

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Cohort Selection

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

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/4/2020
----	--------------	---

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[12601069]
2.	Birth Date:	(b) (6) 1949
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[Form Comments](#)

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Sep/4/2020
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: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hypertension]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hypercholesteromia]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Former tobacco smoker]
	Start Date:	UNK/UNK/1965
	Ongoing:	NO End Date: UNK/UNK/1999

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/4/2020
2.	Weight:	[96.3]
3.	Unit:	kg
4.	Height:	[167.0]
5.	Unit:	cm
6.	Body Mass Index:	[34.5]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[36.7]
	Unit:	C
	Temperature Location:	ORAL CAVITY

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Sep/4/2020
2.	Randomization Number:	[252980]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPT7BC]
5.b	Sample ID	[BNV680]
5.c	Sample ID	[BNV681]

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPT7BB]
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090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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/4/2020 15:41
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

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
----	--	---

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/24/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/24/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.4]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/24/2020
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	[BP26PM]
-----	-----------	----------

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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/24/2020 13:32
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

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/27/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/27/2020
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	[BP26WH]
5.b	Sample ID	[BNTX5G]
5.c	Sample ID	[BNTX5H]

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (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: 1260 **Site Name:** (1260) UMass Memorial Medical Center

Subject No: 12601069 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

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

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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:	[]
----	------------------------	-----

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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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090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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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090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

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

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Health Care Utilization

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

Health Care Utilization Other

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

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	
----	--	--

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (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: 1260 **Site Name:** (1260) UMass Memorial Medical Center

Subject No: 12601069 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

Illness Details

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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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090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Unplanned Assessments

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

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Oct/27/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Disposition - Follow-Up

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

Header Text: c4591001

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

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

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

Header Text: c4591001

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

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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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090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	acute appendicitis	Oct/5/2020 UNK:UNK	NO End Date Time: Oct/7/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	abdominal aortic aneurysm	Oct/7/2020 01:09	YES	Repeating Pages
3.	ADVERSE EVENT	3	soreness at the injection site	Jan/20/2021 08:00	NO End Date Time: Jan/22/2021 08:00	Repeating Pages
4.	ADVERSE EVENT	4	lower back soreness	Jan/20/2021 08:00	NO End Date Time: Jan/22/2021 08:00	Repeating Pages
5.	ADVERSE EVENT	5	slight backache	Feb/12/2021 08:00	NO End Date Time: Feb/13/2021 08:00	Repeating Pages

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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

Adverse Event Report

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

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [appendicitis]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020421554]

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

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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)	[abdominal aortic aneurysm]
4.	Start Date Time:	Oct/7/2020 01:09
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:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [incidental finding on CT scan]

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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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)	[soreness at the injection site]
4.	Start Date Time:	Jan/20/2021 08:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/22/2021 08:00
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

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

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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)	[lower back soreness]
4.	Start Date Time:	Jan/20/2021 08:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/22/2021 08:00
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

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

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

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[slight backache]
4.	Start Date Time:	Feb/12/2021 08:00
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/13/2021 08:00
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

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

#	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: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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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	[]

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	influenza vaccination	Oct/7/2020	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Concomitant Medications

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[influenza vaccination]
5.	Date:	Oct/7/2020

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Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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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?	

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VITAL SIGNS - TEMP

Form Version: 20-Feb-2021 02:16

Form Status: Not Started

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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?	

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (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: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Contact Outcome

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 6

Form Version: 10-Oct-2020 16:01

Form Status: Not Started

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Contact Outcome

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/8/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[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
----	---	---

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/19/2021
----	--------------	--

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[Form Comments](#)

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation /Death :	Jan/19/2021
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: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/19/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPVNWG]
5.b	Sample ID	[BNTXDY]
5.c	Sample ID	[BNTXDZ]

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/19/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPVNWB]
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090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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/19/2021 12:36
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

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/8/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/11/2021
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	[BPVNYJ]
-----	-----------	----------

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/11/2021 15:13
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

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Mar/8/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Data Complete, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Mar/8/2021
3.	Comments:	[]

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Contact Outcome

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

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Mar/8/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/27/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[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, Verified

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[Audit Trail](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-04-2020 20:36:28 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (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, Frozen, Verified

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-19-2021 16:23:11 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Feb-11-2021 22:15:30 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
Affidavit: N/A				
Robert Finberg	Approved	Jan-25-2021 19:12:22 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
Affidavit: By my dated signature below, I, RobertFinberg, 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-12-2021 15:43:14 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
Affidavit: N/A				
(b) (6)	Approved	Nov-06-2020 15:18:40 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Affidavit:

By my dated signature below, I, (b) (6) verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

(b) (6)	N/A	Nov-03-2020 17:49:10 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Nov-02-2020 15:47:06 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, (b) (6), 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.

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-04-2020 20:34:08 (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-04-2020 20:34:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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I. Consent Was:

Date	Location	User	Value	Reason
Sep-04-2020 20:34:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Sep/4/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Subject ID

Date	Location	User	Value	Reason
Sep-04-2020 20:34:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12601069	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-04-2020 20:33:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) 1949	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-04-2020 20:36:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MALE	Transcription Error
Sep-04-2020 20:34:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-04-2020 20:34:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-04-2020 20:34:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-04-2020 20:34:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/4/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-04-2020 20:34:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/4/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-04-2020 20:34:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-04-2020 20:34:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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I.a

Date	Location	User	Value	Reason
Sep-04-2020 20:37:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History: hypertension Term: Start Date: UNK/UNK/ 2005 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-04-2020 20:37:00 (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-04-2020 20:37:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: hypertension	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Sep-04-2020 20:37:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2005	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Sep-04-2020 20:37:00 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (6)	Data Entry: YES	Initial Entry

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Time (US & Canada)	(b) (4)
--------------------	---------

1.b

Date	Location	User	Value	Reason
Sep-04-2020 20:37:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term: hypercholesterolemia Start Date: UNK/UNK/2005 Ongoing: YES	Initial Entry

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

1.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-04-2020 20:37:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Nov-04-2020 08:58:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Appreciate the prompt response. Thank you.
Nov-03-2020 17:50:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	added information
Nov-03-2020 04:08:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Based on case narrative, the subject has a Med history of tobacco use. This background is not recorded in Med Hx. If the information is accurate, please revise/update Med Hx accordingly. Thank you.
Nov-02-2020 15:39:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Candidate	Based on case narrative, the subject has a Med history of tobacco use. This background is not recorded in Med Hx. If the information is accurate, please revise/update Med Hx accordingly.

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

				Thank you.
Sep-04-2020 20:37:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: hypercholesteromia	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Sep-04-2020 20:37:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2005	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Sep-04-2020 20:37:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.c

Date	Location	User	Value	Reason
Nov-03-2020 17:49:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 3 ber: Medical Histor Former tobacco y Term: smoker Start Date: UNK/UNK/196 5 Ongoing: NO End Date: UNK/UNK/1 999	Initial Entry

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

I.c Line/MH Number:

Date	Location	User	Value	Reason
Nov-03-2020 17:49:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Nov-03-2020 17:49:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Former tobacco smoker	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Nov-03-2020 17:49:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1965	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Nov-03-2020 17:49:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1999	Initial Entry

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date:

Date	Location	User	Value	Reason
Sep-04-2020 20:36:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/4/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-04-2020 20:36:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 96.3	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-04-2020 20:36:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-04-2020 20:36:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 167.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-04-2020 20:36:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
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090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Sep-04-2020 20:36:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 34.5	Initial Entry
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7.a

Date	Location	User	Value	Reason
Sep-04-2020 20:36:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: 1 Temperature: 36.7 Temperature Unit: C Temperature Location: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-04-2020 20:36:21 (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-04-2020 20:36:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.7	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-04-2020 20:36:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
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090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Sep-04-2020 20:36:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry
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090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Randomization Date :

Date	Location	User	Value	Reason
Sep-04-2020 20:35:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/4/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-04-2020 20:35:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 252980	Initial Entry

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (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: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Data Origin

Date	Location	User	Value	Reason
Sep-04-2020 20:34:49 (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-04-2020 20:34:49 (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-08-2020 10:17:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-07-2020 06:07:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-04-2020 20:34:49 (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-04-2020 20:34:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection:	Initial Entry

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (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: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

			Sep/4/2020	
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5.a

Date	Location	User	Value	Reason
Sep-08-2020 10:17:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPT7BC	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-08-2020 10:17:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPT7BC	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-08-2020 10:17:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNV680	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-08-2020 10:17:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNV680	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-08-2020 10:18:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNV681	Initial Entry

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (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: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.c Sample ID

Date	Location	User	Value	Reason
Sep-08-2020 10:18:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNV681	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Data Origin

Date	Location	User	Value	Reason
Sep-04-2020 20:34:56 (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-04-2020 20:34:56 (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-08-2020 10:17:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-07-2020 06:07:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-04-2020 20:34:56 (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-04-2020 20:34:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection:	Initial Entry

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (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: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

			Sep/4/2020	
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5.a

Date	Location	User	Value	Reason
Sep-08-2020 10:17:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPT7BB	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-08-2020 10:17:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPT7BB	Initial Entry

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-04-2020 20:35:32 (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
Sep-04-2020 20:35:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-04-2020 20:35:32 (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
Sep-04-2020 20:35:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/4/2020 15:41	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-04-2020 20:35:32 (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
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090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Sep-04-2020 20:35:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry
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7. Route:

Date	Location	User	Value	Reason
Sep-04-2020 20:35:32 (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
Sep-04-2020 20:35:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-04-2020 20:35:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-04-2020 20:35:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENICITY E- DIARY NOT COLLECTED F OR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-24-2020 12:47:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/24/2020	Initial Entry

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date:

Date	Location	User	Value	Reason
Sep-24-2020 12:47:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sep/24/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-24-2020 12:47:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Record Identifier 1 :: Temperature: 98.4 Temperature Unit: Temperature Location: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-24-2020 12:47:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-24-2020 12:47:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 98.4	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-24-2020 12:47:28 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (6)	<u>Data Entry:</u> F	Initial Entry

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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

Date	Location	User	Value	Reason
Sep-24-2020 12:47:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Data Origin

Date	Location	User	Value	Reason
Sep-24-2020 12:47:35 (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-24-2020 12:47:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-24-2020 14:13:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-24-2020 12:47:35 (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-24-2020 12:47:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/24/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-24-2020 14:13:56	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

(b) (4),
(b) (6)

Sample ID: BP26PM

5.a Sample ID

Date	Location	User	Value	Reason
Sep-24-2020 14:13:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP26PM	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-24-2020 13:36:05 (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-24-2020 13:36:05 (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-24-2020 13:36:05 (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-24-2020 13:36:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/24/2020 13:32	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-24-2020 13:36:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
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090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Sep-24-2020 13:36:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry
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7. Route:

Date	Location	User	Value	Reason
Sep-24-2020 13:36:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-24-2020 13:36:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-24-2020 13:36:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-27-2020 15:15:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/27/2020	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:** 1260**Site Name:** (1260) UMass Memorial Medical Center**Subject No:** 12601069**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-27-2020 15:16:05 (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-27-2020 15:16:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-27-2020 16:18:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-27-2020 15:16:05 (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-27-2020 15:16:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/27/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-27-2020 16:18:40	ACV0PFEINFP6000	(b) (6)	Data Entry:	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: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

(b) (4),
(b) (6)

Sample ID: BP26WH

5.a Sample ID

Date	Location	User	Value	Reason
Oct-27-2020 16:18:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP26WH	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-27-2020 16:18:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNTX5G	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-27-2020 16:18:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNTX5G	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-27-2020 16:18:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNTX5H	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-27-2020 16:18:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNTX5H	Initial Entry

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-27-2020 15:16:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/27/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-27-2020 15:16:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-27-2020 15:16:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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Date	Location	User	Value	Reason
Oct-27-2020 15:26:51 (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: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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Date	Location	User	Value	Reason
Oct-29-2020 18:19:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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Date	Location	User	Value	Reason
Feb-11-2021 22:18:52 (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: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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Date	Location	User	Value	Reason
Feb-11-2021 22:20:26 (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: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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Date	Location	User	Value	Reason
Mar-09-2021 12:43:28 (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: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Category:

Date	Location	User	Value	Reason
Oct-27-2020 15:26:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-27-2020 15:26:51 (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
Nov-13-2020 14:04:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Response satisfies query
Nov-11-2020 12:22:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	not necessary to add it as adverse event
Nov-11-2020 10:11:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	Per case narrative, The subject presented with and additional AE of hyponatremia during hospitalization. Please revise AE log and update with additional event if appropriate. Thank you.
Oct-28-2020 18:20:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: acute appendicitis	Transcription Error

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Oct-27-2020 15:26:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: appendicitis	Initial Entry
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4. Start Date Time:

Date	Location	User	Value	Reason
Oct-31-2020 10:53:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-30-2020 09:51:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-30-2020 09:51:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/5/2020 UNK:UNK	Transcription Error
Oct-30-2020 07:50:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2020421554 ,onset date was recorded as 05Oct2020 in Safety database however, recorded as 06Oct2020 on AE CRF. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form.
Oct-29-2020 12:39:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/6/2020 UNK:UNK	Transcription Error
Oct-27-2020 15:26:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/7/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
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090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Oct-29-2020 12:40:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/7/2020 UNK:UNK	Transcription Error
Oct-27-2020 15:26:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/8/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-27-2020 15:26:51 (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.

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

Date	Location	User	Value	Reason
Nov-05-2020 13:37:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Closed	Response satisfies query
Nov-05-2020 10:58:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	ok we will send the followup report with the negative test result once MD signs it today
Nov-04-2020 20:30:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Opened	Clinical - per Data Monitoring Committee, each hospitalized subject requires a report of COVID test status.

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

				If test performed = YES, NO or Not available, kindly provide FU report with results/status. Thank you.
Oct-30-2020 07:49:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Oct-29-2020 13:06:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-29-2020 12:39:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	For AE acute appendicitis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Oct-29-2020 12:39:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-29-2020 12:39:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES	Transcription Error

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

			<p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	
Oct-28-2020 19:51:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	CLINQUERY: Per SAE definition in protocol section 10.3.2.c, an in-patient hospitalization with an overnight stay for observation meets the definition for an SAE. Please review and update the CRF and submit SAE forms as appropriate, else clarify.
Oct-28-2020 18:21:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	patient was observed overnight and had surgery-but PI did not consider it an SAE
Oct-28-2020 15:04:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Please confirm event of APPENDICITIS is considered non-serious and not medically important, else

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

				update the CRF and submit SAE forms to the DSU as appropriate.
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Oct-27-2020 15:26:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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8. Is this adverse event the result of a study Medication Error?

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

Date	Location	User	Value	Reason
Oct-27-2020 15:26:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-27-2020 15:26:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> appendicitis	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-27-2020 15:26:51 (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
Oct-27-2020 15:26:51	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	YES	
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-27-2020 15:26:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Oct-27-2020 15:26:51 (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
Oct-27-2020 15:26:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Oct-30-2020 07:49:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020421554	Initial Entry

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Category:

Date	Location	User	Value	Reason
Oct-29-2020 18:19:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-29-2020 18:19:52 (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
Oct-29-2020 18:19:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: abdominal aortic aneurysm	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-29-2020 18:19:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/7/2020 01:09	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-29-2020 18:19:52 (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
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090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Oct-29-2020 18:19:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-29-2020 18:19:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Oct-29-2020 18:19:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-29-2020 18:19:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: incidental finding on CT scan	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Verified

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Oct-29-2020 18:19:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-29-2020 18:19:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-29-2020 18:19:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-29-2020 18:19:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/NOT RE SOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-29-2020 18:19:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Feb-11-2021 22:18:52 (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-11-2021 22:18:52 (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-11-2021 22:18:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: soreness at the injection site	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-11-2021 22:18:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/20/2021 08:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-11-2021 22:18:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/22/2021 08:00	Initial Entry

6. Toxicity Grade:

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Feb-11-2021 22:18:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-11-2021 22:18:52 (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
Feb-11-2021 22:18:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-11-2021 22:18:52 (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-11-2021 22:18:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Feb-11-2021 22:18:52 (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-11-2021 22:18:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-11-2021 22:18:52 (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-11-2021 22:18:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Feb-11-2021 22:20:26 (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-11-2021 22:20:26 (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-11-2021 22:20:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: lower back soreness	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-11-2021 22:20:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/20/2021 08:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-11-2021 22:20:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/22/2021 08:00	Initial Entry

6. Toxicity Grade:

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Feb-11-2021 22:20:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-11-2021 22:20:26 (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
Feb-11-2021 22:20:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-11-2021 22:20:26 (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-11-2021 22:20:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Feb-11-2021 22:20:26 (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-11-2021 22:20:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-11-2021 22:20:26 (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-11-2021 22:20:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Category:

Date	Location	User	Value	Reason
Mar-09-2021 12:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Mar-09-2021 12:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-09-2021 12:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: slight backache	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-09-2021 12:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/12/2021 08:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-09-2021 12:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Feb/13/2021 08:00	Initial Entry

6. Toxicity Grade:

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Mar-09-2021 12:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Mar-09-2021 12:43:28 (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-09-2021 12:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-09-2021 12:43:28 (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
Mar-09-2021 12:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Mar-09-2021 12:43:28 (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
Mar-09-2021 12:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Mar-09-2021 12:43:28 (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
Mar-09-2021 12:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Date	Location	User	Value	Reason
Oct-27-2020 15:29:19 (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: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Oct-27-2020 15:29:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Oct-27-2020 15:29:19 (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
Oct-27-2020 15:29:19 (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
Oct-27-2020 15:29:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: influenza vaccination	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Oct-27-2020 15:29:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/7/2020	Initial Entry

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-12-2021 15:43:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/8/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History

Form Status: Data Complete, Frozen

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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

Date	Location	User	Value	Reason
Jan-12-2021 15:43:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return f or Vaccination 3 Participant is: eligible per local/national re commendations and confir med to have received only p lacebo at Vaccination 1/2	Initial Entry

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-19-2021 16:22:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/19/2021	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, Frozen, Verified

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Consent Was:

Date	Location	User	Value	Reason
Jan-19-2021 16:22:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtain ed Jan/19/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Jan-19-2021 16:23:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/19/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-19-2021 16:23:38 (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
Jan-19-2021 16:23:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001**Visit:** V101_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
- eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1260**Site Name:** (1260) UMass Memorial Medical Center**Subject No:** 12601069**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-19-2021 16:23:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-19-2021 16:23:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-19-2021 19:14:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-19-2021 16:23:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-19-2021 16:23:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/19/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-19-2021 19:14:49	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

(b) (4),
(b) (6)

Sample ID: BPVNWG

5.a Sample ID

Date	Location	User	Value	Reason
Jan-19-2021 19:14:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPVNWG	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-19-2021 19:15:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNTXDY	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-19-2021 19:15:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNTXDY	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-19-2021 19:15:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNTXDZ	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-19-2021 19:15:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNTXDZ	Initial Entry

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001**Visit:** V101_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1260**Site Name:** (1260) UMass Memorial Medical Center**Subject No:** 12601069**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-19-2021 16:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-19-2021 16:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-19-2021 19:14:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-19-2021 16:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-19-2021 16:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/19/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-19-2021 19:14:39	ACV0PFEINFP6000	(b) (6)	Data Entry:	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, Frozen, Verified

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

(b) (4), (b) (6)

Sample ID: BPVNWB

5.a Sample ID

Date	Location	User	Value	Reason
Jan-19-2021 19:14:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPVNWB	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-19-2021 16:24:36 (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-19-2021 16:24:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-19-2021 16:24:36 (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-19-2021 16:24:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/19/2021 12:36	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-19-2021 16:24:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
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090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Jan-19-2021 16:24:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry
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7. Route:

Date	Location	User	Value	Reason
Jan-19-2021 16:24:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-19-2021 16:24:36 (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-19-2021 16:24:36 (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-19-2021 16:24:36 (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-19-2021 16:24:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-12-2021 15:43:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/8/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-12-2021 15:43:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATIO N	Initial Entry

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-11-2021 22:15:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/11/2021	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Data Origin

Date	Location	User	Value	Reason
Feb-11-2021 22:15:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-11-2021 22:15:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-12-2021 10:13:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-12-2021 04:59:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-11-2021 22:15:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-11-2021 22:15:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection:	Initial Entry

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

			Feb/11/2021	
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5.a

Date	Location	User	Value	Reason
Feb-12-2021 10:13:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPVNYJ	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-12-2021 10:13:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPVNYJ	Initial Entry

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-11-2021 22:16:32 (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
Feb-11-2021 22:16:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-11-2021 22:16:32 (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
Feb-11-2021 22:16:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/11/2021 15:13	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-11-2021 22:16:32 (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
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090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Feb-11-2021 22:16:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry
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7. Route:

Date	Location	User	Value	Reason
Feb-11-2021 22:16:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-11-2021 22:16:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-11-2021 22:16:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-11-2021 22:16:32 (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
Feb-11-2021 22:16:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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I. Date of Visit

Date	Location	User	Value	Reason
Mar-11-2021 00:35:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	As per site confirmation - updated PD tracker
Mar-10-2021 11:07:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Original value is correct
Mar-10-2021 05:49:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	PDQ: Date of visit V103_MONTH1 is out of window for -3 days from V102_VAX4 DOV or Vaccination date. Please verify and update. Else, confirm in query response appropriately.
Mar-10-2021 05:48:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Invalid query
Mar-10-2021 05:44:00 (UTC-05:00) Eastern Time	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	PDQ: Date of visit V103_MONTH1 is out of window

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

(US & Canada)				for 3 days from V102_VAX4 DOV or Vaccination date. Please verify and update. Else, confirm in query response appropriately. (b) (4)
Mar-09-2021 12:39:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Mar/8 /2021	Initial Entry

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1260

Subject No: 12601069

Generated By: (b) (4)

Form: CONTACT OUTCOME - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1260) UMass Memorial Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Contact Type:

Date	Location	User	Value	Reason
Mar-09-2021 12:40:09 (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
Mar-09-2021 12:40:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Contact: Mar/8/2021	Initial Entry

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Mar-09-2021 12:42:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/8/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-09-2021 12:42:10 (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-09-2021 12:42:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Subject Status

Date	Location	User	Value	Reason
Oct-27-2020 15:16:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-04-2020 20:35:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-04-2020 20:34:39 (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
Oct-27-2020 15:16:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/27/2020	Initial Entry
Sep-04-2020 20:35:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/4/2020	Initial Entry
Sep-04-2020 20:34:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/4/2020	Initial Entry

090177e196ae3ff4\Final\Final On: 01-Apr-2021 05:26 (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, Verified

Site No: 1260

Site Name: (1260) UMass Memorial Medical Center

Subject No: 12601069

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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I. Casebook Signature

Date	Location	User	Value	Reason
Jan-25-2021 11:28:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry
Jan-25-2021 11:27:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	New Information
Nov-06-2020 14:57:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry
Nov-06-2020 14:57:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Nov-02-2020 14:32:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry

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