

Header Text: C4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

[eCRF Audit Trail History](#)

Cohort Selection

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

1.	Select appropriate response - Protocol version	08 SEP 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

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: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

[eCRF Audit Trail History](#)

Informed Consent

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

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[12041234]
2.	Birth Date:	(b) (6) 1982
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:	

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Form Comments

Inclusion Criteria Not Met

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

2.	Description of Exclusion Criterion Met	Not Applicable _____
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090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Disposition - Screening

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

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Spondylolysis]
	Start Date:	Jan/1/2017
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Tonsillectomy]
	Start Date:	UNK/UNK/1999
	Ongoing:	NO End Date: UNK/UNK/1999

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

1.c	Line/MH Number:	[3]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Strep Throat]
	Start Date:	UNK/UNK/1999
	Ongoing:	NO End Date: UNK/UNK/1999

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: HIV STATUS

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

HIV Status

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

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Oct/14/2020
2.	Weight:	[199.0]
3.	Unit:	LB
4.	Height:	[71.0]
5.	Unit:	in
6.	Body Mass Index:	[27.8]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[98.8]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Oct/14/2020
2.	Randomization Number:	[107705]
3.	Randomization Group:	[]

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPYN7S]
5.b	Sample ID	[BNWLMH]
5.c	Sample ID	[BNWLMK]

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: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPYN78]
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/14/2020 16:13
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

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
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090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Nov/4/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.3]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001**Visit:** V2_VAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1204**Site Name:** (1204) Icahn School of Medicine at Mount Sinai**Subject No:** 12041234**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

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

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Nov/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	[BRBZY1]
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Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[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:	Nov/4/2020 12:49
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

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT

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

Site No: 1204 **Site Name:** (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Dec/3/2020
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, Frozen, Verified**Site No:** 1204**Site Name:** (1204) Icahn School of Medicine at Mount Sinai**Subject No:** 12041234**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

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

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/3/2020
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	[BS5HDL]
5.b	Sample ID	[BS5HDN]
5.c	Sample ID	[BS5HDM]
5.d	Sample ID	[BPVRYZ]

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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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090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:03

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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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090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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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090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (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: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 20-Feb-2021 02:17

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Not Started

Site Name: (1204) Icahn School of Medicine at Mount
Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Signs and Symptoms

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

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

5.	Symptoms - Other Text:	[]
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090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

Form Status: Not Started

Site Name: (1204) Icahn School of Medicine at Mount
Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: C4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Status: Not Started

Site Name: (1204) Icahn School of Medicine at Mount
Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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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090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 20-Feb-2021 02:19

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: HEALTH CARE UTILIZATION

Form Status: Not Started

Site Name: (1204) Icahn School of Medicine at Mount
Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Health Care Utilization

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

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[]
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Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	
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Header Text: C4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 06-Jul-2020 21:52

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: ILLNESS DETAILS

Form Status: Not Started

Site Name: (1204) Icahn School of Medicine at Mount
Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Illness Details

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

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

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: 1204

Site Name: (1204) Icahn School of Medicine at Mount
Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount
Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

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

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

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

3.	COVID-19 Repeat Swab:	
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Header Text: C4591001**Visit:** POT_COVID_REPEAT_SWAB - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB**Form Version:** 10-Oct-2020 15:57 **Form Status:** Not Started**Site No:** 1204**Site Name:** (1204) Icahn School of Medicine at Mount Sinai**Subject No:** 12041234**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 13:11

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Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: C4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

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#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Muscle tenderness at injection site	Oct/15/2020 08:00	NO End Date Time: Oct/18/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	Swollen, tender left axillary lymph node	Oct/17/2020 05:00	NO End Date Time: Oct/22/2020 10:00	Repeating Pages
3.	ADVERSE EVENT	3	Fatigue	Oct/15/2020 05:00	NO End Date Time: Oct/15/2020 14:00	Repeating Pages
4.	ADVERSE EVENT	4	Muscle tenderness at injection site	Nov/4/2020 14:00	NO End Date Time: Nov/6/2020 18:00	Repeating Pages
5.	ADVERSE EVENT	5	Low grade fever, 100.7	Nov/5/2020 02:00	NO End Date Time:	Repeating Pages

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Header Text: C4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
					Nov/6/2020 11:00	
6.	ADVERSE EVENT	6	Chills	Nov/5/2020 02:00	NO End Date Time: Nov/6/2020 18:00	Repeating Pages
7.	ADVERSE EVENT	7	Headache	Nov/5/2020 02:00	NO End Date Time: Nov/6/2020 18:00	Repeating Pages
8.	ADVERSE EVENT	8	Right axillary lymph node swelling	Nov/5/2020 12:00	NO End Date Time: Nov/11/2020 UNK:UNK	Repeating Pages

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Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Muscle tenderness at injection site]
4.	Start Date Time:	Oct/15/2020 08:00
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/18/2020 UNK:UNK
6.	Toxicity Grade:	1

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Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject Initials: ---

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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).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES

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Header Text: C4591001

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Form: ADVERSE EVENT REPORT

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Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

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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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Subject No: 12041234

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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)	[Swollen, tender left axillary lymph node]
4.	Start Date Time:	Oct/17/2020 05:00
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/22/2020 10:00
6.	Toxicity Grade:	1

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Header Text: C4591001

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Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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

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Header Text: C4591001

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Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

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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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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Fatigue]
4.	Start Date Time:	Oct/15/2020 05:00
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/15/2020 14:00
6.	Toxicity Grade:	1

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Site No: 1204

Subject No: 12041234

Generated By:

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Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject Initials: ---

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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).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

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Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

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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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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Muscle tenderness at injection site]
4.	Start Date Time:	Nov/4/2020 14:00
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/6/2020 18:00
6.	Toxicity Grade:	1

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Site Name: (1204) Icahn School of Medicine at Mount Sinai

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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).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES

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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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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Low grade fever, 100.7]
4.	Start Date Time:	Nov/5/2020 02:00
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/6/2020 11:00
6.	Toxicity Grade:	1

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Form Status: Data Complete, Frozen, Verified

Site Name: (1204) Icahn School of Medicine at Mount Sinai

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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).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES

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Header Text: C4591001

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Form Status: Data Complete, Frozen, Verified

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Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

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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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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[6]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Chills]
4.	Start Date Time:	Nov/5/2020 02:00
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/6/2020 18:00
6.	Toxicity Grade:	1

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Form Status: Data Complete, Frozen, Verified

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject Initials: ---

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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).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES

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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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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[7]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Headache]
4.	Start Date Time:	Nov/5/2020 02:00
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/6/2020 18:00
6.	Toxicity Grade:	2

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Header Text: C4591001

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Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1204) Icahn School of Medicine at Mount Sinai

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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).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES

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Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

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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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Subject Initials: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[8]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Right axillary lymph node swelling]
4.	Start Date Time:	Nov/5/2020 12:00
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/11/2020 UNK:UNK
6.	Toxicity Grade:	1

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Subject No: 12041234

Generated By:

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Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1204) Icahn School of Medicine at Mount Sinai

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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).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

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Subject No: 12041234

Subject Initials: ---

Generated By:

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

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Header Text: C4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Form Status: Not Started

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

[Back to Form](#)

Medication Error

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

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	Influenza Vaccines	Nov/25/2020	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, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

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[Form Audit Trail](#)

Concomitant Medications

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Influenza Vaccine]
5.	Date:	Nov/25/2020

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

[Back to Form](#)

Concomitant Medications

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

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

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Radiation Treatment

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

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

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

Header Text: C4591001

Visit: Unplanned - New Unscheduled **Form:** DATE OF VISIT
Visit

Form Version: 22-Apr-2020 21:02 **Form Status:** Not Started

Site No: 1204 **Site Name:** (1204) Icahn School of Medicine at Mount
Sinai

Subject No: 12041234 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

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: 1204 **Site Name:** (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

Unplanned Assessments

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

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount
Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VITAL SIGNS - TEMP

Form Version: 20-Feb-2021 02:16

Form Status: Not Started

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount
Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

Vital Signs

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

Vital Signs Details

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

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount
Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

Vaccination

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

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination -
Unscheduled

Form Version: 10-Oct-2020 15:57

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: CONTACT OUTCOME - MONTH 1

Form Status: Not Started

Site Name: (1204) Icahn School of Medicine at Mount
Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Contact Outcome

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

Header Text: C4591001

Visit: Unplanned Vaccination -
Unscheduled

Form Version: 10-Oct-2020 16:01

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: CONTACT OUTCOME - MONTH 6

Form Status: Not Started

Site Name: (1204) Icahn School of Medicine at Mount
Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Contact Outcome

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

Header Text: C4591001

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

Form Version: 22-Apr-2020 21:02 **Form Status:** Not Started

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount
Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

Informed Consent - Asymptomatic Surveillance

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

Header Text: C4591001**Visit:** V201_SURVEIL_CONSENT -
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1204**Site Name:** (1204) Icahn School of Medicine at Mount
Sinai**Subject No:** 12041234**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: C4591001**Visit:** V201_SURVEIL_CONSENT -
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING - NASAL
SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1204**Site Name:** (1204) Icahn School of Medicine at Mount
Sinai**Subject No:** 12041234**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: C4591001

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

Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

[eCRF Audit Trail History](#)

Disposition - Treatment

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

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

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

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

Site No: 1204 **Site Name:** (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/6/2021
2.	Erroneous Visit	

Header Text: C4591001

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

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen, Verified

Site No: 1204 **Site Name:** (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234 **Subject Initials:** ---

Generated By:
(b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Disposition - Follow-Up

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

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/7/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Withdrawal Of Consent

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

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Death Details

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

Cause of Death

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

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Dec/3/2020

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: 1204

Site Name: (1204) Icahn School of Medicine at Mount
Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount
Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

[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: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Version: 10-Oct-2020 16:00

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount
Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

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Item	Date	User	Comment
Form	Oct-14-2020 16:24:48 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (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: 1204

Site Name: (1204) Icahn School of Medicine at Mount
Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

[Back to Form](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
(b) (6) [REDACTED]	N/A	Feb-24-2021 20:24:45 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

Judith Aberg	Approved	Jan-25-2021 16:24:35 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
-----------------	----------	--	------	--------

Affidavit:

By my dated signature below, I, JudithAberg, 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.

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (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: 1204

Site Name: (1204) Icahn School of Medicine at Mount
Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

(b) (6) [Redacted]	N/A	Nov-23-2020 11:19:57 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6) [Redacted]	Approved	Nov-11-2020 15:33:26 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
-----------------------	----------	--	------	--------

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.

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Oct-14-2020 16:23:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: 08 SEP 2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-14-2020 16:23:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: STAGE 3 COHORT S	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

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1. Consent Was:

Date	Location	User	Value	Reason
Oct-14-2020 16:24:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: OBTAINED Date Written Cons ent Obtained Oct/14/2020	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Subject ID

Date	Location	User	Value	Reason
Oct-14-2020 16:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12041234	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Oct-14-2020 16:23:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) 1982	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Oct-14-2020 16:24:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: MALE	Initial Entry

4. Ethnicity:

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

Date	Location	User	Value	Reason
Oct-14-2020 16:24:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NOT HISPANIC O R LATINO(A) OR OF SPANISH ORIG IN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-14-2020 16:24:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: WHITE	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Oct-14-2020 16:24:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Oct/14/2020	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Oct-14-2020 16:25:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Oct/14/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-14-2020 16:25:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-14-2020 16:25:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: COMPLETED	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1204**Subject No:** 12041234**Generated By:**

(b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1204) Icahn School of Medicine at Mount Sinai**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:11[Back to Form](#)*1.a*

Date	Location	User	Value	Reason
Oct-14-2020 16:27:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 1 mber: Medical Hist Spondy ory Term: lolysis Start Date: Jan/1/2 017 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Oct-14-2020 16:27:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Oct-14-2020 16:27:15 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Spondylolysis	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

Eastern Time (US & Canada)

1.a Start Date:

Date	Location	User	Value	Reason
Oct-14-2020 16:27:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/1/2017	Initial Entry

1.a Ongoing:

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

1.b

Date	Location	User	Value	Reason
Oct-14-2020 16:27:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 2 Number: Medical H Tonsillecto istory Ter my m:	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

			Start Date UNK/UN : K/1999	
			Ongoing: NO	
			End Date :	
			UNK/U NK/199 9	

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

1.b Line/MH Number:

Date	Location	User	Value	Reason
Oct-14-2020 16:27:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Oct-19-2020 09:26:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Site confirmed condition and added to Med History
Oct-16-2020 10:24:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Oct-15-2020 14:00:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPDClinical: As per data guidelines conditions which caused a surgical procedure should be added

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

				as a separate condition on Medical History. Please add as a separate condition which resulted in Tonsillectomy.
Oct-14-2020 16:27:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Tonsillectomy	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Oct-14-2020 16:27:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1999	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Oct-14-2020 16:27:54 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date:	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

Eastern Time (US & Canada)

UNK/UNK/1999

I.c

Date	Location	User	Value	Reason
Oct-16-2020 10:23:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 3 Number: Medical History Term: Strep Throm: Start Date: UNK/UNK/1999 Ongoing: NO End Date: UNK/UNK/1999 9	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

1.c Line/MH Number:

Date	Location	User	Value	Reason
Oct-16-2020 10:23:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Oct-16-2020 10:23:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Strep Throat	Initial Entry

1.c Start Date:

Date	Location	User	Value	Reason
Oct-16-2020 10:23:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1999	Initial Entry

1.c Ongoing:

Date	Location	User	Value	Reason
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090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

Oct-16-2020 10:23:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO End Date: UNK/UNK/1999	Initial Entry
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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

Date	Location	User	Value	Reason
Oct-14-2020 16:28:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: The subject is NOT known to be HIV P OSITIVE	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Date:

Date	Location	User	Value	Reason
Oct-14-2020 16:28:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Oct/14/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Oct-14-2020 16:28:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: 199.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Oct-14-2020 16:28:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: LB	Initial Entry

4. Height:

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

Date	Location	User	Value	Reason
Oct-14-2020 16:28:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: 71.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Oct-14-2020 16:28:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Oct-14-2020 16:28:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 27.8	Initial Entry

7.a

Date	Location	User	Value	Reason
Oct-14-2020 16:28:30	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry:	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

(UTC-05:00) Eastern Time (US & Canada)			Record Identifier: 1	
			Temperature: 98.8	
			Temperature Unit: F	
			Temperature Location: ORAL CAVIT	
			Y: Y	

7.a Record Identifier:

Date	Location	User	Value	Reason
Oct-14-2020 16:28:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Oct-14-2020 16:28:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: 98.8	Initial Entry

7.a Unit:

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

Date	Location	User	Value	Reason
Oct-14-2020 16:28:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Oct-14-2020 16:28:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Randomization Date :

Date	Location	User	Value	Reason
Oct-14-2020 17:17:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/14/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Oct-14-2020 17:17:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 107705	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Data Origin

Date	Location	User	Value	Reason
Oct-14-2020 16:29:07 (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-14-2020 16:29:07 (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-15-2020 09:51:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-15-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (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: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

04:28:57 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-14-2020 16:29:07 (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-14-2020 16:29:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/14/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-15-2020 09:51:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPYN7S	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (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: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

5.a Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 09:51:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPYN7S	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-15-2020 09:51:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BNWLM D: H	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 09:51:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNWLMH	Initial Entry

5.c

Date	Location	User	Value	Reason
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090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (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: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

Oct-15-2020 09:51:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BNWLM D: K	Initial Entry
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5.c Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 09:51:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNWLMK	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Data Origin

Date	Location	User	Value	Reason
Oct-14-2020 16:29:16 (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-14-2020 16:29:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-15-2020 09:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-15-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (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: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

04:28:57 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-14-2020 16:29:16 (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-14-2020 16:29:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/14/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-15-2020 09:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPYN78	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (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: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

5.a Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 09:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: BPYN78	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-14-2020 17:13:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Oct-14-2020 17:13:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-14-2020 17:13:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Date	Location	User	Value	Reason
Oct-14-2020 17:13:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Oct/14/2020 16:13	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-14-2020 17:13:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Oct-14-2020 17:13:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Oct-14-2020 17:13:17 (UTC-05:00)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Eastern Time (US & Canada)

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-14-2020 17:13:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Oct-14-2020 17:13:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Oct-14-2020 17:13:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Nov-04-2020 12:18:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Nov/4/2020	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Date:

Date	Location	User	Value	Reason
Nov-04-2020 12:19:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/4/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-04-2020 12:19:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Id 1 entifier:: Temperat 98.3 ure: Temperat F ure Unit: Temperat ORAL ure Locati CAVIT on:: Y	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-04-2020 12:19:12	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

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

2.a Temperature:

Date	Location	User	Value	Reason
Nov-04-2020 12:19:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.3	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Nov-04-2020 12:19:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Nov-04-2020 12:19:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

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1. Data Origin

Date	Location	User	Value	Reason
Nov-04-2020 12:19:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-04-2020 12:19:40 (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
Nov-04-2020 15:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-04-2020	ACV0PFEINFP6000	auto query	Query 1: Candidate	'Sample

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

12:19:40 (UTC-05:00) Eastern Time (US & Canada)		(autoquery)		Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-04-2020 12:19:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/4/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-04-2020 15:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BRBZY : 1	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-04-2020 15:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRBZY1	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

& Canada)

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Nov-04-2020 14:28:16 (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
Nov-04-2020 14:28:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Nov-04-2020 14:28:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

Date	Location	User	Value	Reason
Nov-04-2020 14:28:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/4/2020 12:49	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Nov-04-2020 14:28:16 (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
Nov-04-2020 14:28:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Nov-04-2020 14:28:16 (UTC-05:00)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

Eastern Time (US & Canada)

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Nov-04-2020 14:28:16 (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
Nov-04-2020 14:28:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

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

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

Site No: 1204 **Site Name:** (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

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1. Date of Visit

Date	Location	User	Value	Reason
Dec-03-2020 13:54:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4)	Data Entry: Dec/3/2020	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, Frozen, Verified

Site No: 1204 **Site Name:** (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

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1. Data Origin

Date	Location	User	Value	Reason
Dec-03-2020 13:55:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-03-2020 13:55:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-03-2020 15:38:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-03-2020	ACV0PFEINFP6000	auto query	Query 1: Candidate	'Sample

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

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

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

Site No: 1204 **Site Name:** (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

13:55:25 (UTC-05:00) Eastern Time (US & Canada)		(autoquery)		Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-03-2020 13:55:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/3/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-03-2020 15:38:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BS5HD : L	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-03-2020 15:38:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS5HDL	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

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

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

Site No: 1204 Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 13:11

& Canada)				
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5.b

Date	Location	User	Value	Reason
Dec-03-2020 15:38:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BS5HD : N	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-03-2020 15:38:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS5HDN	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-03-2020 15:39:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BS5HD : M	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

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

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

Site No: 1204 **Site Name:** (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

5.c Sample ID

Date	Location	User	Value	Reason
Dec-03-2020 15:39:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS5HDM	Initial Entry

5.d

Date	Location	User	Value	Reason
Dec-03-2020 15:39:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BPVRY : Z	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Dec-03-2020 15:39:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPVRYZ	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Date	Location	User	Value	Reason
Oct-20-2020 16:53:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

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Date	Location	User	Value	Reason
Oct-20-2020 16:54:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-20-2020 16:55:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

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Date	Location	User	Value	Reason
Nov-05-2020 10:43:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

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Date	Location	User	Value	Reason
Nov-05-2020 11:14:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

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Date	Location	User	Value	Reason
Nov-05-2020 11:15:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

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Date	Location	User	Value	Reason
Nov-05-2020 11:16:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

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Date	Location	User	Value	Reason
Nov-05-2020 14:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

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1. Category:

Date	Location	User	Value	Reason
Oct-20-2020 16:53:09 (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-20-2020 16:53:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-20-2020 16:53:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Muscle tenderness at injection site	Initial Entry

4. Start Date Time:

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

Date	Location	User	Value	Reason
Oct-20-2020 16:53:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/15/2020 08:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-20-2020 16:53:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/18/2020 U NK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-20-2020 16:53:09 (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.

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

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Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

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Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

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-20-2020 16:53:09 (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-20-2020 16:53:09 (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-20-2020 16:53:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

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Header Text: C4591001

Visit: Logs - Unscheduled

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Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-20-2020 16:53:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICAB LE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-20-2020 16:53:09 (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
Oct-20-2020 16:53:09 (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
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090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

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Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

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Generated By:

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(b) (4)

Oct-20-2020 16:53:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RE SOLVED	Initial Entry
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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-20-2020 16:53:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

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Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Category:

Date	Location	User	Value	Reason
Oct-20-2020 16:54:06 (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-20-2020 16:54:06 (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-20-2020 16:54:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Swollen, tender left axillary lymph node	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

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Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-20-2020 16:54:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/17/2020 05:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-26-2020 18:47:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-23-2020 10:08:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-23-2020 10:08:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/22/2020 10:00	Changed Information
Oct-22-2020	ACV0PFEINFP6000	(b) (6)	Query 1: Opened	Per source the

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

21:47:52 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		end date is 22Oct2020 10:00 Please confirm and update EDC if appropriate.
Oct-20-2020 16:54:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-20-2020 16:54:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
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090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

Oct-20-2020 16:54:06 (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-20-2020 16:54:06 (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-20-2020 16:54:06 (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
Oct-20-2020 16:54:06	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICAB	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	LE	
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-20-2020 16:54:06 (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-20-2020 16:54:06 (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-23-2020 10:08:39 (UTC-05:00) Eastern Time (US &	ACV0PFEINFP6000	auto query (autoquery)	Query 1: C losed	Close Auto Query

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

Canada)				
Oct-23-2020 10:08:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Changed Information
Oct-23-2020 10:08:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Swollen, tender left axillary lymph node: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Oct-20-2020 16:54:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Oct-20-2020 16:54:06 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

& Canada)

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

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1. Category:

Date	Location	User	Value	Reason
Oct-20-2020 16:55:09 (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-20-2020 16:55:09 (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
Oct-20-2020 16:55:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Fatigue	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-20-2020 16:55:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/15/2020 05:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-20-2020 16:55:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/15/2020 14:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-20-2020 16:55:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

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090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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(b) (4)

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-20-2020 16:55:09 (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-20-2020 16:55:09 (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-20-2020 16:55:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

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Subject No: 12041234

Subject Initials: ---

Generated By:

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(b) (4)

& Canada)

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-20-2020 16:55:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICAB LE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-20-2020 16:55:09 (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-20-2020 16:55:09 (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?:

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

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Site Name: (1204) Icahn School of Medicine at Mount Sinai

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Date	Location	User	Value	Reason
Oct-20-2020 16:55:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RE SOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-20-2020 16:55:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

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Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Category:

Date	Location	User	Value	Reason
Nov-05-2020 10:43:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-05-2020 10:43:39 (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
Nov-05-2020 10:43:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Muscle tenderness at injection site	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-05-2020 10:43:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/4/2020 14:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-09-2020 16:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Nov/6/2020 18:00	Changed Information
Nov-05-2020 10:43:39 (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
Nov-05-2020 10:43:39 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

Eastern Time (US & Canada)

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 10:43:39 (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
Nov-05-2020 10:43:39 (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:

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

Date	Location	User	Value	Reason
Nov-05-2020 10:43:39 (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
Nov-05-2020 10:43:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-05-2020 10:43:39 (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
Nov-05-2020 10:43:39	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

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

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

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

Date	Location	User	Value	Reason
Nov-09-2020 16:42:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: C losed	Close Auto Query
Nov-09-2020 16:42:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Changed Information
Nov-09-2020 16:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: O pened	For AE Muscle tenderness at injection site: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Nov-05-2020 10:43:39	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

(UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	RECOVERING/RESOLVING
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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Nov-05-2020 10:43:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

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1. Category:

Date	Location	User	Value	Reason
Nov-05-2020 11:14:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-05-2020 11:14:18 (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
Nov-05-2020 11:14:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Low grade fever, 1 00.7	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-05-2020 11:14:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/5/2020 02:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-23-2020 18:20:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Error
Dec-23-2020 18:19:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Please verify the stop time, it does not match the source.
Dec-23-2020 18:18:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-14-2020 10:39:03	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

(UTC-05:00) Eastern Time (US & Canada)				
Dec-14-2020 10:39:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO End Date Time : Nov/6/2020 1 1:00	Transcription Error
Dec-13-2020 14:34:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	Please verify the stop date and time, update CRFs as needed.
Nov-09-2020 16:43:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO End Date Time : Nov/5/2020 0 2:00	Changed Information
Nov-05-2020 11:14:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: YES	Initial Entry

6. Toxicity Grade:

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

Date	Location	User	Value	Reason
Nov-05-2020 11:14:18 (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
Nov-05-2020 11:14:18 (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
Nov-05-2020 11:14:18 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

Eastern Time (US & Canada)				
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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-05-2020 11:14:18 (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
Nov-05-2020 11:14:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-05-2020 11:14:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-05-2020 11:14:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-09-2020 16:44:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-09-2020 16:44:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Changed Information
Nov-09-2020 16:43:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Low grade fever, 100.7: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving'

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

				but AE End Date/Time is present.
Nov-05-2020 11:14:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Nov-05-2020 11:14:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Nov-05-2020 11:15:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-05-2020 11:15:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-05-2020 11:15:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Chills	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-05-2020 11:15:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/5/2020 02:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-23-2020 18:19:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-14-2020 10:39:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-14-2020 10:39:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time : Nov/6/2020 1 8:00	Transcription Error

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

Dec-13-2020 14:32:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Please verify the stop date and time, update as needed.
Nov-09-2020 16:43:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time : Nov/5/2020 02:00	Changed Information
Nov-05-2020 11:15:56 (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
Nov-05-2020 11:15:56 (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.

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

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 11:15:56 (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
Nov-05-2020 11:15:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-05-2020 11:15:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-05-2020 11:15:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICAB LE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-05-2020 11:15:56 (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
Nov-05-2020 11:15:56 (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
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090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

Nov-09-2020 16:44:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-09-2020 16:44:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Changed Information
Nov-09-2020 16:43:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Chills: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Nov-05-2020 11:15:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

Nov-05-2020 11:15:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry
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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Nov-05-2020 11:16:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-05-2020 11:16:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-05-2020 11:16:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Headache	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-05-2020 11:16:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/5/2020 02:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-09-2020 16:45:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Nov/6/2020 1 8:00	Changed Information
Nov-05-2020 11:16:56 (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
Nov-05-2020 11:16:56 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

Eastern Time (US & Canada)

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 11:16:56 (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
Nov-05-2020 11:16:56 (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:

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

Date	Location	User	Value	Reason
Nov-05-2020 11:16:56 (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
Nov-05-2020 11:16:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-05-2020 11:16:56 (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
Nov-05-2020 11:16:56	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

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

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

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

Date	Location	User	Value	Reason
Nov-09-2020 17:05:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: C losed	Close Auto Query
Nov-09-2020 17:05:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: RECOVERED/RESOLVED	Changed Information
Nov-09-2020 16:45:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: O pened	For AE Headache: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Nov-05-2020 11:16:56 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: RECOVERED/RESOLVED	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

(US & Canada)			SOLVING	
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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Nov-05-2020 11:16:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

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1. Category:

Date	Location	User	Value	Reason
Nov-05-2020 14:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-05-2020 14:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-05-2020 14:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Right axillary lymph node swelling	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-05-2020 14:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/5/2020 12:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-27-2020 12:08:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 1: Closed	Response satisfies query
Nov-23-2020 11:19:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-23-2020 11:19:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Nov/11/2020 UNK:UNK	Changed Information
Nov-23-2020	ACV0PFEINFP6000	Juleen Gayed	Query 1: Opened	Clin: Please

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

09:41:09 (UTC-05:00) Eastern Time (US & Canada)		(b) (4)		confirm if this AE is still ongoing
Nov-05-2020 14:44:21 (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
Nov-05-2020 14:44:21 (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
Nov-05-2020	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

14:44:21 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	NO	
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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
Nov-05-2020 14:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-05-2020 14:44:21 (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
Nov-05-2020 14:44:21 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

Eastern Time (US & Canada)

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-05-2020 14:44:21 (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
Nov-05-2020 14:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-23-2020 11:20:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

Nov-23-2020 11:20:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Changed Information
Nov-23-2020 11:19:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Right axillary lymph node swelling: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Nov-05-2020 14:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Nov-05-2020 14:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (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: 1204

Site Name: (1204) Icahn School of Medicine at Mount
Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

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Date	Location	User	Value	Reason
Dec-03-2020 13:55:58 (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, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Dec-03-2020 13:55:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Dec-03-2020 13:55:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Dec-03-2020 13:55:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

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
Dec-03-2020 13:55:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Influenza Vaccine	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Dec-03-2020 13:55:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Nov/25/2020	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (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, Frozen, Verified

Site No: 1204 **Site Name:** (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Dec-03-2020 13:56:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/3/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Dec-03-2020 13:56:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Dec-03-2020 13:56:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT - eCRF Audit Trail History
Unscheduled

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

Site No: 1204 **Site Name:** (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-25-2021 07:54:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-24-2021 20:24:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-24-2021 20:24:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/6/2021	New Information
Feb-24-2021 17:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Please verify if the date of subject confirmation to unblinded was on 06Jan2021. Update CRF as needed.

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen, Verified

Site No: 1204 **Site Name:** (1204) Icahn School of Medicine at Mount
Sinai

Subject No: 12041234 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

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

Date	Location	User	Value	Reason
Jan-11-2021 15:07:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willi ng to return for Va ccination 3 Participant is: eligible and NO T confirmed to have received o nly placebo at Vaccination 1/2	Initial Entry

Header Text: C4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-11-2021 15:06:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/7/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-11-2021 15:06:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBI LITY FOR ADDI TIONAL VACCI NATION	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (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: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

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1. Subject Status

Date	Location	User	Value	Reason
Dec-03-2020 13:56:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Oct-14-2020 17:17:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Oct-14-2020 16:25:05 (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
Dec-03-2020 13:56:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Dec/3/2020	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (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: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041234

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

Oct-14-2020 17:17:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/14/2020	Initial Entry
Oct-14-2020 16:25:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/14/2020	Initial Entry

090177e196ae2f83\Final\Final On: 01-Apr-2021 03:45 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1204

Subject No: 12041234

Generated By:

(b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit
Trail History

Form Status: Data Complete, Verified

Site Name: (1204) Icahn School of Medicine at Mount
Sinai

Subject Initials: ---

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1. Casebook Signature

Date	Location	User	Value	Reason
Oct-21-2020 11:56:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Ena ble	Initial Entry