

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:55

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: COHORT_SELECTION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Cohort Selection

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

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

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/16/2020
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Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: DEMOGRAPHY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[12231181]
2.	Birth Date:	(b) (6)/1972
3.	Sex:	MALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: C4591001	Form: DATE OF VISIT
Visit: V1_DAY1_VAX1_L	Form Status: Data Complete, Locked, Frozen, Verified
Form Version: 22-Apr-2020 21:02	Site Name: (1223) Yale New Haven Medical Center
Site No: 1223	Subject Initials: ---
Subject No: 12231181	Generated Time (GMT): 29-Mar-2021 13:30
Generated By: (b) (4)	

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Sep/16/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable _____
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Exclusion Criteria Met

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

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1223

Subject No: 12231181

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/16/2020
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: 12231181

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:	[migraines headaches]
	Start Date:	Dec/UNK/2011
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[diabetes type I]
	Start Date:	UNK/UNK/1989
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[left ventricular hypertrophy]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[peripheral neuropathy]
	Start Date:	UNK/UNK/2011
	Ongoing:	YES
1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hypothyroidism]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Barrett's esophagus]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231181

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.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[abnormal central nervous system vascular]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1223

Subject No: 12231181

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/16/2020
2.	Weight:	[226.6]
3.	Unit:	LB
4.	Height:	[70.5]
5.	Unit:	in
6.	Body Mass Index:	[32.1]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.7]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001
Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:03
Site No: 1223
Subject No: 12231181
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/16/2020
2.	Randomization Number:	[91293]
3.	Randomization Group:	[]

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/16/2020
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	[BPXXM8]
5.b	Sample ID	[BPXXM9]
5.c	Sample ID	[BPXXMB]

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231181

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/16/2020
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	[BPXXM7]
-----	-----------	----------

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1223

Subject No: 12231181

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/16/2020 13:00
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

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1223

Subject No: 12231181

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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Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231181

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: 12231181

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:	[98.0]
	Unit:	F
	Temperature Location:	FOREHEAD

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231181

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	[BPW1N4]
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090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1223

Subject No: 12231181

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 12:36
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

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231181

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	Nov/5/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/5/2020
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	[BR375W]
5.b	Sample ID	[BR375X]
5.c	Sample ID	[BPW1PX]

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231181

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_ILL - New Unscheduled Visit

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 28-Mar-2021 02:35

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231181

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:	[]
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Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231181

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

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: 12231181

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: C4591001

Visit: 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: 12231181

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:	[]
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Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	
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090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (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: 12231181

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 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT
on Mar/09/2021

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231181

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	Mar/9/2021	
2.	Erroneous Visit	ERRONEOUS VISIT	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	Not Applicable	Comments
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090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
on Mar/09/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231181

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

S.a	Sample ID	[BRJ4L2]
S.b	Sample ID	[BRJ4L3]
S.c	Sample ID	[BRJ4L4]
S.d	Sample ID	[BRV2Z9]
S.e	Sample ID	[BRV2ZB]
S.f	Sample ID	[]
S.g	Sample ID	[]

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231181

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Repeat Swab		
3.	COVID-19 Repeat Swab:	

Header Text: C4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231181

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: C4591001

Visit: Unplanned - 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: 12231181

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: 12231181

Subject Initials: ---

Generated By: (b) (4)

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

Unplanned Assessments

1.	Assessments	
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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: 12231181

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Nov/5/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

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: 12231181

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: 12231181

Subject Initials: ---

Generated By: (b) (4)

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

Vital Signs

1.	Date:	//
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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: 12231181

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?	

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (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: 12231181

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	Form: CONTACT OUTCOME - MONTH 6
Visit: Unplanned Vaccination - Unscheduled	Form Status: Not Started
Form Version: 10-Oct-2020 16:01	Site Name: (1223) Yale New Haven Medical Center
Site No: 1223	Subject Initials: ---
Subject No: 12231181	Generated Time (GMT): 29-Mar-2021 13:30
Generated By: (b) (4)	

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

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

Disposition - Follow-Up

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

Header Text: C4591001

Visit: 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: 12231181

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	Dec/18/2020
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

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231181

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	---

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231181

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	Dec/20/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Dec/20/2020
----	--------------	--

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:30

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation /Death :	Dec/20/2020
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/20/2020
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	[BPW8XC]
5.b	Sample ID	[BPW8XD]
5.c	Sample ID	[BPW8XF]
5.d	Sample ID	[BRV2MZ]
5.e	Sample ID	[BRV2N0]

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231181

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: Dec/20/2020
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	[BPW8XG]
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090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Dec/20/2020 10:11
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231181

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	Jan/8/2021
2.	Erroneous Visit	

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231181

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: Jan/8/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPW90V]
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Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/8/2021 10:02
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: CONTACT OUTCOME

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](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Feb/5/2021
3.	Comments:	[]

Header Text: C4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

Contact Outcome

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

Header Text: C4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

Contact Outcome

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

Header Text: C4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231181

Subject Initials: ---

Generated By: (b) (4)

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Feb/5/2021	Comments
2.	Phase of Disposition:	OPEN LABEL TREATMENT	Comments
3.	Status:	COMPLETED	Comments
4.	Specify Status:	[]	Comments

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: 12231181

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	injection site pain	Jan/9/2021 09:00	NO End Date Time: Jan/11/2021 09:00	Repeating Pages
2.	ADVERSE EVENT	2	generalized weakness	Jan/9/2021 09:00	NO End Date Time: Jan/11/2021 09:00	Repeating Pages
3.	ADVERSE EVENT	3	abdominal pain	Jan/31/2021 UNK: UNK	YES	Repeating Pages
4.	ADVERSE EVENT	4	Submandibular lymphadenopathy	Feb/1/2021 UNK:UNK	YES	Repeating Pages

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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Adverse Event Report

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

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

15.	Serious Adverse Event Number: For Pfizer Use Only	[]
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090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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Adverse Event Report

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

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

15.	Serious Adverse Event Number: For Pfizer Use Only	[]
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090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[abdominal pain]
4.	Start Date Time:	Jan/31/2021 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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Adverse Event Report

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

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (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: 12231181

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: 12231181

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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Medication Error

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

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (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: 12231181

Subject Initials: ---

Generated By: (b) (4)

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

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	influenza vaccine	Oct/30/2020	Repeating Pages

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Concomitant Medications

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[influenza vaccine]
5.	Date:	Oct/30/2020

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (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: 12231181

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: 12231181

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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Concomitant Medications

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

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (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: 12231181

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: 12231181

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: 12231181

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: 12231181

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

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

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231181

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 :	Dec/18/2020
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

Withdrawal Of Consent

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

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

Death Details

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

Cause of Death

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

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231181

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/5/2020

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231181

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 21:15:20 (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.

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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Item	Date	User	Comment
Form	Sep-16-2020 14:53:14 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_CONVA 1

Form Version: 22-Apr-2020 21:04

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: DATE OF VISIT - ILLNESS CONVALESCENT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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Item	Date	User	Comment
3	Mar-11-2021 14:21:08 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231181

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
3	Mar-10-2021 16:48:46 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_CONVA 1

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231181

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
4	Mar-12-2021 09:02:18 (UTC-05:00) Eastern Time (US & Canada)	Jessica Tuan (b) (4)	Not Applicable

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231181

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Dec-20-2020 11:10:48 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT - Comments

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231181

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Mar-02-2021 15:40:08 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
Form	Jan-28-2021 11:26:54 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	data entered in error Not Applicable

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: FURTHER_VACCINATION_EOT

Form Version: 10-Dec-2020 02:29

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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Item	Date	User	Comment
1	Mar-02-2021 15:40:08 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
1	Jan-28-2021 11:26:54 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	data entered in error Not Applicable

Header Text: C4591001

Visit: FURTHER_VACCINATION_EOT

Form Version: 10-Dec-2020 02:29

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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Item	Date	User	Comment
2	Mar-02-2021 15:40:08 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
2	Jan-28-2021 11:26:54 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	data entered in error Not Applicable

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: FURTHER_VACCINATION_EOT

Form Version: 10-Dec-2020 02:29

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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Item	Date	User	Comment
3	Mar-02-2021 15:40:08 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
3	Jan-28-2021 11:26:54 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	data entered in error Not Applicable

Header Text: C4591001

Visit: FURTHER_VACCINATION_EOT

Form Version: 10-Dec-2020 02:29

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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Item	Date	User	Comment
4	Mar-02-2021 15:40:08 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
4	Jan-28-2021 11:26:54 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	data entered in error 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: 12231181

Subject Initials: ---

Generated By: (b) (4)

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

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Jessica Tuan	Approved	Mar-19-2021 21:15:20 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

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

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

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

(b) (6)	N/A	Jan-27-2021 09:03:56 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Jessica Tuan	Approved	Jan-21-2021 14:10:55 (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	Dec-20-2020 11:08:52 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Onyema Ogbuagu	Approved	Nov-07-2020 13:27:27 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Status: Data Complete, Signed, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

Affidavit:

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

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

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

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:55

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-16-2020 14:52:10 (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-16-2020 14:52:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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I. Consent Was:

Date	Location	User	Value	Reason
Sep-16-2020 14:52:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: OBTAINED Date Written Consent Obtained Sep/16/2020	Initial Entry

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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1. Subject ID

Date	Location	User	Value	Reason
Sep-16-2020 14:52:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12231181	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-16-2020 14:51:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1972	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-16-2020 14:52:46 (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-16-2020 14:52:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: HISPANIC OR LATINO(A) OR OF S PANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 14:52:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: WHITE	Initial Entry

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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I. Date of Visit

Date	Location	User	Value	Reason
Sep-16-2020 14:53:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sep/16/2020	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-16-2020 14:53:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sep/16/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-16-2020 14:53:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-16-2020 14:53:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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I.a

Date	Location	User	Value	Reason
Sep-17-2020 13:25:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: migraines headaches Start Date: Dec/UNK/2011 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-17-2020 13:25:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-17-2020 13:25:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: migraines headaches	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Sep-17-2020 13:25:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Dec/UNK/2011	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Sep-17-2020 13:25:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES	Initial Entry

I.b

Date	Location	User	Value	Reason
Sep-17-2020 13:26:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2	Initial Entry

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

			Medical History Term: diabetes type I Start Date: UNK/UNK/1989 Ongoing: YES
--	--	--	--

I.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-17-2020 13:26:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Sep-17-2020 13:26:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: diabetes type I	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Sep-17-2020 13:26:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: UNK/UNK/1989	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Sep-17-2020 13:26:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES	Initial Entry

I.c

Date	Location	User	Value	Reason
Sep-17-2020 13:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Term: left ventricular hypertrophy Start Date: UNK/UNK/2019 Ongoing: YES	Initial Entry

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

I.c Line/MH Number:

Date	Location	User	Value	Reason
Sep-17-2020 13:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Sep-17-2020 13:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: left ventricular hypertrophy	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Sep-17-2020 13:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: UNK/UNK/2019	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Sep-17-2020 13:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Sep-17-2020 13:28:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: peripheral neuropathy Start Date: UNK/UNK/2011 Ongoing: YES	Initial Entry

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231181

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.d Line/MH Number:

Date	Location	User	Value	Reason
Sep-17-2020 13:28:06 (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
Sep-17-2020 13:28:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: peripheral neuropathy	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Sep-17-2020 13:28:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: UNK/UNK/2011	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Sep-17-2020 13:28:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES	Initial Entry

I.e

Date	Location	User	Value	Reason
Sep-17-2020 13:28:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Term: hypothyroidism Start Date: UNK/UNK/2017 Ongoing: YES	Initial Entry

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

I.e Line/MH Number:

Date	Location	User	Value	Reason
Sep-17-2020 13:28:34 (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
Sep-17-2020 13:28:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: hypothyroidism	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Sep-17-2020 13:28:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: UNK/UNK/2017	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Sep-17-2020 13:28:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Sep-17-2020 13:30:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 6 Medical History Term: Barrett's esophagus Start Date: UNK/UNK/2019 Ongoing: YES	Initial Entry

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

I.f Line/MH Number:

Date	Location	User	Value	Reason
Sep-17-2020 13:30:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Sep-25-2020 11:25:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gary Steven Friedman (b) (4)	Query 1: Closed	Response satisfies query
Sep-25-2020 11:07:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 1: Answered	per patients emr had an endoscopy 6/2019 absence of ESOPHAGEAL ADENOCARCINOMA.
Sep-23-2020 12:01:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gary Steven Friedman (b) (4)	Query 1: Opened	BARRETT'S ESOPHAGUS (ONGOING): please confirm that the participant HAS or HAS NOT been evaluated with upper endoscopy within the past 12 months to confirm ABSENCE OF ESOPHAGEAL ADENOCARCINOMA.
Sep-17-2020 13:30:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Barrett's esophagus	Initial Entry

I.f Start Date:

Date	Location	User	Value	Reason
Sep-17-2020 13:30:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: UNK/UNK/2019	Initial Entry

I.f Ongoing:

Date	Location	User	Value	Reason
Sep-17-2020 13:30:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES	Initial Entry

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

I.g

Date	Location	User	Value	Reason
Sep-17-2020 13:32:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 7 mber: Medical Histo abnormal central nervou ry Term: s system vascular Start Date: UNK/UNK/2019 Ongoing: YES	Initial Entry

I.g Line/MH Number:

Date	Location	User	Value	Reason
Sep-17-2020 13:32:27 (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
Sep-17-2020 13:32:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: abnormal central nervous system vascu lar	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Sep-17-2020 13:32:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: UNK/UNK/2019	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Sep-17-2020 13:32:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES	Initial Entry

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1223

Subject No: 12231181

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

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1. Date:

Date	Location	User	Value	Reason
Sep-16-2020 14:56:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sep/16/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-16-2020 14:56:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: 226.6	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-16-2020 14:56:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-16-2020 14:56:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: 70.5	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-16-2020 14:56:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-16-2020 14:56:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 32.1	Initial Entry

7.a

Date	Location	User	Value	Reason
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090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1223

Subject No: 12231181

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-16-2020 14:56:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Record Identifier:: 1 Temperature: 97.7 Temperature Unit: F Temperature Location:: ORAL CAVITY	Initial Entry
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7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-16-2020 14:56:51 (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-16-2020 14:56:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: 97.7	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-16-2020 14:56:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-16-2020 14:56:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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1. Randomization Date :

Date	Location	User	Value	Reason
Sep-16-2020 14:58:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sep/16/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-16-2020 14:58:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: 91293	Initial Entry

Header Text: C4591001
Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231181

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Sep-16-2020 14:58:23 (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-16-2020 14:58:23 (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 17:27:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-16-2020 14:58:23 (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-16-2020 14:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES Date of Collection: Sep/16/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-16-2020 17:27:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPXXM8	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-16-2020 17:27:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPXXM8	Initial Entry

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (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: 12231181

Subject Initials: ---

Generated By: (b) (4)

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

5.b

Date	Location	User	Value	Reason
Sep-16-2020 17:28:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BPXXM9	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-16-2020 17:28:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPXXM9	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-16-2020 17:28:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BPXXMB	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-16-2020 17:28:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPXXMB	Initial Entry

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (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: 12231181

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Sep-16-2020 14:58:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-16-2020 14:58:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-16-2020 17:33:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-16-2020 14:58:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-16-2020 14:58:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES Date of Collection: Sep/16/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-16-2020 17:33:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPXXM7	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-16-2020 17:33:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPXXM7	Initial Entry

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-16-2020 14:59:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-16-2020 14:59:19 (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-16-2020 14:59:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-16-2020 14:59:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sep/16/2020 13:00	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-16-2020 14:59:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-16-2020 14:59:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
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090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1223

Subject No: 12231181

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-16-2020 14:59:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry
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10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-16-2020 14:59:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSER VATION 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-16-2020 14:59:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES	Initial Entry

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-16-2020 14:59:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJ ECT	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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I. Date of Visit

Date	Location	User	Value	Reason
Oct-07-2020 13:43:44 (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: 12231181

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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1. Date:

Date	Location	User	Value	Reason
Oct-07-2020 13:44:22 (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 13:44:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Record Identifier:: 1 Temperature: 98.0 Temperature Unit: F Temperature Location: FOREHEA : D	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-07-2020 13:44:22 (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 13:44:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: 98.0	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Oct-07-2020 13:44:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Oct-07-2020 13:44:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: FOREHEAD	Initial Entry

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (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: 12231181

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Oct-07-2020 13:44:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-07-2020 13:44:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-12-2020 12:08:53 (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 13:44:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-07-2020 13:44:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/7/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-12-2020 12:08:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPW1N4	Initial Entry

5.a Sample ID

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (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: 12231181

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-12-2020 12:08:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPW1N4	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-07-2020 13:45:32 (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 13:45:32 (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 13:45:32 (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
Nov-07-2020 03:45:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: C losed	Auto closed by Validation Check: VC_EC001_2_12_AN
Nov-06-2020 20:07:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Nov-05-2020 15:46:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW5294152;Date is after 'Date of Completion/Discontinuation '/Death' on the Disposition - Treatment eCRF. Please clarify or correct.
Oct-07-2020 13:45:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entr y: Oct/7/202 0 12:36	Initial Entry

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1223

Subject No: 12231181

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

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-07-2020 13:45:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Oct-07-2020 13:45:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Oct-07-2020 13:45:32 (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 13:45:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSER VATION 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 13:45:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES	Initial Entry

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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I. Date of Visit

Date	Location	User	Value	Reason
Nov-05-2020 12:17:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Nov/5/2020	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:** 12231181**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-05-2020 12:17:15 (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-05-2020 12:17:15 (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-05-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-05-2020 12:17:15 (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-05-2020 12:17:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES Date of Collection: Nov/5/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-05-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR375W	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-05-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR375W	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: 12231181

Subject Initials: ---

Generated By: (b) (4)

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

5.b

Date	Location	User	Value	Reason
Nov-05-2020 15:15:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR375X	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-05-2020 15:15:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR375X	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-05-2020 15:15:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPW1PX	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-05-2020 15:15:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPW1PX	Initial Entry

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled Visit
on Mar/09/2021**Form:** DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail
History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Frozen, Verified**Site No:** 1223**Site Name:** (1223) Yale New Haven Medical Center**Subject No:** 12231181**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:30[Back to Form](#)**I. Date of Visit**

Date	Location	User	Value	Reason
Mar-12-2021 09:49:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Deleted	Query is invalid or does not apply
Mar-11-2021 13:55:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark any forms containing data within this visit as Not Done/Not Applicable at the form level.
Mar-11-2021 13:54:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-11-2021 04:11:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark any forms containing data within this visit as Not Done/Not Applicable at the form level.
Mar-10-2021 16:41:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark any forms containing data within this visit as Not Done/Not Applicable at the form level.
Mar-09-2021 14:55:01	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Mar/09/2021

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

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231181

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	Mar/9/2021	
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2. Erroneous Visit

Date	Location	User	Value	Reason
Mar-11-2021 13:55:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ERRONEOUS VISIT	Initial Entry
Mar-11-2021 13:54:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Mar-10-2021 16:41:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ERRONEOUS VISIT	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Mar-12-2021 04:40:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-11-2021 14:21:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Mar-11-2021 14:21:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Mar-11-2021 11:27:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	COVID-19 Illness Visit is blank, please update. If erroneous visit please use comment function to complete this field as NOT APPLICABLE.
Mar-10-2021 16:37:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Mar-10-2021 16:37:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Mar-10-2021 05:16:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM:Subject has completed Convalescent visit,

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Mar/09/2021

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

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231181

Subject Initials: ---

Generated By: (b) (4)

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

				however corresponding COVID illness visit is not recorded. Please review and update the details as appropriate. Thank you.
Mar-09-2021 14:55:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: COVID_A1	Initial Entry

Header Text: C4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled Visit
on Mar/09/2021**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1223**Site Name:** (1223) Yale New Haven Medical Center**Subject No:** 12231181**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:30[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Mar-10-2021 16:42:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Mar-09-2021 14:55:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-10-2021 16:42:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Mar-09-2021 14:55:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-12-2021 16:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Mar-12-2021 09:02:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Query 2: Answered	Changed data per query
Mar-12-2021 00:01:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	DM : Thanks for response. Please review and add Form level comment as Not Applicable on this form. Else, clarify.
Mar-11-2021 14:57:16 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Changed data per query

Header Text: C4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled Visit on Mar/09/2021**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1223**Site Name:** (1223) Yale New Haven Medical Center**Subject No:** 12231181**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:30

(US & Canada)				
Mar-11-2021 03:35:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Opened	DMW7668989;Sample Collected is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Mar-10-2021 16:48:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Mar-10-2021 16:42:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Mar-10-2021 09:54:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-10-2021 06:51:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-09-2021 14:55:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-09-2021 14:55:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/9/2021	Initial Entry

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

Date	Location	User	Value	Reason
Mar-12-2021 09:02:18 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Jessica Tuan	Data Entry: Not Applicable	Initial Entry

Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Mar/09/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231181

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Mar-10-2021 16:42:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRJ4L2	Transcription Error (DELETED)
Mar-10-2021 09:54:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Suzana Mutic (b) (4)	Data Entry: Sample ID: BRJ4L2	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-10-2021 16:42:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRJ4L2	Transcription Error (DELETED)
Mar-10-2021 09:54:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Suzana Mutic (b) (4)	Data Entry: BRJ4L2	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-10-2021 16:43:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRJ4L3	Transcription Error (DELETED)
Mar-10-2021 09:55:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Suzana Mutic (b) (4)	Data Entry: Sample ID: BRJ4L3	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-10-2021 16:43:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRJ4L3	Transcription Error (DELETED)
Mar-10-2021 09:55:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Suzana Mutic (b) (4)	Data Entry: BRJ4L3	Initial Entry

5.c

Date	Location	User	Value	Reason
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090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Mar/09/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231181

Subject Initials: ---

Generated By: (b) (4)

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

Mar-10-2021 16:43:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRJ4L4	Transcription Error (DELETED)
Mar-10-2021 09:55:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Suzana Mutic (b) (4)	Data Entry: Sample ID: BRJ4L4	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-10-2021 16:43:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRJ4L4	Transcription Error (DELETED)
Mar-10-2021 09:55:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Suzana Mutic (b) (4)	Data Entry: BRJ4L4	Initial Entry

5.d

Date	Location	User	Value	Reason
Mar-10-2021 16:43:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRV2Z9	Transcription Error (DELETED)
Mar-10-2021 10:36:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Suzana Mutic (b) (4)	Data Entry: Sample ID: BRV2Z9	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Mar-10-2021 16:43:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRV2Z9	Transcription Error (DELETED)
Mar-10-2021 10:36:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Suzana Mutic (b) (4)	Data Entry: BRV2Z9	Initial Entry

5.e

Date	Location	User	Value	Reason
Mar-10-2021 16:44:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRV2ZB	Transcription Error (DELETED)
Mar-10-2021 10:37:28 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Suzana Mutic (b) (4)	Data Entry: Sample ID: BRV2ZB	Initial Entry

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Mar/09/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231181

Subject Initials: ---

Generated By: (b) (4)

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

(US & Canada)				
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5.e Sample ID

Date	Location	User	Value	Reason
Mar-10-2021 16:44:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRV2ZB	Transcription Error (DELETED)
Mar-10-2021 10:37:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Suzana Mutic (b) (4)	<u>Data Entry:</u> BRV2ZB	Initial Entry

5.f

Date	Location	User	Value	Reason
Mar-11-2021 14:56:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Sample ID:</u>	Transcription Error (DELETED)
Mar-11-2021 14:22:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Sample ID:</u>	Changed Information
Mar-11-2021 14:21:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Sample ID:</u> BRJ4L3	Changed Information
Mar-10-2021 12:51:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Suzana Mutic (b) (4)	<u>Data Entry:</u> <u>Sample ID:</u>	Transcription Error
Mar-10-2021 12:49:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Suzana Mutic (b) (4)	<u>Data Entry:</u> <u>Sample ID:</u> BRV2Z9	Initial Entry

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled Visit
on Mar/09/2021**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1223**Site Name:** (1223) Yale New Haven Medical Center**Subject No:** 12231181**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:30**5.f Sample ID**

Date	Location	User	Value	Reason
Mar-11-2021 14:56:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error (DELETED)
Mar-11-2021 14:22:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Mar-11-2021 14:21:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRJ4L3	Changed Information
Mar-10-2021 12:51:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Suzana Mucic (b) (4)	Data Entry:	Transcription Error
Mar-10-2021 12:49:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Suzana Mucic (b) (4)	Data Entry: BRV2Z9	Initial Entry

5.g

Date	Location	User	Value	Reason
Mar-11-2021 14:56:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID:	Transcription Error (DELETED)
Mar-11-2021 14:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID:	Transcription Error
Mar-11-2021 14:19:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRJ4L2	Initial Entry

5.g Sample ID

Date	Location	User	Value	Reason
Mar-11-2021 14:56:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error (DELETED)
Mar-11-2021 14:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Mar-11-2021 14:19:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRJ4L2	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:** 12231181**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-07-2020 04:06:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-06-2020 20:06:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-06-2020 20:06:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/5/2020	Transcription Error
Nov-06-2020 11:22:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	As per CRF guidelines, the treatment period is defined as 1st vaccination visit through the 1-month post vaccination visit after the 2nd vaccination. Please complete treatment disposition CRF and update date of EOT to match the date of Visit 3.
Nov-05-2020 12:17:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Oct/5/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Nov-05-2020 12:17:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-05-2020 12:17:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: COMPLETED	Initial Entry

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: 12231181

Subject Initials: ---

Generated By: (b) (4)

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

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-25-2021 10:09:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Dec/18/2020	Transcription Error
Dec-20-2020 11:08:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6) [Redacted]	Data Entry: Dec/20/2020	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

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231181

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Jan-04-2021 18:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-21-2020 06:53:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Dec-20-2020 11:09:18 (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.
Dec-20-2020 11:09:18 (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 per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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I. Date of Visit

Date	Location	User	Value	Reason
Dec-20-2020 11:09:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Dec/20/2020	Initial Entry

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231181

Subject Initials: ---

Generated By: (b) (4)

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

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I. Consent Was:

Date	Location	User	Value	Reason
Dec-20-2020 11:09:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: OBTAINED Date Written Consent Obtained Dec/20/2020	Initial Entry

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231181

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Dec-20-2020 11:11:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Dec/20/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Dec-20-2020 11:11:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Dec-20-2020 11:11:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231181

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Dec-20-2020 11:11:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-20-2020 11:11:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-20-2020 11:24:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-20-2020 11:11:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-20-2020 11:11:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES Date of Collection: Dec/20/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-20-2020 11:24:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Suzana Mutic (b) (4)	Data Entry: Sample ID: BPW8XC	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-20-2020 11:24:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Suzana Mutic (b) (4)	Data Entry: BPW8XC	Initial Entry

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231181

Subject Initials: ---

Generated By: (b) (4)

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

5.b

Date	Location	User	Value	Reason
Dec-20-2020 11:24:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Suzana Mutic (b) (4)	<u>Data Entry:</u> Sample ID: BPW8XD	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-20-2020 11:24:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Suzana Mutic (b) (4)	<u>Data Entry:</u> BPW8XD	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-20-2020 11:25:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Suzana Mutic (b) (4)	<u>Data Entry:</u> Sample ID: BPW8XF	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-20-2020 11:25:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Suzana Mutic (b) (4)	<u>Data Entry:</u> BPW8XF	Initial Entry

5.d

Date	Location	User	Value	Reason
Dec-20-2020 11:54:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Suzana Mutic (b) (4)	<u>Data Entry:</u> Sample ID: BRV2MZ	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Dec-20-2020 11:54:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Suzana Mutic (b) (4)	<u>Data Entry:</u> BRV2MZ	Initial Entry

5.e

Date	Location	User	Value	Reason
Dec-20-2020 11:54:24 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Suzana Mutic	<u>Data Entry:</u> Sample ID: BRV2N0	Initial Entry

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231181

Subject Initials: ---

Generated By: (b) (4)

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

(US & Canada)

(b) (4)

5.e Sample ID

Date	Location	User	Value	Reason
Dec-20-2020 11:54:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Suzana Mutic (b) (4)	<u>Data Entry:</u> BRV2N0	Initial Entry

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231181

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Dec-20-2020 11:11:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-20-2020 11:11:57 (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
Dec-20-2020 11:13:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-20-2020 11:11:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-20-2020 11:11:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES Date of Collection: Dec/20/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-20-2020 11:13:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Suzana Mucic (b) (4)	Data Entry: Sample ID: BPW8XG	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-20-2020 11:13:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Suzana Mucic (b) (4)	Data Entry: BPW8XG	Initial Entry

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Dec-20-2020 11:12:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Dec-20-2020 11:12:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Dec-20-2020 11:12:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Dec-20-2020 11:12:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Dec/20/2020 10:11	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Dec-20-2020 11:12:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Dec-20-2020 11:12:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
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090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231181

Subject Initials: ---

Generated By: (b) (4)

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

Dec-20-2020 11:12:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry
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8. Actual Dose:

Date	Location	User	Value	Reason
Dec-20-2020 11:12:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Dec-20-2020 11:12:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Dec-20-2020 11:12:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Dec-20-2020 11:12:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES	Initial Entry

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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I. Date of Visit

Date	Location	User	Value	Reason
Jan-08-2021 10:48:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Jan/8/2021	Initial Entry

Header Text: C4591001**Visit:** V102_VAX4**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1223**Site Name:** (1223) Yale New Haven Medical Center**Subject No:** 12231181**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
Jan-08-2021 10:09:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-08-2021 10:09:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-08-2021 10:10:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-08-2021 10:09:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-08-2021 10:09:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Suzana Mutic (b) (4)	Data Entry: YES Date of Collection: Jan/8/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-08-2021 10:10:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Suzana Mutic (b) (4)	Data Entry: Sample ID: BPW90V	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-08-2021 10:10:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Suzana Mutic (b) (4)	Data Entry: BPW90V	Initial Entry

Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-08-2021 10:49:54 (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
Jan-08-2021 10:49:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-08-2021 10:49:54 (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
Jan-08-2021 10:49:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Jan/8/2021 10:02	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-08-2021 10:49:54 (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
Jan-08-2021 10:49:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: RIGHT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
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090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1223

Subject No: 12231181

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

Jan-08-2021 10:49:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry
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8. Actual Dose:

Date	Location	User	Value	Reason
Jan-08-2021 10:49:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-08-2021 10:49:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-08-2021 10:49:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-08-2021 10:49:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES	Initial Entry

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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I. Date of Visit

Date	Location	User	Value	Reason
Mar-02-2021 22:02:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Clo sed	Auto closed by Validation Check: VC_SV001_11
Mar-02-2021 15:41:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	Changed data per query
Mar-01-2021 08:25:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW7478544;V103 Visit Date is entered, but Disposition - Treatment form at FURTHER_VACCINATION_EOT visit is not completed. Please review and update as appropriate.
Feb-25-2021 09:44:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Feb/5/ 2021	Initial Entry

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: CONTACT OUTCOME - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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1. Contact Type:

Date	Location	User	Value	Reason
Feb-25-2021 09:44:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Feb-25-2021 09:44:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Contact: Feb/5/2021	Initial Entry

Header Text: C4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231181

Subject Initials: ---

Generated By: (b) (4)

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

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I. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Mar-04-2021 06:47:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	incorrect
Mar-03-2021 03:11:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Opened	DMW7580830;Status on the Disposition - Treatment form is COMPLETED, but Date is different than Visit 3 Date. Please review and update as appropriate.
Mar-02-2021 15:40:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/5/2021	Initial Entry
Mar-02-2021 15:40:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Jan-28-2021 15:12:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-28-2021 11:26:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-28-2021 11:26:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Jan-28-2021 11:26:28	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231181

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-05:00) Eastern Time (US & Canada)				
Jan-27-2021 15:37:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Open ed	DMW7034175;Status on the Disposition - Treatment form is COMPLETED, but Date is different than Visit 3 Date. Please review and update as appropriate.
Jan-27-2021 09:03:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/8/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-02-2021 15:40:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: OPEN LABEL TREATMENT	Initial Entry
Mar-02-2021 15:40:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry
Jan-28-2021 11:26:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jan-28-2021 11:26:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Changed Information
Jan-27-2021 09:03:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: OPEN LABEL TREATMENT	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Mar-02-2021 15:40:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry
Mar-02-2021 15:40:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231181

Subject Initials: ---

Generated By: (b) (4)

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

Jan-28-2021 11:26:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Not Applicable	Initial Entry
Jan-28-2021 11:26:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry:	Changed Information
Jan-27-2021 09:03:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: COMPLETED	Initial Entry

4. Specify Status:

Date	Location	User	Value	Reason
Mar-02-2021 15:40:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry:	Initial Entry
Jan-28-2021 11:26:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Feb-26-2021 18:05:04 (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: 12231181

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Feb-26-2021 18:06:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Form Created	

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Feb-26-2021 18:09:00 (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: 12231181

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Feb-26-2021 18:10:40 (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: 12231181

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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1. Category:

Date	Location	User	Value	Reason
Feb-26-2021 18:05:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-26-2021 18:05:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-26-2021 18:05:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: injection site pain	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-26-2021 18:05:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Jan/9/2021 09:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-26-2021 18:05:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO End Date Time: Jan/11/2021 09:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-26-2021 18:05:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-26-2021 18:05:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Feb-26-2021 18:05:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-26-2021 18:05:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-26-2021 18:05:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-26-2021 18:05:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-26-2021 18:05:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

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

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

Date	Location	User	Value	Reason
Feb-26-2021 18:05:04 (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
Feb-26-2021 18:05:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO	Initial Entry

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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1. Category:

Date	Location	User	Value	Reason
Feb-26-2021 18:06:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-26-2021 18:06:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-26-2021 18:06:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: generalized weakness	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-26-2021 18:06:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Jan/9/2021 09:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-26-2021 18:06:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO End Date Time: Jan/11/2021 09:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-26-2021 18:06:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-26-2021 18:06:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Feb-26-2021 18:06:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-26-2021 18:06:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-26-2021 18:06:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-26-2021 18:06:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-26-2021 18:06:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Mar-03-2021 09:43:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-02-2021 16:13:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Mar-02-2021 16:13:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry
Mar-01-2021 03:10:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for "What was the outcome of this adverse event?" is missing. Kindly review and update.

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

Date	Location	User	Value	Reason
Feb-26-2021 18:06:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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1. Category:

Date	Location	User	Value	Reason
Feb-26-2021 18:09:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-26-2021 18:09:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-26-2021 18:09:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: abdominal pain	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-26-2021 18:09:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Jan/31/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-26-2021 18:09:00 (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
Mar-11-2021 04:12:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-10-2021 12:46:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1223**Subject No:** 12231181**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1223) Yale New Haven Medical Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:30

Mar-10-2021 12:46:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Data Entry: 3	Changed Information
Mar-10-2021 03:27:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	clinical query: your answered is changed data per query but there is no change. Please check again if to confirm the value or to change it in the appropriate field. Thanks
Mar-09-2021 15:57:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Query 1: Answered	Changed data per query
Mar-09-2021 09:32:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical query: toxicity grade is 4 which stand for life threatening but the event is reported as not serious. Please check toxicity grade
Feb-26-2021 18:09:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: 4	Initial Entry

7. Is the adverse event serious?**If Yes, NOTIFY PFIZER IMMEDIATELY.****Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).**

Date	Location	User	Value	Reason
Feb-26-2021 18:09:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?**If Yes, record the type of medication error on the Medication Error Log.**

Date	Location	User	Value	Reason
Mar-03-2021 09:38:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-02-2021 14:46:17 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

(US & Canada)				
Mar-02-2021 14:46:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Tuan (b) (4)	Data Entry: NO	Changed Information
Mar-02-2021 10:48:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM Query: Response to question "Is this adverse event the result of a study Medication Error" is YES, however corresponding detail on MEDICATION ERROR FORM is missing. Please update the data else clarify.
Feb-26-2021 18:09:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-26-2021 18:09:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-26-2021 18:09:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-26-2021 18:09:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-26-2021 18:09:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO	Initial Entry

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Feb-26-2021 18:09:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Feb-26-2021 18:09:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

Header Text: C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1223**Subject No:** 12231181**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1223) Yale New Haven Medical Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:30[Back to Form](#)**1. Category:**

Date	Location	User	Value	Reason
Feb-26-2021 18:10:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-26-2021 18:10:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Feb-26-2021 18:10:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Submandibular lymphadenopathy	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-26-2021 18:10:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Feb/1/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-26-2021 18:10:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-26-2021 18:10:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?**If Yes, NOTIFY PFIZER IMMEDIATELY.**

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Feb-26-2021 18:10:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Feb-26-2021 18:10:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-26-2021 18:10:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-26-2021 18:10:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-26-2021 18:10:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-26-2021 18:10:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231181

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

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

Feb-26-2021 18:10:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: RECOVERING/RESOLVING	Initial Entry
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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Feb-26-2021 18:10:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO	Initial Entry

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS -
Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231181

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Nov-05-2020 12:18:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231181

Subject Initials: ---

Generated By: (b) (4)

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

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Nov-05-2020 12:18:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Nov-05-2020 12:18:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Nov-05-2020 12:18:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Nov-05-2020 12:18:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: influenza vaccine	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Nov-05-2020 12:18:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Oct/30/2020	Initial Entry

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231181

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-25-2021 15:49:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-25-2021 10:10:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Feb-23-2021 18:49:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7353198;Date Treatment Unblinded should be equal to or after DOV in REVAX CONTACT visit when Reason is ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION.Please review and update as appropriate.
Jan-04-2021 18:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/18/2020	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-04-2021 18:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (GMT)

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1223

Subject No: 12231181

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

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1. Subject Status

Date	Location	User	Value	Reason
Nov-05-2020 12:17:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-16-2020 14:58:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-16-2020 14:53:37 (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 20:06:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/5/2020	Transcription Error
Nov-05-2020 12:17:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/5/2020	Initial Entry
Sep-16-2020 14:58:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/16/2020	Initial Entry
Sep-16-2020 14:53:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/16/2020	Initial Entry

090177e196ae3018\Final\Final On: 01-Apr-2021 04:00 (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: 12231181

Subject Initials: ---

Generated By: (b) (4)

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

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I. Casebook Signature

Date	Location	User	Value	Reason
Nov-07-2020 13:27:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Onyema Ogbuagu (b) (4)	Data Entry: Click Here to Enable	Initial Entry