

Header Text: C4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1204

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

Subject No: 12041138

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

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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: 12041138

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 Sep/21/2020
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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: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[12041138]
2.	Birth Date:	(b) (6) 1988
3.	Sex:	MALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1204

Subject No: 12041138

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	Sep/21/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 1204

Subject No: 12041138

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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090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1204

Subject No: 12041138

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	Sep/21/2020
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: 12041138

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:	[Pernicious Anemia]
	Start Date:	Mar/21/2019
	Ongoing:	YES

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1204

Subject No: 12041138

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: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1204

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

Subject No: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/21/2020
2.	Weight:	[140.0]
3.	Unit:	LB
4.	Height:	[72.0]
5.	Unit:	in
6.	Body Mass Index:	[19.0]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[98.7]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1204

Subject No: 12041138

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 :	Sep/21/2020
2.	Randomization Number:	[95019]
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:** 12041138**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: Sep/21/2020
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	[BPYM8F]
5.b	Sample ID	[BNWLC0]
5.c	Sample ID	[BNWLC4]

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:** 12041138**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: Sep/21/2020
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	[BPYM8B]
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1204

Subject No: 12041138

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:	Sep/21/2020 15:20
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1204

Subject No: 12041138

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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Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1204

Subject No: 12041138

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/12/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP

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: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Oct/12/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.6]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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: 12041138

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/12/2020
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	[BPYNBT]
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090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1204

Subject No: 12041138

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/12/2020 12:42
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001

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

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

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

Subject No: 12041138 **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	Nov/16/2020
2.	Erroneous Visit	

Header Text: C4591001**Visit:** V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1204**Site Name:** (1204) Icahn School of Medicine at Mount Sinai**Subject No:** 12041138**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: Nov/16/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPVRMD]
5.b	Sample ID	[BRV5DV]
5.c	Sample ID	[BRV5DX]

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1204

Subject No: 12041138

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: 12041138

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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Header Text: C4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1204

Subject No: 12041138

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: 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: 12041138

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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Header Text: C4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1204

Subject No: 12041138

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: 12041138

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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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: 12041138

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:	
----	-------------------------	--

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 20-Feb-2021 02:17

Site No: 1204

Subject No: 12041138

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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Header Text: C4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1204

Subject No: 12041138

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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090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL - New
Unscheduled Visit**Form Version:** 22-Apr-2020 21:03**Site No:** 1204**Subject No:** 12041138**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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Header Text: C4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1204

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

Subject No: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

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?	
----	--	--

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 06-Jul-2020 21:52

Site No: 1204

Subject No: 12041138

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:	

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: 12041138

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:	
----	-------------------------	--

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:** 12041138**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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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: 12041138

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:** 12041138**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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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: 12041138 **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: 12041138 **Subject Initials:** ---

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

Unplanned Assessments

1.	Assessments	
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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: 12041138

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
1.	ADVERSE EVENT	1	muscle pain - abdominal	Sep/22/2020 20:00	NO End Date Time: Sep/23/2020 22:00	Repeating Pages
2.	ADVERSE EVENT	2	opposite shoulder pain intermittent	Sep/22/2020 12:00	NO End Date Time: Sep/23/2020 10:00	Repeating Pages
3.	ADVERSE EVENT	3	Muscle tenderness at injection site	Oct/12/2020 22:00	NO End Date Time: Oct/14/2020 09:00	Repeating Pages
4.	ADVERSE EVENT	4	Low grade fever, 99.0	Oct/13/2020 12:00	NO End Date Time: Oct/14/2020 09:00	Repeating Pages
5.	ADVERSE EVENT	5	Fatigue	Oct/12/2020 22:00	NO End Date Time:	Repeating Pages

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

Subject No: 12041138

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
					Oct/14/2020 09:00	
6.	ADVERSE EVENT	6	Swollen submandibular lymph nodes	Oct/13/2020 20:00	NO End Date Time: Oct/15/2020 UNK:UNK	Repeating Pages
7.	ADVERSE EVENT	7	Polydipsia	Oct/12/2020 22:00	NO End Date Time: Oct/15/2020 UNK:UNK	Repeating Pages

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Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

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Form Status: Data Complete, Locked, Frozen

Site No: 1204

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

Subject No: 12041138

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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 pain - abdominal]
4.	Start Date Time:	Sep/22/2020 20:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/23/2020 22:00
6.	Toxicity Grade:	1

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Generated By:

(b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

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, Locked, Frozen

Site No: 1204

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

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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:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[opposite shoulder pain intermittent]
4.	Start Date Time:	Sep/22/2020 12:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/23/2020 10:00
6.	Toxicity Grade:	1

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Header Text: C4591001

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Subject No: 12041138

Generated By:

(b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

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:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [repetitive stress from work]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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Form Status: Data Complete, Locked, Frozen

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

Subject No: 12041138

Subject Initials: ---

Generated By:

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11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
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:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Muscle tenderness at injection site]
4.	Start Date Time:	Oct/12/2020 22:00
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/14/2020 09:00
6.	Toxicity Grade:	1

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Subject No: 12041138

Generated By:

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Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

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:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Low grade fever, 99.0]
4.	Start Date Time:	Oct/13/2020 12:00
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/14/2020 09:00
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?	NO

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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:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Fatigue]
4.	Start Date Time:	Oct/12/2020 22:00
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/14/2020 09:00
6.	Toxicity Grade:	1

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Subject No: 12041138

Generated By:

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Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

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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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)	[Swollen submandibular lymph nodes]
4.	Start Date Time:	Oct/13/2020 20:00
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/15/2020 UNK:UNK
6.	Toxicity Grade:	1

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Form Status: Data Complete, Frozen

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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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)	[Polydipsia]
4.	Start Date Time:	Oct/12/2020 22:00
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/15/2020 UNK:UNK
6.	Toxicity Grade:	2

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Header Text: C4591001

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Site No: 1204

Subject No: 12041138

Generated By:

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Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

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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Site No: 1204

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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: 12041138

Subject Initials: ---

Generated By:

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

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1204

Subject No: 12041138

Generated By:

(b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

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

Subject Initials: ---

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

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Medication Error

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

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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: 12041138

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 Vaccine	Oct/30/2020	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: 12041138

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Generated By:

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Concomitant Medications

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

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Header Text: C4591001

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Form: CONCOMITANT MEDICATIONS - PROHIBITED

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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:

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#	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: 12041138

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?	

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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: 12041138

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: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Radiation Treatment

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

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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: 12041138

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: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

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

Header Text: C4591001

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

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

Site No: 1204

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

Subject No: 12041138

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 :	Nov/16/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: C4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1204

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

Subject No: 12041138

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: 12041138

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:	

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: 12041138

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?	

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1204

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

Subject No: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

Contact Outcome

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

Header Text: C4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: CONTACT OUTCOME - MONTH 6

Form Version: 10-Oct-2020 16:01

Form Status: Not Started

Site No: 1204

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

Subject No: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

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: 12041138

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: 12041138

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:** 12041138**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: 12041138

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: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1204

Subject No: 12041138

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: 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: 12041138 **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/14/2021
2.	Erroneous Visit	

Header Text: C4591001

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

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

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

Subject No: 12041138 **Subject Initials:** ---

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

[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: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1204

Subject No: 12041138

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 :	Feb/9/2021
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: 12041138

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: DEATH DETAILS CODED

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: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

Death Details

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

Cause of Death

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

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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: 12041138

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	Nov/16/2020

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: 12041138

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: 12041138

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: 15-Sep-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: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-21-2020 16:48:23 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1204

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

Subject No: 12041138

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)	N/A	Feb-18-2021 19:10:13 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

(b) (6)	Approved	Nov-16-2020 19:00:08 (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.

(b) (6)	N/A	Nov-16-2020 15:54:38 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

Affidavit:

N/A

(b) (6)	Approved	Nov-06-2020 18:37:47 (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.

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1204

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

Subject No: 12041138

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
Sep-21-2020 16:45:41 (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
Sep-21-2020 16:45:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: STAGE 3 COHORT S	Initial Entry

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1204

Subject No: 12041138

Generated By:

(b) (4)

Form: MAIN INFORMED CONSENT - 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. Consent Was:

Date	Location	User	Value	Reason
Sep-21-2020 16:45:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: OBTAINED Date Written Cons ent Obtained Sep/21/2020	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1204

Subject No: 12041138

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

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Sep-21-2020 16:45:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12041138	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-21-2020 16:45:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) 1988	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-21-2020 16:45:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: MALE	Initial Entry

4. Ethnicity:

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Sep-21-2020 16:45:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: HISPANIC OR LAT INO(A) OR OF SPA NISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-21-2020 16:45:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: WHITE	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1204

Subject No: 12041138

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

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-21-2020 16:46:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Sep/21/2020	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1204

Subject No: 12041138

Generated By:

(b) (4)

Form: DISPOSITION - SCREENING - 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 of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-21-2020 16:49:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Sep/21/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-21-2020 16:49:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-21-2020 16:49:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: COMPLETED	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1204**Subject No:** 12041138**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](#)*I.a*

Date	Location	User	Value	Reason
Sep-21-2020 16:50:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 1 umber: Medical Hi Perniciou story Term s Anemia : Start Date: Mar/21/2 019 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-21-2020 16:50:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-21-2020 16:50:23	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Pernicious Anemia	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: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

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

1.a Start Date:

Date	Location	User	Value	Reason
Sep-21-2020 16:50:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Mar/21/2019	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Sep-21-2020 16:50:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: YES	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1204

Subject No: 12041138

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
Sep-21-2020 16:51:03 (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: 15-Sep-2020 21:56

Site No: 1204

Subject No: 12041138

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
Sep-21-2020 16:51:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Sep/21/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-21-2020 16:51:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: 140.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-21-2020 16:51:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: LB	Initial Entry

4. Height:

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1204

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

Subject No: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Sep-21-2020 16:51:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<u>Data Entry:</u> 72.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-21-2020 16:51:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<u>Data Entry:</u> in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-21-2020 16:51:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 19.0	Initial Entry

7.a

Date	Location	User	Value	Reason
Sep-21-2020 16:51:49	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<u>Data Entry:</u>	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1204

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

Subject No: 12041138

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: 98.7	
			Temperature Unit: F	
			Temperature Location: ORAL CAVIT	
			Y: Y	

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-21-2020 16:51:49 (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
Sep-21-2020 16:51:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: 98.7	Initial Entry

7.a Unit:

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1204

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

Subject No: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Sep-21-2020 16:51:49 (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
Sep-21-2020 16:51:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1204

Subject No: 12041138

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
Sep-21-2020 19:10:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/21/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-21-2020 19:10:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 95019	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1204

Subject No: 12041138

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
Sep-21-2020 16:52:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-21-2020 16:52:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-21-2020 17:00:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-21-2020	ACV0PFEINFP6000	auto query	Query 1: Candidate	'Sample

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

16:52:22 (UTC-05:00) Eastern Time (US & Canada)		(autoquery)		Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-21-2020 16:52:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/21/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-21-2020 17:00:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BPYM8 : F	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-21-2020 17:00:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPYM8F	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

& Canada)				
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5.b

Date	Location	User	Value	Reason
Sep-21-2020 17:01:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Sample ID BNWLC : 0	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-21-2020 17:01:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: BNWLC0	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-21-2020 17:01:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Sample ID BNWLC : 4	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1204

Subject No: 12041138

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

5.c Sample ID

Date	Location	User	Value	Reason
Sep-21-2020 17:01:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: BNWLC4	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1204

Subject No: 12041138

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
Sep-21-2020 16:52:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-21-2020 16:52:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-21-2020 17:00:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-21-2020	ACV0PFEINFP6000	auto query	Query 1: Candidate	'Sample

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

16:52:29 (UTC-05:00) Eastern Time (US & Canada)		(autoquery)		Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-21-2020 16:52:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collectio n: Sep/21/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-21-2020 17:00:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BPYM8 : B	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-21-2020 17:00:06 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPYM8B	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

& Canada)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1204

Subject No: 12041138

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
Sep-21-2020 19:11:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-21-2020 19:11:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-21-2020 19:11:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1204

Subject No: 12041138

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
Sep-21-2020 19:11:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Sep/21/2020 15:20	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-21-2020 19:11:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-21-2020 19:11:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: RIGHT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-21-2020 19:11:23 (UTC-05:00)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_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: 12041138

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
Sep-21-2020 19:11:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-21-2020 19:11:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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: 12041138

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
Sep-21-2020 19:11:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: NO - REACTOGEN ICITY E-DIARY N OT COLLECTED F OR THIS SUBJECT	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1204

Subject No: 12041138

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

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-12-2020 15:22:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/12/2020	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1204

Subject No: 12041138

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
Oct-13-2020 08:48:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/12/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-13-2020 08:48:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: : Temperature: Temperature Unit: Temperature Location: Temperature Unit: TY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
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090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

Oct-13-2020 08:48:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry
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2.a Temperature:

Date	Location	User	Value	Reason
Oct-13-2020 08:48:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.6	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Oct-13-2020 08:48:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Oct-13-2020 08:48:34 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1204

Subject No: 12041138

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

& Canada)

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: 12041138

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
Oct-12-2020 15:23:19 (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-12-2020 15:23:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-12-2020 16:20:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-12-2020	ACV0PFEINFP6000	auto query	Query 1: Candida	'Sample

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

15:23:19 (UTC-05:00) Eastern Time (US & Canada)		(autoquery)	te	Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-12-2020 15:23:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/12/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-12-2020 16:20:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BPYNB : T	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-12-2020 16:20:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPYNB T	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

& Canada)

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1204

Subject No: 12041138

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-13-2020 08:48:16 (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
Oct-13-2020 08:48:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-13-2020 08:48:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Oct-13-2020 08:48:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/12/2020 12:42	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-13-2020 08:48:16 (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
Oct-13-2020 08:48:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Oct-13-2020 08:48:16 (UTC-05:00)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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: 12041138

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
Oct-13-2020 08:48:16 (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
Oct-13-2020 08:48:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001

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

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

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

Subject No: 12041138 **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
Nov-16-2020 15:54:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4)	<u>Data Entry:</u> Nov/16/2020	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001

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

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

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

Subject No: 12041138 **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
Nov-16-2020 15:55:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-16-2020 15:55:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-16-2020 17:14:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-16-2020	ACV0PFEINFP6000	auto query	Query 1: Candidate	'Sample

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001

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

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

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

Subject No: 12041138 **Subject Initials:** ---

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

15:55:25 (UTC-05:00) Eastern Time (US & Canada)		(autoquery)		Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-16-2020 15:55:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/16/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-16-2020 17:14:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BPVRM : D	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-16-2020 17:14:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPVRMD	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001

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

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

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

Subject No: 12041138 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
Nov-16-2020 17:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Sample ID BRV5D : V	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-16-2020 17:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: BRV5DV	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-16-2020 17:14:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Sample ID BRV5D : X	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001

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

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

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

Subject No: 12041138 **Subject Initials:** ---

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

5.c Sample ID

Date	Location	User	Value	Reason
Nov-16-2020 17:14:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: BRV5DX	Initial Entry

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1204

Subject No: 12041138

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
Sep-24-2020 12:20:51 (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: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

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Date	Location	User	Value	Reason
Sep-28-2020 13:54:03 (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: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

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Date	Location	User	Value	Reason
Oct-14-2020 14:10:28 (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: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

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Date	Location	User	Value	Reason
Oct-14-2020 14:11:34 (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: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

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Date	Location	User	Value	Reason
Oct-14-2020 14:12:23 (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: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

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Date	Location	User	Value	Reason
Oct-14-2020 14:13:23 (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: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

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Date	Location	User	Value	Reason
Oct-14-2020 14:14:11 (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, Locked, Frozen

Site No: 1204

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

Subject No: 12041138

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
Sep-24-2020 12:20:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Sep-24-2020 12:20:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-16-2020 10:32:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-15-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answer	Symptom is

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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, Locked, Frozen

Site No: 1204

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

Subject No: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

<p>16:07:07 (UTC-05:00) Eastern Time (US & Canada)</p>		<p>(b) (4), (b) (6)</p>	<p>red</p>	<p>evaluated by clinician to be within 7 days of reactogenicity and not COVID-related</p>
<p>Oct-15-2020 11:17:18 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>Query 1: Opened</p>	<p>CLIQUEY: Please confirm if the PI considered MUSCLE PAIN for COVID related illness? COVID-19 symptoms should trigger a potential COVID Illness Visit and be documented ONLY on the COVID Illness SOD CRF form and not on the AE CRF form.</p>
<p>Oct-15-2020 10:51:24 (UTC-05:00)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>Query 1: Candidate</p>	<p>CLIQUEY: Please confirm if the PI</p>

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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, Locked, Frozen

Site No: 1204

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

Subject No: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

Eastern Time (US & Canada)				considered MUSCLE PAIN for COVID related illness? COVID-19 symptoms should trigger a potential COVID Illness Visit and be documented ONLY on the COVID Illness SOD CRF form and not on the AE CRF form.
Sep-24-2020 12:20:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: muscle pain - ab dominal	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-24-2020 12:20:51 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/22/2020 20:00	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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, Locked, Frozen

Site No: 1204

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

Subject No: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

& Canada)

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-24-2020 12:20:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Sep/23/2020 22 :00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-24-2020 12:20:51 (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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090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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, Locked, Frozen

Site No: 1204

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

Subject No: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

Sep-24-2020 12:20:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Sep-24-2020 12:20:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-24-2020 12:20:51 (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
Sep-24-2020 12:20:51	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICAB	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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, Locked, Frozen

Site No: 1204

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

Subject No: 12041138

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
Sep-24-2020 12:20:51 (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
Sep-24-2020 12:20:51 (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
Sep-24-2020 12:20:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RE SOLVED	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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, Locked, Frozen

Site No: 1204

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

Subject No: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

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

Date	Location	User	Value	Reason
Sep-24-2020 12:20:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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, Locked, Frozen

Site No: 1204

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

Subject No: 12041138

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
Sep-28-2020 13:54:03 (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
Sep-28-2020 13:54:03 (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
Sep-28-2020 13:54:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: opposite shoulder pain intermittent	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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, Locked, Frozen

Site No: 1204

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

Subject No: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-28-2020 13:54:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/22/2020 12:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-12-2020 16:20:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-12-2020 15:43:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-12-2020 15:43:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Sep/23/2020 10:00	Changed Information
Oct-08-2020	ACV0PFEINFP6000	(b) (6)	Query 1: Opened	ClinQuery:

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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, Locked, Frozen

Site No: 1204

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

Subject No: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

13:54:15 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		Please advise, is the event still ongoing, else please provide an end date. Thanks
Sep-28-2020 13:54:03 (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
Sep-28-2020 13:54:03 (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).

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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, Locked, Frozen

Site No: 1204

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

Subject No: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Sep-28-2020 13:54:03 (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
Sep-28-2020 13:54:03 (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
Sep-28-2020 13:54:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify</i>	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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, Locked, Frozen

Site No: 1204

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

Subject No: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

y:

repetitive stress from work

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-28-2020 13:54:03 (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
Sep-28-2020 13:54:03 (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
Sep-28-2020 13:54:03 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1204

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

Subject No: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

Eastern Time (US & Canada)

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

Date	Location	User	Value	Reason
Oct-14-2020 00:09:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: C losed	Close Auto Query
Oct-14-2020 00:09:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: RECOVERED/RESOLVED	Transcription Error
Oct-12-2020 15:43:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: O pened	For AE opposite shoulder pain intermittent: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Sep-29-2020 14:58:49 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: C losed	Close Auto Query

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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, Locked, Frozen

Site No: 1204

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

Subject No: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

Eastern Time (US & Canada)				
Sep-29-2020 14:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: RECOVERING/RESOLVING	Transcription Error
Sep-29-2020 11:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE opposite shoulder pain intermittent: Response to "What was the outcome of this adverse event?" is 3 but End Date/Time is missing.
Sep-29-2020 11:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-29-2020 11:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: RECOVERED/RESOLVED	Transcription Error

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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, Locked, Frozen

Site No: 1204

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

Subject No: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

Sep-28-2020 13:54:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: O pened	For AE opposite shoulder pain intermittent: Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Sep-28-2020 13:54:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entr y: UNKNOW N	Initial Entry

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

Date	Location	User	Value	Reason
Sep-28-2020 13:54:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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, Locked, Frozen

Site No: 1204

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

Subject No: 12041138

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-14-2020 14:10:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-14-2020 14:10:28 (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-14-2020 14:10:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Muscle tenderness at injection site	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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, Locked, Frozen

Site No: 1204

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

Subject No: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-14-2020 14:10:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/12/2020 22:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-14-2020 14:10:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/14/2020 09:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-14-2020 14:10:28 (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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090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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, Locked, Frozen

Site No: 1204

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

Subject No: 12041138

Subject Initials: ---

Generated By:

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

(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-14-2020 14:10:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Oct-14-2020 14:10:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-14-2020 14:10:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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, Locked, Frozen

Site No: 1204

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

Subject No: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

& Canada)

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-14-2020 14:10:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-14-2020 14:10:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-14-2020 14:10:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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, Locked, Frozen

Site No: 1204

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

Subject No: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Oct-14-2020 14:10:28 (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-14-2020 14:10:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

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Visit: Logs - Unscheduled

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Site No: 1204

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

Subject No: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Oct-14-2020 14:11:34 (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-14-2020 14:11:34 (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
Oct-16-2020 10:33:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Closed	Within 7 days of vaccination.

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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, Locked, Frozen

Site No: 1204

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

Subject No: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

<p>Oct-16-2020 04:46:06 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>Query 1: Opened</p>	<p>CLIQUEY: Please confirm if the PI considered LOW GRADE FEVER for COVID related illness? COVID-19 symptoms should trigger a potential COVID Illness Visit and be documented ONLY on the COVID Illness SOD CRF form and not on the AE CRF form.</p>
<p>Oct-15-2020 11:49:21 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>Query 1: Candidate</p>	<p>CLIQUEY: Please confirm if the PI considered LOW GRADE FEVER for COVID related illness? COVID-19 symptoms should trigger</p>

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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, Locked, Frozen

Site No: 1204

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

Subject No: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

				a potential COVID Illness Visit and be documented ONLY on the COVID Illness SOD CRF form and not on the AE CRF form.
Oct-14-2020 14:11:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Low grade fever, 99.0	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-14-2020 14:11:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/13/2020 12:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-14-2020 14:11:34	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001

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Site No: 1204

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

Subject No: 12041138

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)	End Date Time: Oct/14/2020 09 :00
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6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-14-2020 14:11:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-14-2020 14:11:34 (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?

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Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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

Subject No: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

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

Date	Location	User	Value	Reason
Oct-14-2020 14:11:34 (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-14-2020 14:11:34 (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-14-2020 14:11:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
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090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

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Site No: 1204

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Subject No: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

Oct-14-2020 14:11:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-14-2020 14:11:34 (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-14-2020 14:11:34 (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-14-2020 14:11:34 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen

Site No: 1204

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

Subject No: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

Eastern Time (US & Canada)				
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090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

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Site No: 1204

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

Subject No: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Oct-14-2020 14:12:23 (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-14-2020 14:12:23 (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
Oct-14-2020 14:12:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Fatigue	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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, Locked, Frozen

Site No: 1204

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

Subject No: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-14-2020 14:12:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/12/2020 22:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-14-2020 14:12:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/14/2020 09 :00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-14-2020 14:12:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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, Locked, Frozen

Site No: 1204

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

Subject No: 12041138

Subject Initials: ---

Generated By:

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

(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-14-2020 14:12:23 (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-14-2020 14:12:23 (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-14-2020 14:12:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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, Locked, Frozen

Site No: 1204

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

Subject No: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

& Canada)

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-14-2020 14:12:23 (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-14-2020 14:12:23 (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-14-2020 14:12:23 (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?:

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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, Locked, Frozen

Site No: 1204

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

Subject No: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Oct-14-2020 14:12:23 (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-14-2020 14:12:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1204

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

Subject No: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Oct-14-2020 14:13:23 (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-14-2020 14:13:23 (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
Oct-14-2020 14:13:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Swollen submandi bular lymph nodes	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1204

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

Subject No: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-14-2020 14:13:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/13/2020 20:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-20-2020 10:57:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/15/2020 UNK:UNK	Changed Information
Oct-14-2020 14:13:23 (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-14-2020 14:13:23 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1204

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

Subject No: 12041138

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
Oct-14-2020 14:13:23 (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-14-2020 14:13:23 (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:

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1204

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

Subject No: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Oct-14-2020 14:13:23 (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-14-2020 14:13:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-14-2020 14:13:23 (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-14-2020 14:13:23	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1204

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

Subject No: 12041138

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
Oct-20-2020 16:52:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: C losed	Close Auto Query
Oct-20-2020 16:52:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	New Information
Oct-20-2020 10:57:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: O pened	For AE Swollen submandibular lymph nodes: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Oct-14-2020 14:13:23	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1204

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

Subject No: 12041138

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
Oct-14-2020 14:13:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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, Locked, Frozen

Site No: 1204

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

Subject No: 12041138

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-14-2020 14:14:11 (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-14-2020 14:14:11 (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
Oct-14-2020 14:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Polydipsia	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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, Locked, Frozen

Site No: 1204

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

Subject No: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-14-2020 14:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/12/2020 22:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-15-2020 12:36:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/15/2020 UNK:UNK	Changed Information
Oct-14-2020 14:14:11 (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-14-2020 14:14:11 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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, Locked, Frozen

Site No: 1204

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

Subject No: 12041138

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
Oct-14-2020 14:14:11 (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-14-2020 14:14:11 (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:

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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, Locked, Frozen

Site No: 1204

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

Subject No: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

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

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-14-2020 14:14:11 (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-14-2020 14:14:11	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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, Locked, Frozen

Site No: 1204

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

Subject No: 12041138

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
Oct-15-2020 12:37:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: C losed	Close Auto Query
Oct-15-2020 12:37:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Changed Information
Oct-15-2020 12:36:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: O pened	For AE Polydipsia: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Oct-14-2020 14:14:11 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVED	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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, Locked, Frozen

Site No: 1204

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

Subject No: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

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

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

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

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Date	Location	User	Value	Reason
Nov-16-2020 15:55:59 (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: 12041138

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
Nov-16-2020 15:55:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Nov-16-2020 15:55:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Nov-16-2020 15:55:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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: 12041138

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
Nov-16-2020 15:55:59 (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
Nov-16-2020 15:55:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Oct/30/2020	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

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

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

Subject No: 12041138 **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
Nov-16-2020 15:56:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/16/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Nov-16-2020 15:56:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-16-2020 15:56:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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: 12041138 **Subject Initials:** ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-18-2021 19:10:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/14/2021	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001**Visit:** Potential ReVax Initial Contact - Unscheduled **Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:25**Form Status:** Data Complete, Frozen**Site No:** 1204**Site Name:** (1204) Icahn School of Medicine at Mount Sinai**Subject No:** 12041138**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

[Back to Form](#)*1. Select appropriate response - Is participant willing to return for Vaccination 3?*

Date	Location	User	Value	Reason
Feb-18-2021 19:10:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-18-2021 19:10:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-18-2021 19:10:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willin g to return for Vacc ination 3 Participant is: eligible and NO T confirmed to	Initial Entry

Header Text: C4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled eCRF Audit Trail History

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

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

Subject No: 12041138 **Subject Initials:** ---

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

(b) (4)

			have received o nly placebo at V accination 1/2	
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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: 12041138

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
Feb-18-2021 19:10:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/9/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-18-2021 19:10:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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: 12041138

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
Nov-16-2020 15:56:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-21-2020 19:10:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-21-2020 16:49:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Nov-16-2020 15:56:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/16/2020	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (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: 12041138

Subject Initials: ---

Generated By:

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

(b) (4)

Sep-21-2020 19:10:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/21/2020	Initial Entry
Sep-21-2020 16:49:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/21/2020	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1204

Subject No: 12041138

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: ---

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

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1. Casebook Signature

Date	Location	User	Value	Reason
Oct-21-2020 11:01:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Ena ble	Initial Entry

090177e196ae2f80\Final\Final On: 01-Apr-2021 03:44 (GMT)