Nov-11-2020 14:03:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Nov-11-2020 14:03:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sleep Apnea	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Nov-11-2020 14:03:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: UNK/UNK/2018	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Nov-11-2020 14:03:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Nov-11-2020 14:05:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 6 Medical History: glaucoma Term: Start Date: UNK/UNK/ 2019	Initial Entry

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

			Ongoing:	YES	
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If Line/MH Number:

Date	Location	User	Value	Reason
Nov-11-2020 14:05:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Nov-11-2020 14:05:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: glaucoma	Initial Entry

If Start Date:

Date	Location	User	Value	Reason
Nov-11-2020 14:05:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: UNK/UNK/2019	Initial Entry

If Ongoing:

Date	Location	User	Value	Reason
Nov-11-2020 14:05:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES	Initial Entry

I.g

Date	Location	User	Value	Reason
Nov-11-2020 14:05:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 7 r: Medical History: Depression Term: Start Date: UNK/UNK/ 2018	Initial Entry

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

			Ongoing:	YES	
--	--	--	-----------------	-----	--

I.g Line/MH Number:

Date	Location	User	Value	Reason
Nov-11-2020 14:05:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

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

Date	Location	User	Value	Reason
Nov-11-2020 14:05:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Depression	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Nov-11-2020 14:05:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: UNK/UNK/2018	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Nov-11-2020 14:05:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES	Initial Entry

I.h

Date	Location	User	Value	Reason
Nov-11-2020 14:06:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 8 ber: Medical Histor Chronic Kidne y Term: y Disease Start Date: UNK/UNK/20 18	Initial Entry

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

			Ongoing: YES	
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1.h Line/MH Number:

Date	Location	User	Value	Reason
Nov-11-2020 14:06:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

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

Date	Location	User	Value	Reason
Nov-11-2020 14:06:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Chronic Kidney Disease	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Nov-11-2020 14:06:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: UNK/UNK/2018	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Nov-11-2020 14:06:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES	Initial Entry

1.i

Date	Location	User	Value	Reason
Nov-11-2020 14:07:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numb 9 er: Medical Histor Cerebellar Stro y Term: ke Start Date: UNK/UNK/20 17	Initial Entry

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

			Ongoing: NO End Date: UNK/UNK /2017	
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1.i Line/MH Number:

Date	Location	User	Value	Reason
Nov-11-2020 14:07:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

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

Date	Location	User	Value	Reason
Nov-11-2020 14:07:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Cerebellar Stroke	Initial Entry

1.i Start Date:

Date	Location	User	Value	Reason
Nov-11-2020 14:07:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: UNK/UNK/2017	Initial Entry

1.i Ongoing:

Date	Location	User	Value	Reason
Nov-11-2020 14:07:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO End Date: UNK/UNK/2017	Initial Entry

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Sep-14-2020 14:45:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sep/14/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-14-2020 14:45:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: 125.7	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-14-2020 14:45:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-14-2020 14:45:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: 180.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-14-2020 14:45:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
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090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

Sep-14-2020 14:45:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 38.8	Initial Entry
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7.a

Date	Location	User	Value	Reason
Sep-14-2020 14:45:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Record Identifier: r:: Temperature: 98.1 Temperature Unit: Temperature Location: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-14-2020 14:45:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-14-2020 14:45:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: 98.1	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-14-2020 14:45:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
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090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

Sep-14-2020 14:45:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: ORAL CAVITY	Initial Entry
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[Back to Form](#)

1. Randomization Date :

Date	Location	User	Value	Reason
Sep-14-2020 14:46:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sep/14/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-14-2020 14:46:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: 89458	Initial Entry

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Sep-14-2020 14:46:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-14-2020 14:46:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-16-2020 08:39:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-15-2020 01:26:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-14-2020 14:46:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-14-2020 14:46:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES Date of Collection:	Initial Entry

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

			Sep/14/2020	
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5.a

Date	Location	User	Value	Reason
Sep-16-2020 08:39:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sample ID: BPXXKS	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-16-2020 08:39:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: BPXXKS	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-16-2020 08:39:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sample ID: BPXXKT	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-16-2020 08:39:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: BPXXKT	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-16-2020 08:39:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sample ID: BPXXKV	Initial Entry

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sample ID

Date	Location	User	Value	Reason
Sep-16-2020 08:39:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: BPXXKV	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Sep-14-2020 14:47:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-14-2020 14:47:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-16-2020 08:24:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-15-2020 01:26:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-14-2020 14:47:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-14-2020 14:47:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES Date of Collection:	Initial Entry

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

			Sep/14/2020	
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5.a

Date	Location	User	Value	Reason
Sep-16-2020 08:24:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sample ID: BPXXKR	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-16-2020 08:24:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: BPXXKR	Initial Entry

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-14-2020 16:26:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-14-2020 16:26:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-14-2020 16:26:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-14-2020 16:26:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sep/14/2020 12:56	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-14-2020 16:26:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
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090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

Sep-14-2020 16:26:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: LEFT	Initial Entry
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7. Route:

Date	Location	User	Value	Reason
Sep-14-2020 16:26:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-14-2020 16:26:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-14-2020 16:26:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES	Initial Entry

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[Back to Form](#)

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-14-2020 14:47:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO - REACTOGENICITY E- DIARY NOT COLLECTED F OR THIS SUBJECT	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Oct-07-2020 16:38:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Oct/7/2020	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Oct-07-2020 16:39:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Oct/7/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-07-2020 16:39:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Record Identifier 1 : Temperature: 97.1 Temperature Uni F t: Temperature Loc FOREHE ation:: AD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-07-2020 16:39:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Oct-07-2020 16:39:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: 97.1	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Oct-07-2020 16:39:39 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (6)	Data Entry: F	Initial Entry

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

Time (US & Canada)	(b) (4)
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2.a Temperature Location:

Date	Location	User	Value	Reason
Oct-07-2020 16:39:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: FOREHEAD	Initial Entry

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: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Oct-07-2020 16:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-07-2020 16:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-12-2020 12:10:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-08-2020 03:29:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-07-2020 16:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-07-2020 16:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES Date of Collection:	Initial Entry

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

			Oct/7/2020	
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5.a

Date	Location	User	Value	Reason
Oct-12-2020 12:10:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sample ID: BR37KP	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-12-2020 12:10:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: BR37KP	Initial Entry

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-07-2020 16:41:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Oct-07-2020 16:41:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-07-2020 16:41:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Oct-07-2020 16:41:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Oct/7/2020 15:22	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-07-2020 16:41:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
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090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

Oct-07-2020 16:41:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: RIGHT	Initial Entry
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7. Route:

Date	Location	User	Value	Reason
Oct-07-2020 16:41:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-07-2020 16:41:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 16:41:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES	Initial Entry

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Nov-06-2020 14:38:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Nov/6/2020	Initial Entry

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Nov-06-2020 14:38:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-06-2020 14:38:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-08-2020 09:53:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-07-2020 02:26:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-06-2020 14:38:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-06-2020 14:38:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES Date of Collection:	Initial Entry

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

			Nov/6/2020	
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5.a

Date	Location	User	Value	Reason
Nov-08-2020 09:53:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sample ID: BPW1RP	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-08-2020 09:53:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: BPW1RP	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-08-2020 09:53:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sample ID: BPW1RR	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-08-2020 09:53:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: BPW1RR	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-08-2020 09:54:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sample ID: BPW1RS	Initial Entry

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sample ID

Date	Location	User	Value	Reason
Nov-08-2020 09:54:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: BPW1RS	Initial Entry

Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Nov-06-2020 14:39:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Nov/6/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Nov-06-2020 14:39:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-06-2020 14:39:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: COMPLETED	Initial Entry

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Feb-22-2021 13:24:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Feb/19/2021	Initial Entry

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Feb-22-2021 13:25:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-22-2021 13:25:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-22-2021 13:25:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-07-2020 16:44:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-06-2020 14:44:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Oct-07-2020 16:44:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-07-2020 16:44:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-17-2020 10:41:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Closed	Response satisfies query
Dec-16-2020 14:20:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 2: Answered	Subject had a COVID 19 test on 28OCT2020 and the result was negative. This will be added to an updated SAE form.
Nov-19-2020 14:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Opened	As per the request of our Data Monitoring Committee, please include in a follow-up SAE form whether COVID testing was conducted during hospitalization for HTN – yes/no including not

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

				available/not performed. If testing was performed, include the results.
Oct-28-2020 10:10:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Closed	Response satisfies query
Oct-27-2020 16:40:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Answered	Gout added to medical history
Oct-20-2020 13:32:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Opened	ClinQuery: Please advise as Medical History does not reflect history of Gout. Please update Medical History accordingly.
Oct-07-2020 16:44:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: exacerbation of gout in shoulder	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-07-2020 16:44:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Oct/4/2020 08:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-28-2020 10:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Closed	Response satisfies query
Oct-27-2020 16:41:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Answered	Original value is correct

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

Oct-08-2020 14:01:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Opened	ClinQuery: please advise, is this event still ongoing, else provide end date.
Oct-07-2020 16:44:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-07-2020 16:44:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-07-2020 16:44:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Oct-07-2020 16:44:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-28-2020	ACV0PFEINFP6000	(b) (6)	Query 1	Closed as MH

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

04:54:14 (UTC-05:00) Eastern Time (US & Canada)		(b) (4)	: Closed	data updated.
Oct-27-2020 16:42:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1 : Answered	Changed data per query
Oct-08-2020 08:11:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1 : Opened	Please review "If not related to study treatment other" field, the following text was indicated in the comment field [food and medical history]. Any symptoms, AEs or other key data should be collected on the appropriate page. Please review and update as necessary. (b) (4)
Oct-07-2020 16:44:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: NOT RELATED If Not	Initial Entry

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

			Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> food and medicinal history
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-07-2020 16:44:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
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090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

Oct-07-2020 16:44:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-07-2020 16:44:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 16:44:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NOT RECOVERED/NOT RE SOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 16:44:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Nov-06-2020 14:44:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-06-2020 14:44:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-17-2020 13:25:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Closed	Response satisfies query
Nov-17-2020 09:56:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 2: Answered	Subject only had hypertensive urgency. No other symptoms.
Nov-13-2020 17:09:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Opened	Per narrative, "the subject reported he was in a fight after getting robbed." Kindly verify/update if there are any additional AEs that need to be reported. Thank you.
Nov-08-2020 16:16:08 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (6)	Query 1: Closed	Response satisfies query

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

Time (US & Canada)		(b) (4)		
Nov-08-2020 10:14:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-08-2020 10:14:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (4), (b)(6)	Data Entry: hypertensive urgency	Transcription Error
Nov-07-2020 13:24:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Opened	SAE reports Hypertensive Urgency. Please confirm if AE term is the same.
Nov-06-2020 14:46:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: hypertension urgency	New Information
Nov-06-2020 14:44:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: hypertension	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-06-2020 14:44:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Oct/28/2020 22:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-06-2020 14:44:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO End Date Time: Nov/5/2020 03:40	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

Nov-06-2020 14:44:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: 2	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Nov-09-2020 04:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Nov-09-2020 04:51:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Query 1: Closed	Response satisfies query
Nov-08-2020 10:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	For AE hypertensive urgency: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-08-2020 10:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-08-2020 10:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES Is this serious event as sociated with congenit al anomaly or birth de fect?	Transcription Error

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

			NO Did this serious event result in death?	
			NO Did this serious event require or prolong hospitalization?	
			YES Did this serious event result in persistent or significant disability/incapacity?	
			NO Is this serious event life threatening?	
			NO Other medically important serious event	
			NO	
Nov-07-2020 11:56:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Opened	SAE RECON:AER#2020437800 Hypertensive urgency(onset date:28Oct2020)was reported as serious in Safety database but non serious in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Nov-06-2020 14:44:59	ACV0PFEINFP6000	(b)(6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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

(b) (4)

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

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

Date	Location	User	Value	Reason
Nov-06-2020 14:44:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-06-2020 14:44:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NOT RELATED If Not Related to study treat ment(s), this event is due to: OTHER If Other, specify: hypertension	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-06-2020 14:44:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-06-2020 14:44:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

Date	Location	User	Value	Reason
Nov-06-2020 14:44:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-06-2020 14:44:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Nov-06-2020 14:44:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Nov-09-2020 04:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Data Entry: 2020437800	Initial Entry

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[Back to Form](#)

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-22-2021 13:25:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Feb/19/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-22-2021 13:25:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATI ON	Initial Entry

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231166

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Nov-06-2020 14:39:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-14-2020 14:46:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-14-2020 14:42:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Nov 06 2020 14 39 33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry Nov/6/2020	Initial Entry
Sep-14-2020 14:46:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/14/2020	Initial Entry
Sep-14-2020 14:42:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/14/2020	Initial Entry

090177e196ae301d\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231166

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Casebook Signature

Date	Location	User	Value	Reason
Nov-10-2020 15:14:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Data Entry: Click Here to Enable	Initial Entry