

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 14-Jan-2021 02:25

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[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	01 DEC 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (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: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/8/2021
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Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 14-Jan-2021 02:25

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11391246]
2.	Birth Date:	(b) (6) /2005
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable _____
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090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Jan/8/2021
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: 1139

Subject No: 11391246

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Acne]
	Start Date:	Jun/30/2019
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[dyslexia]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[sleep disturbance]
	Start Date:	Jun/30/2015
	Ongoing:	YES

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

1.d	Line/MH Number:	[4]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[intermittent muscle strain]
	Start Date:	Jun/30/2018
	Ongoing:	YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

Form: HIV STATUS

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[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 Version: 14-Jan-2021 02:19

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Jan/8/2021
2.	Weight:	[158.0]
3.	Unit:	LB
4.	Height:	[70.5]
5.	Unit:	in
6.	Body Mass Index:	[22.3]

Vital Signs Details

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

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Jan/8/2021
2.	Randomization Number:	[26319]
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: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/8/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP8N55]
5.b	Sample ID	[BP8N56]
5.c	Sample ID	[BP8N57]

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/8/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP8N5F]
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090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:26

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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:	Jan/8/2021 16:52
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
----	---	--

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/29/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY -
SYMPTOM RESOLVED DATES

Form Version: 14-Jan-2021 02:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 14-Jan-2021 02:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	YES Ongoing? NO Stop Date: Jan/15/2021

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY -
SYMPTOM RESOLVED DATES

Form Version: 14-Jan-2021 02:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.h	Symptom:	NEW OR WORSENERD JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	YES Ongoing? NO Stop Date: Jan/15/2021
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 14-Jan-2021 02:22

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Jan/29/2021
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Vital Signs Details

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

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: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/29/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR5RCK]
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090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[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:	Jan/29/2021 13:53
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (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: 1139 **Site Name:** (1139) Duke University Medical Center

Subject No: 11391246 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/26/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 14-Jan-2021 02:28 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1139 **Site Name:** (1139) Duke University Medical Center

Subject No: 11391246 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 14-Jan-2021 02:28 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1139 **Site Name:** (1139) Duke University Medical Center

Subject No: 11391246 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 14-Jan-2021 02:28 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1139 **Site Name:** (1139) Duke University Medical Center

Subject No: 11391246 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

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: 1139 **Site Name:** (1139) Duke University Medical Center

Subject No: 11391246 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/26/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BNWY4P]
5.b	Sample ID	[BRMJV2]
5.c	Sample ID	[BRMJV3]

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	
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Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 30-Apr-2021 01:47

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Not Started

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

Form Status: Not Started

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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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090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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	[]
----	-----------	-----

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 30-Apr-2021 01:37

Form Status: Not Started

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Health Care Utilization

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

Health Care Utilization Other

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

Health Care Utilization

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

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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	[]
----	-----------	-----

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

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

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

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

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

Header Text: c4591001

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

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

Site No: 1139 **Site Name:** (1139) Duke University Medical Center

Subject No: 11391246 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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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090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

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: 1139 **Site Name:** (1139) Duke University Medical Center

Subject No: 11391246 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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: 1139 **Site Name:** (1139) Duke University Medical Center

Subject No: 11391246 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

Unplanned Assessments

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VITAL SIGNS - TEMP

Form Version: 30-Apr-2021 01:41

Form Status: Not Started

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Vital Signs

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

Vital Signs Details

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

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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?	

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (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: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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:** Data Complete, Locked, Frozen, Verified

Site No: 1139 **Site Name:** (1139) Duke University Medical Center

Subject No: 11391246 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Jan/29/2021
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: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Informed Consent - Asymptomatic Surveillance

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/29/2021
----	--------------	--

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING -
Unscheduled IMMUNOGENICITY

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

Site No: 1139 **Site Name:** (1139) Duke University Medical Center

Subject No: 11391246 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/29/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR5RD8]
5.b	Sample ID	[BR5RD6]
5.c	Sample ID	[BR5RD7]

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/29/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR5RCM]
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090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 -
Unscheduled Visit on Feb/12/2021

Form: DATE OF VISIT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:22

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/12/2021
2.	Erroneous Visit	

COVID-19 Surveillance Visit

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK2
----	---------------------------------	-------------

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 -
Unscheduled Visit on Feb/12/2021

Form Version: 10-Oct-2020 15:57

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - REPEAT
SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Feb/12/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[AA09865]
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090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 2 -
Unscheduled Visit on Feb/26/2021

Form: DATE OF VISIT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:22

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/26/2021
2.	Erroneous Visit	

COVID-19 Surveillance Visit

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK4
----	---------------------------------	-------------

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 2 -
Unscheduled Visit on Feb/26/2021

Form: ELECTRONIC SAMPLE TRACKING - REPEAT
SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/26/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRMJTZ]
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090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 3 -
Unscheduled Visit on Mar/12/2021

Form: DATE OF VISIT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Mar/12/2021
2.	Erroneous Visit	

COVID-19 Surveillance Visit

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK6
----	------------------------------	-------------

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 3 -
Unscheduled Visit on Mar/12/2021

Form: ELECTRONIC SAMPLE TRACKING - REPEAT
SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Mar/12/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[AA09866]
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Header Text: c4591001

Visit: V202_SURVEIL_SWAB 4 -
Unscheduled Visit on Mar/26/2021

Form: DATE OF VISIT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Mar/26/2021
2.	Erroneous Visit	

COVID-19 Surveillance Visit

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK8
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Header Text: c4591001

Visit: V202_SURVEIL_SWAB 4 -
Unscheduled Visit on Mar/26/2021

Form Version: 10-Oct-2020 15:57

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - REPEAT
SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Mar/26/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[AA09886]
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090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 5 -
Unscheduled Visit on Apr/09/2021

Form: DATE OF VISIT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Apr/9/2021
2.	Erroneous Visit	

COVID-19 Surveillance Visit

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK10
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090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 5 -
Unscheduled Visit on Apr/09/2021

Form Version: 10-Oct-2020 15:57

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - REPEAT
SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Apr/9/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[AA11363]
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090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 6 -
Unscheduled Visit on Apr/23/2021

Form: DATE OF VISIT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Apr/23/2021
2.	Erroneous Visit	

COVID-19 Surveillance Visit

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK12
----	---------------------------------	--------------

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 6 -
Unscheduled Visit on Apr/23/2021

Form: ELECTRONIC SAMPLE TRACKING - REPEAT
SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Apr/23/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[AA09887]
-----	-----------	-----------

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 7 -
Unscheduled Visit on May/07/2021

Form: DATE OF VISIT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	May/7/2021
2.	Erroneous Visit	

COVID-19 Surveillance Visit

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK14
----	---------------------------------	--------------

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 7 -
Unscheduled Visit on May/07/2021

Form: ELECTRONIC SAMPLE TRACKING - REPEAT
SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: May/7/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[AA09890]
-----	-----------	-----------

Header Text: c4591001

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

Form Version: 20-Feb-2021 02:26 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Feb/26/2021
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	May/13/2021
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: 1139 **Site Name:** (1139) Duke University Medical Center

Subject No: 11391246 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Disposition - Follow-Up

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

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Bilateral knee pain	Jan/11/2021 12:00	NO End Date Time: Feb/15/2021 12:00	Repeating Pages

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Bilateral knee pain]
4.	Start Date Time:	Jan/11/2021 12:00
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/15/2021 12:00
6.	Toxicity Grade:	2

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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: [overuse injury from running, patellar tendonitis]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Form Status: Not Started

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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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	[]

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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Concomitant Medications

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

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	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: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[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?	

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	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: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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Radiation Treatment

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

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	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: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 10-Dec-2020 02:27

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	May/13/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: V101_VAX3

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	May/20/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained May/20/2021
----	--------------	--

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 28-Mar-2021 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation/Death :	May/20/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: May/20/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BNWYBR]
5.b	Sample ID	[BNWYBJ]
5.c	Sample ID	[BRMJ2N]

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: May/20/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRMJ39]
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090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	May/20/2021 16:48
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jun/10/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jun/10/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRMJ6D]
-----	-----------	----------

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jun/10/2021 11:51
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Aug/16/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Data Complete, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Aug/16/2021
3.	Comments:	[]

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

Contact Outcome

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

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

Contact Outcome

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

Header Text: c4591001

Visit:
FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Aug/16/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Feb/26/2021

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[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, Signed, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Emmanuel Walter	Approved	Aug-18-2021 22:14:54 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, EmmanuelWalter, 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.

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Version: 10-Oct-2020 16:00

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-19-2021 13:56:00 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

Form Version: 28-Mar-2021 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
Form	May-20-2021 17:16:11 (UTC-05:00) Eastern Time (US & Canada)	Brenderia Cameron (b) (4)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Emmanuel Walter	Approved	Aug-18-2021 22:14:54 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, EmmanuelWalter, 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	Aug-18-2021 13:49:37 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Emmanuel Walter	Approved	Aug-17-2021 10:43:23 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Affidavit:

By my dated signature below, I, EmmanuelWalter, 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	Aug-17-2021 09:41:42 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Emmanuel Walter	Approved	Jun-19-2021 17:50:36 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, EmmanuelWalter, 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.

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(b) (6)	N/A	Jun-14-2021 16:17:58 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Emmanuel Walter	Approved	Jun-10-2021 16:31:07 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, EmmanuelWalter, 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.

Brenderia Cameron	N/A	Jun-10-2021 16:12:20 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Emmanuel Walter	Approved	Jun-01-2021 20:51:07 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Affidavit:

By my dated signature below, I, EmmanuelWalter, 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	May-20-2021 09:26:33 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Emmanuel Walter	Approved	May-14-2021 16:36:30 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, EmmanuelWalter, 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.

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(b) (6)	N/A	May-07-2021 14:42:47 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Emmanuel Walter	Approved	May-05-2021 15:57:21 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, EmmanuelWalter, 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	Apr-26-2021 13:12:25 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Emmanuel Walter	Approved	Apr-14-2021 19:54:12 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Affidavit:

By my dated signature below, I, EmmanuelWalter, 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.

Brenderia Cameron	N/A	Apr-12-2021 09:16:03 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Emmanuel Walter	Approved	Mar-29-2021 13:14:22 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, EmmanuelWalter, 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.

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(b) (6)	N/A	Mar-29-2021 12:42:01 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Emmanuel Walter	Approved	Mar-15-2021 20:17:04 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, EmmanuelWalter, 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	Mar-15-2021 10:03:59 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Emmanuel Walter	Approved	Mar-05-2021 16:09:20 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Affidavit:

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

(b) (6)	N/A	Feb-26-2021 13:39:30 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Emmanuel Walter	Approved	Feb-18-2021 14:13:13 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(b) (6)	N/A	Feb-16-2021 12:51:27 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Emmanuel Walter	Approved	Feb-14-2021 20:46:09 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

(b) (6)	N/A	Feb-11-2021 11:56:37 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Emmanuel Walter	Approved	Feb-09-2021 16:06:12 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Affidavit:

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

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

(b) (6)	N/A	Feb-09-2021 11:41:12 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Emmanuel Walter	Approved	Feb-06-2021 08:31:31 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, EmmanuelWalter, 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.

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(b) (6)	N/A	Feb-04-2021 09:54:58 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Emmanuel Walter	Approved	Feb-03-2021 21:50:17 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

(b) (6)	N/A	Feb-03-2021 17:23:50 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Emmanuel Walter	Approved	Feb-02-2021 09:11:52 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Affidavit:

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

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

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

(b) (6)	N/A	Jan-29-2021 16:56:33 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Emmanuel Walter	Approved	Jan-28-2021 09:50:25 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, EmmanuelWalter, 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.

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:25

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Jan-19-2021 13:55:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: 01 DEC 2020	Initial Entry

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

Date	Location	User	Value	Reason
Jan-19-2021 13:55:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Jan-19-2021 13:55:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Jan/8/2021	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 14-Jan-2021 02:25

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Jan-19-2021 13:54:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 11391246	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Jan-19-2021 13:54:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: (b) (6) /2005	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Jan-19-2021 13:55:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Jan-19-2021 13:55:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATIN O(A) OR OF SPANISH ORI GIN	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:25

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

Date	Location	User	Value	Reason
Jan-19-2021 13:55:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Jan-19-2021 13:55:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jan/8/2021	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Jan-19-2021 13:56:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jan/8/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-19-2021 13:56:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-19-2021 13:56:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1139**Site Name:** (1139) Duke University Medical Center**Subject No:** 11391246**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44[Back to Form](#)***1.a***

Date	Location	User	Value	Reason
Jan-19-2021 13:56:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Line/MH Number 1 : Medical History T Acne erm: Start Date: Jun/30/20 19 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Jan-19-2021 13:56:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Jan-19-2021 13:56:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Acne	Initial Entry

1.a Start Date:

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: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Jan-19-2021 13:56:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jun/30/2019	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Jan-19-2021 13:56:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Jan-19-2021 13:57:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Line/MH Numb 2 er: Medical Histor dyslexia y Term: Start Date: UNK/UNK /2005 Ongoing: YES	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

1.b Line/MH Number:

Date	Location	User	Value	Reason
Jan-19-2021 13:57:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Jan-19-2021 13:57:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: dyslexia	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Jan-19-2021 13:57:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: UNK/UNK/2005	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Jan-19-2021 13:57:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.c

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Jan-19-2021 13:57:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History Term: sleep disturbance Start Date: Jun/30/2015 Ongoing: YES	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

1.c Line/MH Number:

Date	Location	User	Value	Reason
Jan-19-2021 13:57:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Jan-19-2021 13:57:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: sleep disturbance	Initial Entry

1.c Start Date:

Date	Location	User	Value	Reason
Jan-19-2021 13:57:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jun/30/2015	Initial Entry

1.c Ongoing:

Date	Location	User	Value	Reason
Jan-19-2021 13:57:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.d

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Jan-19-2021 13:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Line/MH N 4 umber: Medical His intermittent tory Term: muscle strain Start Date: Jun/30/2018 Ongoing: YES	Initial Entry
Jan-19-2021 13:58:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Line/MH N 4 umber: Medical His intermittent tory Term: muscle strain Start Date: Jun/30/2018 Ongoing:	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

1.d Line/MH Number:

Date	Location	User	Value	Reason
Jan-19-2021 13:58:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Jan-19-2021 13:58:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: intermittent muscle strain	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Jan-19-2021 13:58:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jun/30/2018	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Jan-19-2021 13:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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

Date	Location	User	Value	Reason
Jan-19-2021 13:58:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: The subject is NOT known t o be HIV POSITIVE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:19

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Date:

Date	Location	User	Value	Reason
Jan-26-2021 04:43:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-25-2021 12:15:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Jan-19-2021 14:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Opened	Vital Signs Date is not the same as Vaccination Date in the same visit. Please review and update as appropriate or clarify.
Jan-19-2021 13:59:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jan/8/2021	Initial Entry

2. Weight:

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:19

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Jan-19-2021 13:59:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 158.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Jan-19-2021 13:59:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Mar-01-2021 18:52:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-26-2021 13:39:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 2: Answered	Changed Information
Feb-26-2021 13:39:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 70.5	Changed Information

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:19

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Canada)				
Feb-19-2021 16:05:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Opened	CLINQUERY: Query response confirms height of 178.7 inches. Please verify as this appears to be the measurement in cm. Please calculate correct result in inches so that BMI can be calculated correctly.
Jan-19-2021 23:58:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-19-2021 13:59:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Jan-19-2021 13:59:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Opened	Height 178.7 is outside of Normal Range 140 - 198 for cm or 55 - 80 for in.

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:19

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Jan-19-2021 13:59:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 178.7	Initial Entry
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5. Unit:

Date	Location	User	Value	Reason
Jan-19-2021 13:59:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Feb-26-2021 13:39:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 22.3	Changed Information
Feb-01-2021 18:42:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-29-2021 16:55:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	Original value is correct

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:19

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Jan-26-2021 19:48:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Query 1: Reissued:Opened	ClinQuery:the derived BMI for this subject is 3.5. Please review height/weight and all units and confirm this information is entirely correct. thanks
Jan-25-2021 12:15:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Query 1: Answered	Original value is correct
Jan-20-2021 20:11:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	ClinQuery: Please can you review the height/weight combinations for this subject as the derived BMI is further out of range than expected. Thank you
Jan-19-2021 13:59:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 3.5	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:19

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

7.a

Date	Location	User	Value	Reason
Jan-19-2021 13:59:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Record Identifier:: Temperature: 98.1 Temperature Unit: Temperature Location: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Jan-19-2021 13:59:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Jan-19-2021 13:59:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 98.1	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
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090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:19

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Jan-19-2021 13:59:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: F	Initial Entry
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7.a Temperature Location:

Date	Location	User	Value	Reason
Jan-19-2021 13:59:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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1. Randomization Date :

Date	Location	User	Value	Reason
Jan-19-2021 13:59:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jan/8/2021	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Jan-19-2021 13:59:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 26319	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (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: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Data Origin

Date	Location	User	Value	Reason
Jan-19-2021 13:59:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-19-2021 13:59:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-25-2021 16:02:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-20-2021 07:26:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (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: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Jan-19-2021 13:59:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-19-2021 13:59:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/8/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-25-2021 16:02:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BP8N55	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-25-2021 16:02:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BP8N55	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (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: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

5.b

Date	Location	User	Value	Reason
Jan-25-2021 16:03:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BP8N56	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-25-2021 16:03:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BP8N56	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-25-2021 16:03:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BP8N57	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (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: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

5.c Sample ID

Date	Location	User	Value	Reason
Jan-25-2021 16:03:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BP8N57	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (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: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Data Origin

Date	Location	User	Value	Reason
Jan-19-2021 14:00:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-19-2021 14:00:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-26-2021 09:47:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-25-2021 15:53:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 2: Closed	Close Auto Query
Jan-25-2021	ACV0PF	auto query	Query 3: Closed	Close Auto

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (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: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

12:17:16 (UTC-05:00) Eastern Time (US & Canada)	EINFP60 00	(autoquery)		Query
Jan-25-2021 12:17:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/8/2021	Transcription Error
Jan-25-2021 12:17:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Jan-25-2021 12:16:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 3: Opened	Nasal Swab sample is collected after Vaccination 1, however response to "If no sample was collected or sample was not collected according to protocol, please provide reason:" is missing. Please update.
Jan-20-2021 07:26:26	ACV0PF EINFP60	(b) (4), (b) (6)	Query 2: Opened	'Sample Collected?' is

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (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: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00			Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-19-2021 14:00:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-19-2021 14:00:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Opened	Date of Collection 11/Jan/2021 is more than 1 day after Date of Visit 08/Jan /2021. Please review and update as appropriate, else clarify.
Jan-19-2021 14:00:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/11/2021	Initial Entry

5.a

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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: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Jan-25-2021 15:53:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BP8N5F	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-25-2021 15:53:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BP8N5F	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:26

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-19-2021 14:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-19-2021 14:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-19-2021 14:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Jan-27-2021 03:36:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Closed	Data updated by site.

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Jan-26-2021 19:46:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Jan-25-2021 12:16:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 3: Answered	Transcription Error
Jan-25-2021 12:16:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 2: Answered	Transcription Error
Jan-25-2021 12:16:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-25-2021 12:16:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jan/8/2021 16:52	Transcription Error
Jan-20-2021 20:11:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 3: Opened	ClinQuery: Please can you review the 3 day discrepancy between rand and vax1 and update as

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

				appropriate? Thank you
Jan-20-2021 03:45:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Opened	eDiary: Per eDiary records, vaccination date is 08-Jan-2021. Please reconcile or confirm in the query response as appropriate.
Jan-19-2021 14:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Opened	Dose Date is before or more than 1 day after Date of Visit 08/Jan/2021 of the corresponding Visit. Please review and update as appropriate.
Jan-19-2021 14:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jan/11/2021 16:52	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-19-2021 14:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

6. Body Side:

Date	Location	User	Value	Reason
Jan-19-2021 14:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jan-19-2021 14:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-19-2021 14:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIE D 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
Jan-19-2021 14:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (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: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Jan-19-2021 14:00:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES - REACTOGENICITY E-DIARY COLLECTED F OR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-29-2021 16:56:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jan/29/2021	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-29-2021 16:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-29-2021 16:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: FE V ER Were fever or systemic N symptoms present on t O he last day the Subject Diary was completed? :	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Jan-29-2021 16:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-29-2021 16:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Jan-29-2021 16:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI GU E Were fever or systemi NO c symptoms present o n the last day the Subj ect Diary was complet ed?:	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.b Symptom:

Date	Location	User	Value	Reason
Jan-29-2021 16:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-29-2021 16:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Jan-29-2021 16:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: HE AD AC HE Were fever or system ic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.c Symptom:

Date	Location	User	Value	Reason
Jan-29-2021 16:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-29-2021 16:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Jan-29-2021 16:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: C HI LL S Were fever or systemi N c symptoms present o O n the last day the Subj ect Diary was complet ed?:	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.d Symptom:

Date	Location	User	Value	Reason
Jan-29-2021 16:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-29-2021 16:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Jan-29-2021 16:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: VO MI TIN G Were fever or system ic symptoms present on the last day the Su bject Diary was com pleted?: NO	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.e Symptom:

Date	Location	User	Value	Reason
Jan-29-2021 16:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-29-2021 16:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Jan-29-2021 16:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: DI AR RH EA Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.f Symptom:

Date	Location	User	Value	Reason
Jan-29-2021 16:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-29-2021 16:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Feb-16-2021 12:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSENE D MUSCLE PAIN	Transcription Error

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

			<p>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</p> <p>YES Ongoing?</p> <p>NO</p> <p>Stop Date:</p> <p>Jan/15/2021</p>	
Feb-11-2021 11:56:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Symptom:: NEW OR WORSENERED MUSCLE PAIN</p> <p>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</p> <p>YES Ongoing?</p> <p>NO</p> <p>Stop Date:</p> <p>Jan/9/2021</p>	Transcription Error
Feb-09-2021 11:41:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Symptom:: NEW OR WORSENERED MUSCLE PAIN</p>	Transcription Error

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

			<p>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</p> <p>YES Ongoing?</p> <p>NO</p> <p>Stop Date:</p> <p>Jan/31/2021</p>	
<p>Jan-29-2021 16:57:22 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PF EINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>Data Entry:</p> <p>Symptom:: NEW OR WORSENER MUSCLE PAIN</p> <p>Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO</p>	<p>Initial Entry</p>

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.g Symptom:

Date	Location	User	Value	Reason
Jan-29-2021 16:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERD MU SCLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-17-2021 04:48:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Data Updated
Feb-16-2021 12:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-16-2021 12:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Ongoing? NO Stop Date: Jan/15/2021	Transcription Error

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY -
SYMPTOM RESOLVED DATES - eCRF Audit Trail
History

Form Version: 14-Jan-2021 02:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

<p>Feb-12-2021 04:43:56 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PF EINFP60 00</p>	<p>(b) (4), (b) (6) [Redacted]</p>	<p>Query 1: Reissued:O pened</p>	<p>eDiary RQ2: Per eDiary record, on last day 14-Jan- 2021(Day 7) 'New or worsened muscle pain occurrence' is reported. However, in Inform, stop date is provided as 09-Jan-2021. Please review and consider to update appropriate stop date, else clarify. Thanks</p>
<p>Feb-11-2021 11:56:37 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PF EINFP60 00</p>	<p>auto query (autoquery)</p>	<p>Query 1: Answered</p>	<p>Transcription Error</p>
<p>Feb-11-2021 11:56:37 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PF EINFP60 00</p>	<p>(b) (4), (b) (6) [Redacted]</p>	<p>Data Entry: YES Ongoing? NO Stop Date:</p>	<p>Transcription Error</p>

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

			Jan/9/2021	
Feb-10-2021 04:01:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Reissued:O pened	eDiary: V2 Vaccination date is 29Jan2021. However, for 'New or worsened muscle pain' stop date is provided as 31Jan2021. Please confirm 'Muscle Pain' reported post Vaccination 1 was ongoing through Vaccination 2. Else, update appropriate stop date. Thanks
Feb-09-2021 11:41:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-09-2021 11:41:12 (UTC-05:00) Eastern Time (US	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Ongoing?	Transcription Error

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

& Canada)			NO Stop Date: Jan/31/2021	
Feb-01-2021 05:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00.InFor mAdapte r.Discrep ancy	PFE SDQ PROD (b) (4)	Query 1: Opened	eDiary: Per eDiary records, "New or worsened muscle pain occurrence" is reported on Last day (Day 7) however the last day in Inform CRF data is entered as No for the same. Please verify and update. Else, clarify. Thanks (b) (4)
Jan-29-2021 16:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Feb-16-2021 12:51:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Symptom:: NEW OR WORSE ED JOINT PAIN</p> <p>Were fever or systemic symptoms present on the last day the Subject Diary was completed?: YES Ongoing? NO</p> <p>Stop Date: Jan/1 5/20 21</p>	Transcription Error
Feb-11-2021 11:56:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Symptom:: NEW OR WORSE ED JOINT PAIN</p>	Transcription Error

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001
Visit: V2_VAX2_L
Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History
Form Version: 14-Jan-2021 02:28
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1139
Site Name: (1139) Duke University Medical Center
Subject No: 11391246
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 10-Nov-2021 20:44

			<p>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</p> <p>YES Ongoing? NO Stop Date: Jan/9/2021</p>	
Feb-09-2021 11:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Symptom:: NEW OR WORSENED JOINT PAIN</p> <p>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</p> <p>YES Ongoing? NO Stop Date: Jan/31/2021</p>	Transcription Error
Jan-29-2021 16:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Symptom:: NEW OR WORSENED</p>	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY -
SYMPTOM RESOLVED DATES - eCRF Audit Trail
History

Form Version: 14-Jan-2021 02:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Canada)			<p style="text-align: right;">JOINT PAIN</p> <p>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</p> <p style="text-align: right;">NO</p>	
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090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.h Symptom:

Date	Location	User	Value	Reason
Jan-29-2021 16:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERD JOI NT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-17-2021 04:49:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Data Updated
Feb-16-2021 12:51:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-16-2021 12:51:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Ongoing? NO Stop Date: Jan/15/2021	Transcription Error

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

<p>Feb-12-2021 04:44:29 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PF EINFP60 00</p>	<p>(b) (4), (b) (6)</p>	<p>Query 1: Reissued:Opened</p>	<p>eDiary RQ2: Per eDiary record, on last day 14-Jan-2021(Day 7) 'New or worsened joint pain occurrence' is reported. However, in Inform, stop date is provided as 09-Jan-2021. Please review and consider to update appropriate stop date, else clarify. Thanks</p>
<p>Feb-11-2021 11:56:53 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PF EINFP60 00</p>	<p>auto query (autoquery)</p>	<p>Query 1: Answered</p>	<p>Transcription Error</p>
<p>Feb-11-2021 11:56:53 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PF EINFP60 00</p>	<p>(b) (4), (b) (6)</p>	<p>Data Entry: YES Ongoing? NO Stop Date:</p>	<p>Transcription Error</p>

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY -
SYMPTOM RESOLVED DATES - eCRF Audit Trail
History

Form Version: 14-Jan-2021 02:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

			Jan/9/2021	
Feb-10-2021 04:02:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Query 1: Reissued:O pened	eDiary: V2 Vaccination date is 29Jan2021. However, for 'New or worsened joint pain' stop date is provided as 31Jan2021. Please confirm 'Joint Pain' reported post Vaccination 1 was ongoing through Vaccination 2. Else, update appropriate stop date. Thanks
Feb-09-2021 11:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-09-2021 11:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: YES Ongoing? NO	Transcription Error

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

			Stop Date: Jan/31/2021	
Feb-01-2021 05:04:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00.InFor mAdapte r.Discrep ancy	PFE SDQ PROD (b) (4)	Query 1: Opened	eDiary: Per eDiary records, "New or worsened joint pain occurrence" is reported on Last day (Day 7) however the last day in Inform CRF data is entered as No for the same. Please verify and update. Else, clarify. Thanks (b) (4)
Jan-29-2021 16:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Jan-29-2021 16:57:22	ACV0PF	auto calc	Data Entry:	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	EINFP6000	(autocalc)	DELTOID MUSCLE	
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4. Injection Site Body Side:

Date	Location	User	Value	Reason
Jan-29-2021 16:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-29-2021 16:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: RE DN ES S Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Jan-29-2021 16:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-29-2021 16:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-29-2021 16:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: SW ELL ING Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Jan-29-2021 16:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-29-2021 16:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-29-2021 16:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: PAIN AT IN JECTI ON SI TE Were injection site reactions present o n the last day the S ubject Diary was c ompleted?: NO	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Jan-29-2021 16:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-29-2021 16:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 14-Jan-2021 02:22

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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1. Date:

Date	Location	User	Value	Reason
Jan-29-2021 16:57:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jan/29/2021	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-29-2021 16:57:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Record Identifier:: Temperature: 98.6 Temperature U F nit: Temperature L ORAL CA ocation:: VITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jan-29-2021 16:57:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:22

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Jan-29-2021 16:57:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 98.6	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Jan-29-2021 16:57:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Jan-29-2021 16:57:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (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: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jan-29-2021 16:57:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-29-2021 16:57:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-04-2021 09:54:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-31-2021 22:05:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (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: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

				appropriate.
Jan-29-2021 16:57:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-29-2021 16:57:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/29/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-04-2021 09:54:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BR5RCK	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-04-2021 09:54:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BR5RCK	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-29-2021 17:04:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-29-2021 17:04:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-29-2021 17:04:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Jan-29-2021 17:04:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jan/29/2021 13:53	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-29-2021 17:04:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jan-29-2021 17:04:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jan-29-2021 17:04:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-29-2021 17:04:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIE D 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
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090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Jan-29-2021 17:04:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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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: 1139 **Site Name:** (1139) Duke University Medical Center

Subject No: 11391246 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-26-2021 16:50:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Feb/26/2021	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1139 **Site Name:** (1139) Duke University Medical Center

Subject No: 11391246 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-26-2021 16:51:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Feb-26-2021 16:51:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: FE V E R Were fever or systemi c symptoms present o n the last day the Sub ject Diary was comple ted?: N O	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Feb-26-2021 16:51:30	ACV0PF EINFP60	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139 Site Name: (1139) Duke University Medical Center

Subject No: 11391246 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00	(b) (4), (b) (6)		
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2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-26-2021 16:51:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Feb-26-2021 16:51:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI GU E Were fever or systemi NO c symptoms present o n the last day the Sub ject Diary was compl eted?:	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139 Site Name: (1139) Duke University Medical Center

Subject No: 11391246 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

2.b Symptom:

Date	Location	User	Value	Reason
Feb-26-2021 16:51:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-26-2021 16:51:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Feb-26-2021 16:51:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: HE AD AC HE Were fever or system NO ic symptoms present on the last day the S ubject Diary was co mpleted?:	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139 Site Name: (1139) Duke University Medical Center

Subject No: 11391246 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

2.c Symptom:

Date	Location	User	Value	Reason
Feb-26-2021 16:51:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-26-2021 16:51:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Feb-26-2021 16:51:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: C HI LL S Were fever or systemi N c symptoms present o O n the last day the Sub ject Diary was comple ted?:	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139 Site Name: (1139) Duke University Medical Center

Subject No: 11391246 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

2.d Symptom:

Date	Location	User	Value	Reason
Feb-26-2021 16:51:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-26-2021 16:51:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Feb-26-2021 16:51:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: VO MI TIN G Were fever or syste mic symptoms prese nt on the last day the Subject Diary was co mpleted?: NO	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139 Site Name: (1139) Duke University Medical Center

Subject No: 11391246 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

2.e Symptom:

Date	Location	User	Value	Reason
Feb-26-2021 16:51:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-26-2021 16:51:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Feb-26-2021 16:51:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: DI AR RH EA Were fever or system ic symptoms present on the last day the S ubject Diary was co mpleted?: NO	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139 Site Name: (1139) Duke University Medical Center

Subject No: 11391246 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

2.f Symptom:

Date	Location	User	Value	Reason
Feb-26-2021 16:51:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-26-2021 16:51:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Feb-26-2021 16:51:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: NEW O R WOR SENED MUSCL E PAIN	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139 Site Name: (1139) Duke University Medical Center

Subject No: 11391246 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

			Were fever or sy NO stemic symptom s present on the l ast day the Subj ect Diary was co mpleted?:	
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2.g Symptom:

Date	Location	User	Value	Reason
Feb-26-2021 16:51:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR WORSENER M USCLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-26-2021 16:51:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Feb-26-2021 16:51:30 (UTC-05:00) Eastern	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: NEW O R WOR	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139 Site Name: (1139) Duke University Medical Center

Subject No: 11391246 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

Time (US & Canada)			SENE JOINT PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
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2.h Symptom:

Date	Location	User	Value	Reason
Feb-26-2021 16:51:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR WORSENE JOINT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-26-2021 16:51:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
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090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139 Site Name: (1139) Duke University Medical Center

Subject No: 11391246 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

Feb-26-2021 16:51:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry
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4. Injection Site Body Side:

Date	Location	User	Value	Reason
Feb-26-2021 16:51:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-26-2021 16:51:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: Were injection site reactions present on the last day the Subject Diary was completed?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
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090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139 Site Name: (1139) Duke University Medical Center

Subject No: 11391246 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

Feb-26-2021 16:51:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry
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5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-26-2021 16:51:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-26-2021 16:51:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: SW ELL ING Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139 Site Name: (1139) Duke University Medical Center

Subject No: 11391246 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Feb-26-2021 16:51:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-26-2021 16:51:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-26-2021 16:51:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Injection Site Rea PAIN ction:: AT IN JECTI ON SI TE	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1139 **Site Name:** (1139) Duke University Medical Center

Subject No: 11391246 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

			Were injection site NO reactions present on the last day the Subject Diary was completed?:	
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5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Feb-26-2021 16:51:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SIT E	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-26-2021 16:51:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (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: 1139 **Site Name:** (1139) Duke University Medical Center

Subject No: 11391246 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Feb-26-2021 16:51:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-26-2021 16:51:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-01-2021 16:07:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-01-2021 06:04:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (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: 1139 Site Name: (1139) Duke University Medical Center

Subject No: 11391246 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

				review and correct as appropriate.
Feb-26-2021 16:51:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-26-2021 16:51:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/26/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-01-2021 16:07:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BNWY4P	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-01-2021 16:07:20 (UTC-05:00) Eastern	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BNWY4P	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (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: 1139 **Site Name:** (1139) Duke University Medical Center

Subject No: 11391246 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

Time (US & Canada)				
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5.b

Date	Location	User	Value	Reason
Mar-01-2021 16:07:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BRMJV2	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-01-2021 16:07:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BRMJV2	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-01-2021 16:07:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BRMJV3	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (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: 1139 **Site Name:** (1139) Duke University Medical Center

Subject No: 11391246 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

5.c Sample ID

Date	Location	User	Value	Reason
Mar-01-2021 16:07:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BRMJV3	Initial Entry

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - **Form:** DATE OF VISIT - eCRF Audit Trail History
Unscheduled

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

Site No: 1139 **Site Name:** (1139) Duke University Medical Center

Subject No: 11391246 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-29-2021 17:05:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jan/29/2021	Initial Entry

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC
SURVEILLANCE - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Consent Was:

Date	Location	User	Value	Reason
Jan-29-2021 17:05:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Jan/29/2021	Initial Entry

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

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: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Data Origin

Date	Location	User	Value	Reason
Jan-29-2021 17:05:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-29-2021 17:05:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-03-2021 17:23:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-31-2021 22:05:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

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: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

				appropriate.
Jan-29-2021 17:05:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-29-2021 17:05:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/29/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-03-2021 17:23:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BR5RD8	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-03-2021 17:23:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BR5RD8	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

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: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

5.b

Date	Location	User	Value	Reason
Feb-03-2021 17:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BR5RD6	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-03-2021 17:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BR5RD6	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-03-2021 17:43:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BR5RD7	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-03-2021 17:43:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BR5RD7	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING - NASAL
Unscheduled SWAB - eCRF Audit Trail History

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

Site No: 1139 **Site Name:** (1139) Duke University Medical Center

Subject No: 11391246 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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1. Data Origin

Date	Location	User	Value	Reason
Jan-29-2021 17:05:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-29-2021 17:05:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-04-2021 10:00:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-31-2021 22:05:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - **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: 1139 **Site Name:** (1139) Duke University Medical Center
Subject No: 11391246 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

				appropriate.
Jan-29-2021 17:05:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-29-2021 17:05:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/29/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-04-2021 10:00:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BR5RCM	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-04-2021 10:00:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BR5RCM	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 -
Unscheduled Visit on Feb/12/2021

Form Version: 14-Jan-2021 02:22

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

Form: DATE OF VISIT - ASYMPTOMATIC
SURVEILLANCE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-16-2021 12:52:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Feb/12/2021	Initial Entry

3. COVID-19 Surveillance Visit:

Date	Location	User	Value	Reason
Feb-16-2021 12:52:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: SSWAB_WEEK2	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 -
Unscheduled Visit on Feb/12/2021

Form Version: 10-Oct-2020 15:57

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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1. Data Origin

Date	Location	User	Value	Reason
Feb-16-2021 12:52:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-16-2021 12:52:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-16-2021 12:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-16-2021 12:52:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 -
Unscheduled Visit on Feb/12/2021

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

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

				correct as appropriate.
Feb-16-2021 12:52:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/12/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-16-2021 12:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: AA09865	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-16-2021 12:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: AA09865	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 2 -
Unscheduled Visit on Feb/26/2021

Form Version: 14-Jan-2021 02:22

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

Form: DATE OF VISIT - ASYMPTOMATIC
SURVEILLANCE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-05-2021 00:15:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-04-2021 13:03:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	I'm not understand the duplicate query. Visit 03 was the same day as when they were due to swab for week 4
Mar-02-2021 06:28:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM1: Thanks for your response. The Date of Visit at Visit at Visit 'COVID-19 Surveillance Visit = SSWAB_WEEK4' is the same as the other Date of Visit at Visit V3POSTVX2L. Please review for duplication and update as appropriate.

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 2 -
 Unscheduled Visit on Feb/26/2021

Form: DATE OF VISIT - ASYMPTOMATIC
 SURVEILLANCE - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:22

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Mar-01-2021 15:21:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Mar-01-2021 10:01:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00.InFor mAdapte r.Discrep ancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7482491;The Date of Visit at Visit at Visit 'COVID-19 Surveillance Visit = SSWAB_WEEK4' is the same as the other Date of Visit at Visit V3POSTVX2L. Please review for duplication and update as appropriate.
Feb-26-2021 16:52:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Feb/26/2021	Initial Entry

3. COVID-19 Surveillance Visit:

Date	Location	User	Value	Reason
Feb-26-2021 16:52:13 (UTC-05:00) Eastern	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: SSWAB_WEEK4	Initial Entry

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 2 -
Unscheduled Visit on Feb/26/2021

Form Version: 14-Jan-2021 02:22

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

Form: DATE OF VISIT - ASYMPTOMATIC
SURVEILLANCE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

Time (US & Canada)				
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090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 2 -
Unscheduled Visit on Feb/26/2021

Form Version: 10-Oct-2020 15:57

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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1. Data Origin

Date	Location	User	Value	Reason
Feb-26-2021 16:52:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-01-2021 15:22:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NASAL_SWAB	Transcription Error
Feb-26-2021 16:52:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-01-2021 15:22:03 (UTC-05:00) Eastern Time (US &	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 2 -
Unscheduled Visit on Feb/26/2021

Form Version: 10-Oct-2020 15:57

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

Canada)				
Mar-01-2021 06:04:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-26-2021 16:52:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-26-2021 16:52:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/26/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-01-2021 15:22:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BRMJTZ	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 2 -
Unscheduled Visit on Feb/26/2021

Form Version: 10-Oct-2020 15:57

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

5.a Sample ID

Date	Location	User	Value	Reason
Mar-01-2021 15:22:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-01-2021 15:22:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Opened	Sample Type is NASAL_SWAB_SELF and barcode is not 7 characters in length. Please review and correct as appropriate.
Mar-01-2021 15:22:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BRMJTZ	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 3 -
Unscheduled Visit on Mar/12/2021

Form Version: 14-Jan-2021 02:22

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

Form: DATE OF VISIT - ASYMPTOMATIC
SURVEILLANCE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-15-2021 10:03:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Mar/12/2021	Initial Entry

3. COVID-19 Surveillance Visit:

Date	Location	User	Value	Reason
Mar-15-2021 10:03:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: SSWAB_WEEK6	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 3 -
Unscheduled Visit on Mar/12/2021

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

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Data Origin

Date	Location	User	Value	Reason
Mar-15-2021 10:04:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-15-2021 10:04:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-15-2021 10:05:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-15-2021 10:04:12 (UTC-05:00) Eastern Time (US &	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 3 -
Unscheduled Visit on Mar/12/2021

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

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Canada)				entered. Please review and correct as appropriate.
Mar-15-2021 10:04:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/12/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-15-2021 10:12:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: AA09866	Transcription Error
Mar-15-2021 10:05:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: AA11491	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-15-2021 10:12:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: AA09866	Transcription Error

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 3 -
Unscheduled Visit on Mar/12/2021

Form Version: 10-Oct-2020 15:57

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

Mar-15-2021 10:05:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: AA11491	Initial Entry
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Header Text: c4591001

Visit: V202_SURVEIL_SWAB 4 -
Unscheduled Visit on Mar/26/2021

Form Version: 14-Jan-2021 02:22

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

Form: DATE OF VISIT - ASYMPTOMATIC
SURVEILLANCE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-29-2021 12:42:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Mar/26/2021	Initial Entry

3. COVID-19 Surveillance Visit:

Date	Location	User	Value	Reason
Mar-29-2021 12:42:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: SSWAB_WEEK8	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 4 -
Unscheduled Visit on Mar/26/2021

Form Version: 10-Oct-2020 15:57

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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1. Data Origin

Date	Location	User	Value	Reason
Mar-29-2021 12:42:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-29-2021 12:42:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-29-2021 12:42:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-29-2021 12:42:19 (UTC-05:00) Eastern Time (US &	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 4 -
Unscheduled Visit on Mar/26/2021

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

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Canada)				entered. Please review and correct as appropriate.
Mar-29-2021 12:42:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/26/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-29-2021 12:42:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: AA09886	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-29-2021 12:42:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: AA09886	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 5 -
Unscheduled Visit on Apr/09/2021

Form Version: 14-Jan-2021 02:22

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

Form: DATE OF VISIT - ASYMPTOMATIC
SURVEILLANCE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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1. Date of Visit

Date	Location	User	Value	Reason
Apr-12-2021 09:16:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Brenderia Cameron (b) (4)	Data Entry: Apr/9/2021	Initial Entry

3. COVID-19 Surveillance Visit:

Date	Location	User	Value	Reason
Apr-12-2021 09:16:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Brenderia Cameron (b) (4)	Data Entry: SSWAB_WEEK10	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 5 -
Unscheduled Visit on Apr/09/2021

Form Version: 10-Oct-2020 15:57

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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1. Data Origin

Date	Location	User	Value	Reason
Apr-12-2021 09:16:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Apr-12-2021 09:16:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Brenderia Cameron (b) (4)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Apr-12-2021 09:16:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Apr-12-2021 09:16:18 (UTC-05:00) Eastern Time (US &	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 5 -
Unscheduled Visit on Apr/09/2021

Form Version: 10-Oct-2020 15:57

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

Canada)				entered. Please review and correct as appropriate.
Apr-12-2021 09:16:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Brenderia Cameron (b) (4)	Data Entry: YES Date of Collection: Apr/9/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Apr-12-2021 09:16:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Brenderia Cameron (b) (4)	Data Entry: Sample ID: AA11363	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Apr-12-2021 09:16:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Brenderia Cameron (b) (4)	Data Entry: AA11363	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 6 -
Unscheduled Visit on Apr/23/2021

Form: DATE OF VISIT - ASYMPTOMATIC
SURVEILLANCE - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Date of Visit

Date	Location	User	Value	Reason
Apr-26-2021 13:12:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Apr/23/2021	Initial Entry

3. COVID-19 Surveillance Visit:

Date	Location	User	Value	Reason
Apr-26-2021 13:12:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: SSWAB_WEEK12	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 6 -
Unscheduled Visit on Apr/23/2021

Form Version: 10-Oct-2020 15:57

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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1. Data Origin

Date	Location	User	Value	Reason
Apr-26-2021 13:12:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Apr-26-2021 13:12:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Apr-26-2021 13:12:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Apr-26-2021 13:12:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 6 -
Unscheduled Visit on Apr/23/2021

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

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

				correct as appropriate.
Apr-26-2021 13:12:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Apr/23/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Apr-26-2021 13:12:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: AA09887	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Apr-26-2021 13:12:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: AA09887	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 7 -
Unscheduled Visit on May/07/2021

Form Version: 14-Jan-2021 02:22

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

Form: DATE OF VISIT - ASYMPTOMATIC
SURVEILLANCE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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1. Date of Visit

Date	Location	User	Value	Reason
May-07-2021 14:42:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: May/7/2021	Initial Entry

3. COVID-19 Surveillance Visit:

Date	Location	User	Value	Reason
May-07-2021 14:42:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: SSWAB_WEEK14	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 7 -
Unscheduled Visit on May/07/2021

Form Version: 10-Oct-2020 15:57

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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1. Data Origin

Date	Location	User	Value	Reason
May-07-2021 14:43:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
May-07-2021 14:43:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
May-07-2021 14:43:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
May-07-2021 14:43:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 7 -
Unscheduled Visit on May/07/2021

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

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

				review and correct as appropriate.
May-07-2021 14:43:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: May/7/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
May-07-2021 14:43:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: AA09890	Transcription Error
May-07-2021 14:43:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: AA0989	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
May-07-2021 14:43:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 7 -
Unscheduled Visit on May/07/2021

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

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

May-07-2021 14:43:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: AA09890	Transcription Error
May-07-2021 14:43:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Opened	Sample Type is NASAL_SWAB_SELF and barcode is not 7 characters in length. Please review and correct as appropriate.
May-07-2021 14:43:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: AA0989	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

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

Form Version: 20-Feb-2021 02:26 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1139 **Site Name:** (1139) Duke University Medical Center

Subject No: 11391246 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Feb-26-2021 16:51:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Feb/26/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-26-2021 16:51:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Feb-26-2021 16:51:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (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: 1139 **Site Name:** (1139) Duke University Medical Center

Subject No: 11391246 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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1. Date of Visit

Date	Location	User	Value	Reason
May-20-2021 09:26:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: May/13/2021	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

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

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

Site No: 1139 **Site Name:** (1139) Duke University Medical Center

Subject No: 11391246 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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

Date	Location	User	Value	Reason
May-20-2021 09:26:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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Date	Location	User	Value	Reason
Jan-29-2021 17:09:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Category:

Date	Location	User	Value	Reason
Jan-29-2021 17:09:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-29-2021 17:09:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-29-2021 17:09:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Bilateral knee pain	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-29-2021 17:09:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jan/11/2021 12:00	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (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: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
May-25-2021 10:00:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
May-24-2021 16:19:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Answered	New Information
May-24-2021 16:19:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO End Date Time: Feb/15/2021 12:00	New Information
May-20-2021 16:33:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Please verify if Bilateral Knee Pain is ongoing, then update the END DATE and OUTCOME as appropriate
Jan-29-2021 17:09:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (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: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Jan-29-2021 17:09:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Jan-29-2021 17:09:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(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
Jan-29-2021 17:09:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (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: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Jan-29-2021 17:09:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(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> overuse injury from running, patellar tendinitis	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-29-2021 17:09:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-29-2021 17:09:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (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: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Jan-29-2021 17:09:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
May-24-2021 16:19:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query
May-24-2021 16:19:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	New Information
May-24-2021 16:19:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Opened	For AE Bilateral knee pain: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Jan-29-2021 17:09:22 (UTC-05:00) Eastern Time (US	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (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: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

& Canada)

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

Date	Location	User	Value	Reason
Jan-29-2021 17:09:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:27

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
May-20-2021 09:26:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: May/13/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
May-20-2021 09:26:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FO R ADDITIONAL VACCIN ATION	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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1. Date of Visit

Date	Location	User	Value	Reason
May-20-2021 17:15:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Brenderia Cameron (b) (4)	Data Entry: May/20/2021	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Consent Was:

Date	Location	User	Value	Reason
May-20-2021 17:15:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Brenderia Cameron (b) (4)	Data Entry: OBTAINED Date Written Consent Obtained May/20/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
May-20-2021 17:16:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Brenderia Cameron (b) (4)	Data Entry: May/20/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
May-20-2021 17:16:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
May-20-2021 17:16:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Brenderia Cameron (b) (4)	Data Entry: COMPLETED	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Data Origin

Date	Location	User	Value	Reason
May-20-2021 17:17:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
May-20-2021 17:17:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
May-24-2021 14:34:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query
May-21-2021 08:56:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

				review and correct as appropriate.
May-20-2021 17:17:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
May-20-2021 17:17:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Brenderia Cameron (b) (4)	Data Entry: YES Date of Collection: May/20/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
May-24-2021 14:34:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BNWYBR	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
May-24-2021 14:34:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BNWYBR	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

5.b

Date	Location	User	Value	Reason
May-24-2021 14:34:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BNWYBJ	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
May-24-2021 14:34:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BNWYBJ	Initial Entry

5.c

Date	Location	User	Value	Reason
May-24-2021 14:35:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BRMJ2N	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
May-24-2021 14:35:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BRMJ2N	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Data Origin

Date	Location	User	Value	Reason
May-20-2021 17:17:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
May-20-2021 17:17:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
May-24-2021 14:36:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query
May-21-2021 08:56:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

				review and correct as appropriate.
May-20-2021 17:17:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
May-20-2021 17:17:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Brenderia Cameron (b) (4)	Data Entry: YES Date of Collection: May/20/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
May-24-2021 14:36:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BRMJ39	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
May-24-2021 14:36:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BRMJ39	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
May-20-2021 17:18:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Brenderia Cameron (b) (4)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
May-20-2021 17:18:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
May-20-2021 17:18:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
May-20-2021 17:18:16	ACV0PF EINFP60	Brenderia Cameron	Data Entry: May/20/2021 16:48	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00	(b) (4)		
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5. Anatomical Location:

Date	Location	User	Value	Reason
May-20-2021 17:18:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
May-20-2021 17:18:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Brenderia Cameron (b) (4)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
May-20-2021 17:18:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
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090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

May-20-2021 17:18:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 30.0	Initial Entry
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9. Unit:

Date	Location	User	Value	Reason
May-20-2021 17:18:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
May-20-2021 17:18:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
May-20-2021 17:18:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Brenderia Cameron (b) (4)	Data Entry: YES	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1139

Subject No: 11391246

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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1. Date of Visit

Date	Location	User	Value	Reason
Jun-10-2021 16:12:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Brenderia Cameron (b) (4)	Data Entry: Jun/10/2021	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Data Origin

Date	Location	User	Value	Reason
Jun-10-2021 16:12:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jun-10-2021 16:12:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jun-14-2021 16:17:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jun-11-2021 07:04:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

				appropriate.
Jun-10-2021 16:12:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jun-10-2021 16:12:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Brenderia Cameron (b) (4)	Data Entry: YES Date of Collection: Jun/10/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jun-14-2021 16:17:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BRMJ6D	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jun-14-2021 16:17:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BRMJ6D	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jun-10-2021 16:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Brenderia Cameron (b) (4)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jun-10-2021 16:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jun-10-2021 16:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Jun-10-2021 16:13:08 (UTC-05:00) Eastern Time (US &	ACV0PF EINFP60 00	Brenderia Cameron (b) (4)	Data Entry: Jun/10/2021 11:51	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Canada)

5. Anatomical Location:

Date	Location	User	Value	Reason
Jun-10-2021 16:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jun-10-2021 16:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Brenderia Cameron (b) (4)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jun-10-2021 16:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jun-10-2021 16:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

9. Unit:

Date	Location	User	Value	Reason
Jun-10-2021 16:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jun-10-2021 16:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Jun-10-2021 16:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Brenderia Cameron (b) (4)	Data Entry: YES	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Date of Visit

Date	Location	User	Value	Reason
Aug-23-2021 01:15:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2 : Close d	As per site confirmation - updated PD tracker
Aug-20-2021 10:16:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2 : Answ ered	Original value is correct
Aug-20-2021 03:54:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00.InFor mAdapte r.Discrep ancy	PFE SDQ PROD (b) (4)	Query 2 : Opene d	PDQ: Date of visit V103_MONTH1 is out of window for 32 days from V102_VAX4 DOV or Vaccination date. Please verify and update. Else, confirm in query response appropriately. (b) (4)
Aug-19-2021 02:39:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1 : Close d	data updated.
Aug-18-2021	ACV0PF	(b) (4), (b) (6)	Query 1	Changed data per query

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

13:49:56 (UTC-05:00) Eastern Time (US & Canada)	EINFP60 00	(b) (4), (b) (6)	: Answered	
Aug-18-2021 04:52:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1 : Opened	DM : Visit 103 Date is entered but Disposition Treatment at FURTHER_VACCINATION_EOT visit is missing. Please check and update. Else, clarify.
Aug-17-2021 09:41:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Aug/16 /2021	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form: CONTACT OUTCOME - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Contact Type:

Date	Location	User	Value	Reason
Aug-17-2021 09:41:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Aug-17-2021 09:41:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Contact: Aug/16/2021	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit:
FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit
Trail History

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Aug-18-2021 13:49:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Aug/16/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-18-2021 13:49:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: OPEN LABEL TREATMENT	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-18-2021 13:49:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (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: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Subject Status

Date	Location	User	Value	Reason
Feb-26-2021 16:51:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Jan-19-2021 13:59:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Jan-19-2021 13:56:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Feb-26-2021 16:51:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Feb/26/2021	Initial Entry
Jan-19-2021 13:59:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Jan/8/2021	Initial Entry
Jan-19-2021 13:56:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Jan/8/2021	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit
Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391246

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Casebook Signature

Date	Location	User	Value	Reason
Jan-28-2021 08:36:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry

090177e19891a03a\Final\Final On: 11-Nov-2021 01:20 (GMT)