

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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 Dec/12/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11471281]
2.	Birth Date:	(b) (6) 2007
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:	

090177e19891a03c\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471281

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Dec/12/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1147

Subject No: 11471281

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

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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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1147

Subject No: 11471281

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation/Death	Dec/12/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471281

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Constipation]
	Start Date:	Jul/2/2014
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Psoriasis]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Perforation of right tympanic membrane]
	Start Date:	Jul/2/2014
	Ongoing:	YES

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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:	[Other iron deficiency anemia]
	Start Date:	May/27/2020
	Ongoing:	YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1147

Subject No: 11471281

Generated By: (b) (4)

Form: HIV STATUS

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

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
----	--	---

090177e19891a03c\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Dec/12/2020
2.	Weight:	[67.65]
3.	Unit:	kg
4.	Height:	[172.5]
5.	Unit:	cm
6.	Body Mass Index:	[22.7]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[98.0]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e19891a03c\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: 1147

Subject No: 11471281

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Dec/12/2020
2.	Randomization Number:	[22214]
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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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: Dec/12/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP8H52]
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090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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: Dec/12/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP8H5C]
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090177e19891a03c\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Dec/12/2020 10:44
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

090177e19891a03c\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: 1147

Subject No: 11471281

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

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
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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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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/4/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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

090177e19891a03c\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: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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

090177e19891a03c\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: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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

090177e19891a03c\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP

Form Version: 10-Dec-2020 02:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Jan/4/2021
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.0]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e19891a03c\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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/4/2021
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	[BP8HDN]
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090177e19891a03c\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/4/2021 16:37
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

090177e19891a03c\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: 1147 **Site Name:** (1147) Ochsner Health System

Subject No: 11471281 **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/6/2021
2.	Erroneous Visit	

Header Text: c4591001

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

Form Version: 10-Dec-2020 02:30 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1147 **Site Name:** (1147) Ochsner Health System

Subject No: 11471281 **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?	YES Ongoing? NO Stop Date: Jan/9/2021
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	YES Ongoing? NO Stop Date: Jan/9/2021

090177e19891a03c\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: 10-Dec-2020 02:30 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1147 **Site Name:** (1147) Ochsner Health System

Subject No: 11471281 **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?	YES Ongoing? NO Stop Date: Jan/9/2021
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

090177e19891a03c\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: 10-Dec-2020 02:30 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1147 **Site Name:** (1147) Ochsner Health System

Subject No: 11471281 **Subject Initials:** ---

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

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

090177e19891a03c\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: 1147 **Site Name:** (1147) Ochsner Health System

Subject No: 11471281 **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/6/2021
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	[BSGV4N]
5.b	Sample ID	[BR5J35]

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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: 1147

Subject No: 11471281

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Not Started

Site Name: (1147) Ochsner Health System

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

090177e19891a03c\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 SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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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090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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?	
----	--	--

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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: 1147 **Site Name:** (1147) Ochsner Health System

Subject No: 11471281 **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	[]
----	-----------	-----

090177e19891a03c\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: 1147 **Site Name:** (1147) Ochsner Health System

Subject No: 11471281 **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: 1147 **Site Name:** (1147) Ochsner Health System

Subject No: 11471281 **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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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:	

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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?	

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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

Form Version: 10-Dec-2020 02:29 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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/6/2021
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e19891a03c\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: 1147 **Site Name:** (1147) Ochsner Health System

Subject No: 11471281 **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/10/2021
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: 1147 **Site Name:** (1147) Ochsner Health System

Subject No: 11471281 **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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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	Acute appendicitis	Jan/22/2021 16:00	NO End Date Time: Jan/23/2021 00:01	Repeating Pages
2.	ADVERSE EVENT	2	localized peritonitis, without perforation or gangrene	Jan/22/2021 16:00	NO End Date Time: Jan/23/2021 00:01	Repeating Pages

090177e19891a03c\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, Locked, Frozen

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Acute appendicitis]
4.	Start Date Time:	Jan/22/2021 16:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/23/2021 00:01
6.	Toxicity Grade:	4

090177e19891a03c\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, Locked, Frozen

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

7.	<p>Is the adverse event serious?</p> <p>If Yes, NOTIFY PFIZER IMMEDIATELY.</p> <p>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).</p>	<p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect? NO</p> <p>Did this serious event result in death? NO</p> <p>Did this serious event require or prolong hospitalization? YES</p> <p>Did this serious event result in persistent or significant disability/incapacity? NO</p> <p>Is this serious event life threatening? YES</p> <p>Other medically important serious event YES</p>
8.	<p>Is this adverse event the result of a study Medication Error?</p> <p>If Yes, record the type of medication error on the Medication Error Log.</p>	NO
9.	<p>Is this event related to study treatment:</p>	<p>NOT RELATED</p> <p>If Not Related to study treatment(s), this event is due to: OTHER</p> <p>If Other, specify: [Acute appendicitis]</p>
10.	<p>Latest Action Taken with Study Treatment:</p>	NOT APPLICABLE

090177e19891a03c\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, Locked, Frozen

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021104203]

090177e19891a03c\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471281

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1147) Ochsner Health System

Subject Initials: ---

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[localized peritonitis, without perforation or gangrene]
4.	Start Date Time:	Jan/22/2021 16:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/23/2021 00:01
6.	Toxicity Grade:	4

090177e19891a03c\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1147**Subject No:** 11471281**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1147) Ochsner Health System**Subject Initials:** ---**Generated Time (GMT):** 10-Nov-2021 20:44

7.	<p>Is the adverse event serious?</p> <p>If Yes, NOTIFY PFIZER IMMEDIATELY.</p> <p>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).</p>	<p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect? NO</p> <p>Did this serious event result in death? NO</p> <p>Did this serious event require or prolong hospitalization? NO</p> <p>Did this serious event result in persistent or significant disability/incapacity? NO</p> <p>Is this serious event life threatening? YES</p> <p>Other medically important serious event YES</p>
8.	<p>Is this adverse event the result of a study Medication Error?</p> <p>If Yes, record the type of medication error on the Medication Error Log.</p>	NO
9.	<p>Is this event related to study treatment:</p>	<p>NOT RELATED</p> <p>If Not Related to study treatment(s), this event is due to: OTHER</p> <p>If Other, specify: [Acute appendicitis]</p>
10.	<p>Latest Action Taken with Study Treatment:</p>	NOT APPLICABLE

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021104203]

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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	[]

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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:	//

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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.	Dose:	[]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
10.	Ongoing?	

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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?	

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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/12/2021
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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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/14/2021
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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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/14/2021
----	--------------	--

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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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 _____
----	--	-------------------------

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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/14/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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/14/2021
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	[BV1K43]
5.b	Sample ID	[BV1K44]
5.c	Sample ID	[BSC42G]
5.d	Sample ID	[BSC42V]

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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/14/2021
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	[BV1K3D]
-----	-----------	----------

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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/14/2021 14:36
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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/3/2021
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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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/3/2021
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	[BV1K5H]
-----	-----------	----------

090177e19891a03c\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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/3/2021 10:32
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

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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	Jul/7/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1147

Subject No: 11471281

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Data Complete, Frozen, Verified

Site Name: (1147) Ochsner Health System

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: Jul/7/2021
3.	Comments:	[]

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471281

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1147) Ochsner Health System

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: 1147

Subject No: 11471281

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1147) Ochsner Health System

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: 1147

Subject No: 11471281

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1147) Ochsner Health System

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: 1147

Subject No: 11471281

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1147) Ochsner Health System

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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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 :	Jul/7/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e19891a03c\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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/6/2021

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Version: 10-Oct-2020 16:00

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
Form	Dec-13-2020 14:17:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable

090177e19891a03c\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: 1147

Subject No: 11471281

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-05-2021 13:02:09 (UTC-06:00) Central Time (US & Canada)	James McMullen (b) (4)	
Form	Dec-13-2020 14:22:35 (UTC-06:00) Central 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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	May-17-2021 21:23:19 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
Fredrick Okwori	N/A	May-13-2021 16:01:52 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Julia Garcia-Diaz	Approved	Mar-18-2021 20:50:51 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
-------------------	----------	--	------	--------

Affidavit:

By my dated signature below, I, JuliaGarcia-Diaz, 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.

090177e19891a03c\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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
Dec-13-2020 14:06:16 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 01 DEC 2020	Initial Entry

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

Date	Location	User	Value	Reason
Dec-13-2020 14:06:16 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e19891a03c\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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
Dec-13-2020 14:06:43 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Dec/12/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Dec-13-2020 14:06:04 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 11471281	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Dec-13-2020 14:05:55 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: (b) (6) /2007	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Dec-13-2020 14:17:07 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Dec-13-2020 14:17:07	ACV0PF EINFP60	(b) (4), (b) (6) [REDACTED]	Data Entry: NOT HISPANIC OR LATI	Initial Entry

090177e19891a03c\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-06:00) Central Time (US & Canada)	00		NO(A) OR OF SPANISH ORIGIN	
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5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Dec-13-2020 14:17:07 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

6. Racial Designation:

Date	Location	User	Value	Reason
Jan-26-2021 23:36:34 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-26-2021 13:15:40 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Answered	Changed Information
Jan-26-2021 13:15:40 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry:	Changed Information

090177e19891a03c\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

Jan-25-2021 04:34:31 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Closed	duplicate query
Jan-25-2021 03:58:59 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Reissued :Opened	DM: If participant does not identify as ASIAN, please leave the Racial Designation field BLANK. Thank you.
Jan-22-2021 12:08:20 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Answered	non Asian
Jan-22-2021 12:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	non asian
Jan-21-2021 10:57:02 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00.InFor mAdapte r.Discrep ancy	DMW QUERY (b) (4)	Query 2: Opened	DMW6937996;Racial Designation is updated, however Race is not ASIAN. Please review and update appropriately or clarify.
Jan-21-2021 09:14:10 (UTC-06:00) Central Time (US	ACV0PF EINFP60 00.InFor mAdapte	DMW QUERY (b) (4)	Query 1: Opened	DMW6937996;Racial Designation is updated, however Race is not ASIAN.

090177e19891a03c\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)	r.Discrepancy			Please review and update appropriately or clarify.
Dec-13-2020 14:46:06 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

090177e19891a03c\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471281

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Dec-13-2020 14:17:18 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Dec/12/2020	Initial Entry

090177e19891a03c\Final\Final On: 11-Nov-2021 01:20 (GMT)

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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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
Dec-13-2020 14:17:57 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Dec/12/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Dec-13-2020 14:17:57 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Dec-13-2020 14:17:57 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

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1.a

Date	Location	User	Value	Reason
Mar-05-2021 13:03:11 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: Constipation Start Date: Jul/2/2014 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Mar-05-2021 13:03:11 (UTC-06:00) Central 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
Mar-05-2021 13:03:11 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Constipation	Initial Entry

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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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

1.a Start Date:

Date	Location	User	Value	Reason
Mar-05-2021 13:03:11 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Jul/2/2014	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Mar-05-2021 13:03:11 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Mar-05-2021 13:07:06 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term: Psoriasis Start Date: UNK/UNK /2016 Ongoing: YES	Initial Entry

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

1.b Line/MH Number:

Date	Location	User	Value	Reason
Mar-05-2021 13:07:06 (UTC-06:00) Central 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
Mar-10-2021 09:40:35 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-10-2021 08:18:34 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Query 1: Answered	Correct. Site is confirming via medical records that subject did not receive corticosteroids or other immunosuppressive medications for psoriasis
Mar-09-2021 09:14:18 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Reissued:Open	To clarify - site is confirming that participant DID NOT receive systemic corticosteroids or

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

				other immunosuppressive medications for psoriasis? Thank you
Mar-09-2021 08:36:12 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Query 1: Answered	Confirmed via medical records
Mar-08-2021 07:59:16 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	GPD Clin: please confirm if participant did/did not receive systemic corticosteroids or other immunosuppressive medications for psoriasis within 28d prior to or during study treatment period.
Mar-05-2021 13:07:06 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Psoriasis	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
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090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

Mar-05-2021 13:07:06 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: UNK/UNK/2016	Initial Entry
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1.b Ongoing:

Date	Location	User	Value	Reason
Mar-05-2021 13:07:06 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Mar-05-2021 13:07:33 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Line/MH 3 Number: Medical History Term: Perforation of right tympanic membrane Start Date Jul/2/2014 : Ongoing: YES	Initial Entry

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

1.c Line/MH Number:

Date	Location	User	Value	Reason
Mar-05-2021 13:07:33 (UTC-06:00) Central 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
Mar-05-2021 13:07:33 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Perforation of right tympanic membrane	Initial Entry

1.c Start Date:

Date	Location	User	Value	Reason
Mar-05-2021 13:07:33 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Jul/2/2014	Initial Entry

1.c Ongoing:

Date	Location	User	Value	Reason
Mar-05-2021 13:07:33 (UTC-06:00)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: YES	Initial Entry

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

Central Time (US & Canada)

1.d

Date	Location	User	Value	Reason
Mar-05-2021 13:09:06 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: Other iron deficiency anemia Start Date: May/27/2020 Ongoing: YES	Initial Entry

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

1.d Line/MH Number:

Date	Location	User	Value	Reason
Mar-05-2021 13:09:06 (UTC-06:00) Central 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
Mar-09-2021 14:23:43 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-09-2021 08:36:40 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Query 1: Answered	Confirmed that the subject did not receive any blood products within 60 days prior to enrollment
Mar-08-2021 09:17:24 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Other Iron Deficiency Anemia reported: Please confirm if subject has received any blood products

090177e19891a03c\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

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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				within 60 days before enrollment.
Mar-05-2021 13:09:06 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Other iron deficiency anemia	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Mar-05-2021 13:09:06 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: May/27/2020	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Mar-05-2021 13:09:06 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: YES	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: HIV STATUS - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:57

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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
Mar-08-2021 16:55:42 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	Giselle Castillo (b) (4)	Query 1: Closed	Response satisfies query
Mar-05-2021 13:21:12 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Query 1: Answered	Medhx updated
Mar-04-2021 05:05:18 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	Giselle Castillo (b) (4)	Query 1: Reissued:Open d	Pls revise and update form accordingly.
Feb-23-2021 17:47:22 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Query 1: Answered	MedHx is frozen.
Feb-22-2021 02:09:56 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Reissued:Open d	Med Hx has been unfrozen.

090177e19891a03c\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: HIV STATUS - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:57

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

Feb-19-2021 11:23:27 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	Giselle Castillo (b) (4)	Query 1: Reissued:Candidate	Med Hx has been unfrozen.
Feb-15-2021 11:15:26 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Query 1: Answered	MedHx is not unfrozen. Please unfreeze.
Feb-15-2021 03:32:09 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Reissued:Opened	Unfrozen, kindly update. Thanks
Feb-13-2021 07:31:02 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	Giselle Castillo (b) (4)	Query 1: Reissued:Candidate	Unfrozen. Thanks
Feb-05-2021 13:49:40 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Query 1: Answered	Please unfreeze
Feb-03-2021 16:29:44 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	Giselle Castillo (b) (4)	Query 1: Opened	Clinical_Per report, the subject has "MedHx_pсориаз, perforation of right tympanic

090177e19891a03c\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: HIV STATUS - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

				membrane, anemia and constipation." However, this additional information is missing on MEDHX form of CRF. Pls revise and update form accordingly. Thanks.
Dec-13-2020 14:22:45 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: The subject is NOT known to be HIV POSITIVE	Initial Entry

090177e19891a03c\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: 10-Dec-2020 02:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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1. Date:

Date	Location	User	Value	Reason
Dec-13-2020 14:24:35 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Dec/12/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Dec-13-2020 14:24:35 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 67.65	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Dec-13-2020 14:24:35 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
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090177e19891a03c\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: 10-Dec-2020 02:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

Dec-13-2020 14:24:35 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 172.5	Initial Entry
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5. Unit:

Date	Location	User	Value	Reason
Dec-13-2020 14:24:35 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Dec-13-2020 14:24:35 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 22.7	Initial Entry

7.a

Date	Location	User	Value	Reason
Dec-13-2020 14:24:35 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Record Identif 1 ier:: Temperature: 98.0 Temperature F Unit:	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

			Temperature	ORAL C	
			Location::	AVITY	

7.a Record Identifier:

Date	Location	User	Value	Reason
Dec-13-2020 14:24:35 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Dec-13-2020 14:24:35 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> 98.0	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Dec-13-2020 14:24:35 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> F	Initial Entry

7.a Temperature Location:

090177e19891a03c\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: 10-Dec-2020 02:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Dec-13-2020 14:24:35 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> ORAL CAVITY	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471281

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

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

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1. Randomization Date :

Date	Location	User	Value	Reason
Dec-13-2020 14:25:50 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Dec/12/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Dec-13-2020 14:25:50 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 22214	Initial Entry

090177e19891a03c\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: 1147

Subject No: 11471281

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

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1. Data Origin

Date	Location	User	Value	Reason
Dec-13-2020 14:26:00 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-13-2020 14:26:00 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-14-2020 08:13:04 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-14-2020 04:52:48 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

				review and correct as appropriate.
Dec-13-2020 14:26:00 (UTC-06:00) Central 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.
Dec-13-2020 14:26:00 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/12/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-14-2020 08:13:04 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BP8H52	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-14-2020 08:13:04 (UTC-06:00) Central	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BP8H52	Initial Entry

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)				
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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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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
Dec-13-2020 14:26:09 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-13-2020 14:26:09 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-14-2020 08:05:11 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-14-2020 04:52:48 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please

090177e19891a03c\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:** 1147**Site Name:** (1147) Ochsner Health System**Subject No:** 11471281**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44

				review and correct as appropriate.
Dec-13-2020 14:26:09 (UTC-06:00) Central 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.
Dec-13-2020 14:26:09 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/12/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-14-2020 08:05:11 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BP8H5C	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-14-2020 08:05:11 (UTC-06:00) Central	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BP8H5C	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)				
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:26

Site No: 1147

Subject No: 11471281

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

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
Dec-13-2020 14:26:46 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Dec-13-2020 14:26:46 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Dec-13-2020 14:26:46 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Dec-13-2020 14:26:46	ACV0PF EINFP60	(b) (4), (b) (6)	Data Entry: Dec/12/2020 10:44	Initial Entry

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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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-06:00) Central
Time (US &
Canada) 00

5. Anatomical Location:

Date	Location	User	Value	Reason
Dec-13-2020 14:26:46 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Dec-13-2020 14:26:46 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Dec-13-2020 14:26:46 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
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090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

Dec-13-2020 14:26:46 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry
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11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Dec-13-2020 14:26:46 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e19891a03c\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: 1147

Subject No: 11471281

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

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

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Dec-13-2020 14:26:53 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES - REACTOGENICIT Y E-DIARY COLLECTED FOR THIS SUBJECT	Initial Entry

090177e19891a03c\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471281

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-03-2021 20:46:28 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	Veronica Gonzalez (b) (4)	Query 1: Closed	Response satisfies query
Feb-02-2021 17:16:42 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Query 1: Answered	ICF and IAF attached to visit on 04JAN2021. Documents corrected
Jan-31-2021 23:53:00 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	Veronica Gonzalez (b) (4)	Query 1: Opened	Showing subject was re-consented using the most up to date ICFs, however, source pdf provided, "Pfizer Peds Consent", is actually a copy of the Medical History log and ConMed Log. Please provide copy of consents for review.

090177e19891a03c\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

Jan-05-2021 16:54:50 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jan/4/2021	Initial Entry
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090177e19891a03c\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: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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-05-2021 16:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-05-2021 16:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: FE V E R Were fever or systemi N c symptoms present o O n the last day the Sub ject Diary was compl eted?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Jan-05-2021 16:58:07	ACV0PF EINFP60	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

090177e19891a03c\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: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-06:00) Central Time (US & Canada)

00

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

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

Date	Location	User	Value	Reason
Jan-05-2021 16:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Jan-05-2021 16:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI G UE Were fever or system N ic symptoms present O on the last day the S ubject Diary was co mpleted?:	Initial Entry

090177e19891a03c\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: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

2.b Symptom:

Date	Location	User	Value	Reason
Jan-05-2021 16:58:07 (UTC-06:00) Central 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-05-2021 16:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Jan-05-2021 16:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e19891a03c\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: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

2.c Symptom:

Date	Location	User	Value	Reason
Jan-05-2021 16:58:07 (UTC-06:00) Central 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-05-2021 16:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Jan-05-2021 16:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: C HI LL S Were fever or system N ic symptoms present O on the last day the Su bject Diary was com pleted?:	Initial Entry

090177e19891a03c\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: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

2.d Symptom:

Date	Location	User	Value	Reason
Jan-05-2021 16:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> 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-05-2021 16:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Jan-05-2021 16:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: VO MI TIN G Were fever or syste mic symptoms prese nt on the last day th e Subject Diary was completed?: NO	Initial Entry

090177e19891a03c\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: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

2.e Symptom:

Date	Location	User	Value	Reason
Jan-05-2021 16:58:07 (UTC-06:00) Central 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-05-2021 16:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Jan-05-2021 16:58:07 (UTC-06:00) Central 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

090177e19891a03c\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: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

2.f Symptom:

Date	Location	User	Value	Reason
Jan-05-2021 16:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> 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-05-2021 16:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Jan-05-2021 16:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: NEW O R WOR SENED MUSCL E PAIN	Initial Entry

090177e19891a03c\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

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Jan-05-2021 16:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR WORSENER MUSCLE 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
Jan-05-2021 16:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Jan-05-2021 16:58:07 (UTC-06:00)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: NEW OR WOR	Initial Entry

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Header Text: c4591001

Visit: V2_VAX2_L

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

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

Central Time (US & Canada)			SENE JOINT PAIN 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.h Symptom:

Date	Location	User	Value	Reason
Jan-05-2021 16:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR WORSENE D 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
Jan-05-2021 16:58:07 (UTC-06:00) Central 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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090177e19891a03c\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: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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Jan-05-2021 16:58:07 (UTC-06:00) Central 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
Jan-05-2021 16:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-05-2021 16:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(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
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090177e19891a03c\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: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

Jan-05-2021 16:58:07 (UTC-06:00) Central 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
Jan-05-2021 16:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-05-2021 16:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: SWELLING Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e19891a03c\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: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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-05-2021 16:58:07 (UTC-06:00) Central 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-05-2021 16:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-05-2021 16:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: PAIN AT IN JECTI ON SI TE	Initial Entry

090177e19891a03c\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: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

			Were injection site reactions present on the last day the Subject Diary was completed?:	NO
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5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Jan-05-2021 16:58:07 (UTC-06:00) Central 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-05-2021 16:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e19891a03c\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: 10-Dec-2020 02:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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-05-2021 16:55:43 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jan/4/2021	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-05-2021 16:55:43 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Record Identifier:: Temperature: 97.0 Temperature F Unit: Temperature ORAL C Location:: AVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jan-05-2021 16:55:43 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e19891a03c\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: 10-Dec-2020 02:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

2.a Temperature:

Date	Location	User	Value	Reason
Jan-05-2021 16:55:43 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 97.0	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Jan-05-2021 16:55:43 (UTC-06:00) Central 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-05-2021 16:55:43 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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-05-2021 16:56:05 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-05-2021 16:56:05 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-06-2021 04:36:25 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-05-2021 16:56:05 (UTC-06:00) Central 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

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

				appropriate.
Jan-05-2021 16:56:05 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/4/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-06-2021 04:36:25 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BP8HDN	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-06-2021 04:36:25 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BP8HDN	Initial Entry

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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1147

Subject No: 11471281

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

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-05-2021 16:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-05-2021 16:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-05-2021 16:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Jan-05-2021 16:57:12 (UTC-06:00) Central Time (US &	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jan/4/2021 16:37	Initial Entry

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

Canada)

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-05-2021 16:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jan-05-2021 16:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jan-05-2021 16:57:12 (UTC-06:00) Central 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-05-2021 16:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIE D OBSERVATION PERIOD	Initial Entry

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Jan-05-2021 16:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e19891a03c\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

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

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

Site No: 1147 **Site Name:** (1147) Ochsner Health System

Subject No: 11471281 **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-07-2021 12:45:18 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: Feb/6/2021	Initial Entry

Header Text: c4591001

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

Form Version: 10-Dec-2020 02:30 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1147 **Site Name:** (1147) Ochsner Health System

Subject No: 11471281 **Subject Initials:** ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Feb-07-2021 12:47:34 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Feb-07-2021 12:47:49 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: FE V E R Were fever or systemi N c symptoms present o O n the last day the Sub ject Diary was compl eted?:	Initial Entry
Feb-07-2021 12:47:34 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: FE V E R	Initial Entry

090177e19891a03c\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: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147 Site Name: (1147) Ochsner Health System

Subject No: 11471281 Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Feb-07-2021 12:47:34 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Feb-07-2021 12:47:49 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Feb-07-2021 12:47:34 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: FATIGUE	Initial Entry

090177e19891a03c\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: 10-Dec-2020 02:30 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1147 **Site Name:** (1147) Ochsner Health System

Subject No: 11471281 **Subject Initials:** ---

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

Canada)			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	YES Ongoing? NO Stop Date: Jan/2021	
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090177e19891a03c\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: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147 Site Name: (1147) Ochsner Health System

Subject No: 11471281 Subject Initials: ---

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

2.b Symptom:

Date	Location	User	Value	Reason
Feb-07-2021 12:47:34 (UTC-06:00) Central 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-07-2021 12:47:34 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Ongoing? NO Stop Date: Jan/9/2021	Initial Entry

2.c

Date	Location	User	Value	Reason
Feb-07-2021 12:47:34 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: HEADACHE	Initial Entry

090177e19891a03c\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: 10-Dec-2020 02:30 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1147 **Site Name:** (1147) Ochsner Health System

Subject No: 11471281 **Subject Initials:** ---

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

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	YES Ongoing? NO Stop Date: Jan/2021
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090177e19891a03c\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: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147 Site Name: (1147) Ochsner Health System

Subject No: 11471281 Subject Initials: ---

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

2.c Symptom:

Date	Location	User	Value	Reason
Feb-07-2021 12:47:34 (UTC-06:00) Central 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-07-2021 12:47:34 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Ongoing? NO Stop Date: Jan/9/2021	Initial Entry

2.d

Date	Location	User	Value	Reason
Feb-07-2021 12:47:34 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: CHILLS	Initial Entry

090177e19891a03c\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: 10-Dec-2020 02:30 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1147 **Site Name:** (1147) Ochsner Health System

Subject No: 11471281 **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/2021</p>	
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090177e19891a03c\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: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147 Site Name: (1147) Ochsner Health System

Subject No: 11471281 Subject Initials: ---

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

2.d Symptom:

Date	Location	User	Value	Reason
Feb-07-2021 12:47:34 (UTC-06:00) Central 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-07-2021 12:47:34 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Ongoing? NO Stop Date: Jan/9/2021	Initial Entry

2.e

Date	Location	User	Value	Reason
Feb-07-2021 12:47:34 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: VO MI TIN G	Initial Entry

090177e19891a03c\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: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147 Site Name: (1147) Ochsner Health System

Subject No: 11471281 Subject Initials: ---

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

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	NO
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2.e Symptom:

Date	Location	User	Value	Reason
Feb-07-2021 12:47:34 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> 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-07-2021 12:47:34 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Feb-07-2021 12:47:34 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom::	Initial Entry
			DI	
			AR	
			RH	

090177e19891a03c\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: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147 Site Name: (1147) Ochsner Health System

Subject No: 11471281 Subject Initials: ---

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

Canada)			EA	
			NO	
Were fever or systemic symptoms present on the last day the Subject Diary was completed?:				

2.f Symptom:

Date	Location	User	Value	Reason
Feb-07-2021 12:47:34 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> 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-07-2021 12:47:34 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Feb-07-2021 12:47:34 (UTC-06:00)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: NEW OR WOR	Initial Entry

090177e19891a03c\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: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147 Site Name: (1147) Ochsner Health System

Subject No: 11471281 Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Feb-07-2021 12:47:34 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR WORSENE MUSCLE 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-07-2021 12:47:34 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
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090177e19891a03c\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: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147 Site Name: (1147) Ochsner Health System

Subject No: 11471281 Subject Initials: ---

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

Feb-07-2021 12:47:34 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: NEW O R WOR SENE D JOINT PAIN Were fever or sy NO stemic symptom s present on the l ast day the Subj ect Diary was co mpleted?:	Initial Entry
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2.h Symptom:

Date	Location	User	Value	Reason
Feb-07-2021 12:47:34 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR WORSENE D JO INT 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-07-2021 12:47:34 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e19891a03c\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: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147 Site Name: (1147) Ochsner Health System

Subject No: 11471281 Subject Initials: ---

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

3. Injection Site Location:

Date	Location	User	Value	Reason
Feb-07-2021 12:47:34 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Feb-07-2021 12:47:34 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-07-2021 12:47:34 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(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

090177e19891a03c\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: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147 Site Name: (1147) Ochsner Health System

Subject No: 11471281 Subject Initials: ---

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

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Feb-07-2021 12:47:34 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Feb-07-2021 12:47:34 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-07-2021 12:47:34 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction: SW ELL ING Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e19891a03c\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: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147 Site Name: (1147) Ochsner Health System

Subject No: 11471281 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-07-2021 12:47:34 (UTC-06:00) Central 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-07-2021 12:47:34 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-07-2021 12:47:34 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Injection Site Rea ction:: PAIN AT IN JECTI ON SI TE	Initial Entry

090177e19891a03c\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: 10-Dec-2020 02:30 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1147 **Site Name:** (1147) Ochsner Health System

Subject No: 11471281 **Subject Initials:** ---

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

			Were injection site 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-07-2021 12:47:34 (UTC-06:00) Central 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
Feb-07-2021 12:47:34 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e19891a03c\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: 1147 **Site Name:** (1147) Ochsner Health System

Subject No: 11471281 **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
Feb-08-2021 07:30:30 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-08-2021 07:30:30 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-08-2021 07:30:57 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-08-2021 07:30:30 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please

090177e19891a03c\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: 1147 **Site Name:** (1147) Ochsner Health System

Subject No: 11471281 **Subject Initials:** ---

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

				review and correct as appropriate.
Feb-08-2021 07:30:30 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/6/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-08-2021 07:30:57 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BSGV4N	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-08-2021 07:30:57 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BSGV4N	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-08-2021 07:47:55	ACV0PF EINFP60	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e19891a03c\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: 1147 **Site Name:** (1147) Ochsner Health System

Subject No: 11471281 **Subject Initials:** ---

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

(UTC-06:00) Central Time (US & Canada)	00	(b) (4), (b) (6)	Sample ID: BR5J35	
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5.b Sample ID

Date	Location	User	Value	Reason
Feb-08-2021 07:47:55 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BR5J35	Initial Entry

090177e19891a03c\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: 10-Dec-2020 02:29 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1147 **Site Name:** (1147) Ochsner Health System

Subject No: 11471281 **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-07-2021 12:48:11 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Feb/6/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-07-2021 12:48:11 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Feb-07-2021 12:48:11 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e19891a03c\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: 1147 **Site Name:** (1147) Ochsner Health System

Subject No: 11471281 **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-13-2021 16:01:52 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	Fredrick Okwori (b) (4)	Data Entry: May/10/2021	Initial Entry

090177e19891a03c\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: 1147 **Site Name:** (1147) Ochsner Health System

Subject No: 11471281 **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-13-2021 16:02:40 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
May-13-2021 16:02:23 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
May-13-2021 16:02:23 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	Fredrick Okwori (b) (4)	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

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Feb-01-2021 14:58:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Form Created	

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Feb-19-2021 08:50:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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
Feb-01-2021 14:58:11 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-01-2021 14:58:11 (UTC-06:00) Central 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
Feb-21-2021 06:33:11 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Feb-19-2021 11:11:24 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00.InFor mAdapte r.Discrep	PFETMS Oracle (b) (4)	Query 2: Closed	Discrepancy has been closed.

090177e19891a03c\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, Locked, Frozen

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

	ancy			
Feb-19-2021 09:36:15 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	Giselle Castillo (b) (4)	Query 1: Closed	Response satisfies query
Feb-19-2021 08:47:54 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 3: Answered	Changed Information
Feb-19-2021 08:47:54 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 2: Answered	Changed Information
Feb-19-2021 08:47:54 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Acute appendicitis	Changed Information
Feb-19-2021 03:43:09 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 3: Opened	SAE RECON: AER#2021104203, event term recorded as 'Acute appendicitis with localized peritonitis, without perforation or gangrene '. Please consider to split

090177e19891a03c\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

				the term an record as separate entries to facilitate coding and match SDB.
Feb-15-2021 12:41:08 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00.InFor mAdapte r.Discrep ancy	PFETMS Oracle (b) (4)	Query 2: Opened	Multiple concepts in the term ACUTE APPENDICITIS WITH LOCALIZED PERITONITIS, WITHOUT PERFORATION OR GANGRENE. Split the term into ACUTE APPENDICITIS and LOCALIZED PERITONITIS, WITHOUT PERFORATION OR GANGRENE and submit separately. Thank you.
Feb-15-2021 11:13:28 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Acute appendicitis with localized peritonitis, without perforation or gangrene	New Information
Feb-15-2021 10:22:41	ACV0PF EINFP60	James McMullen	Query 1: Answered	Per pathology report, no necrosis,

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-06:00) Central Time (US & Canada)	00	(b) (4)		gangrene or perforation occurred
Feb-13-2021 07:23:33 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	Giselle Castillo (b) (4)	Query 1: Reissued:Open ed	It is intended to confirm if necrosis, gangrene or any perforation occurred. Thanks
Feb-05-2021 13:48:50 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Query 1: Answered	Please clarify the desired information from pathology report. Final diagnosis from pathology report is Acute appendicitis
Feb-03-2021 16:32:09 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	Giselle Castillo (b) (4)	Query 1: Opened	CLINICAL_ Pls provide, if available, results from pathology report. Thank you.
Feb-01-2021 14:58:11 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Acute appendicitis	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
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090177e19891a03c\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, Locked, Frozen

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

Feb-01-2021 14:58:11 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Jan/22/2021 16:00	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-01-2021 14:58:11 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: NO End Date Time: Jan/23/2021 00:01	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-01-2021 14:58:11 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: 4	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Feb-05-2021 08:23:11 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-01-2021 14:58:11 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	For AE Acute appendicitis : Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-01-2021 14:58:11 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization?	Initial Entry

090177e19891a03c\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, Locked, Frozen
Site No: 1147
Site Name: (1147) Ochsner Health System
Subject No: 11471281
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 10-Nov-2021 20:44

			<p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>YES</p> <p>Other medically important serious event</p> <p>YES</p>	
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**8. Is this adverse event the result of a study Medication Error?
 If Yes, record the type of medication error on the Medication Error Log.**

Date	Location	User	Value	Reason
Feb-01-2021 14:58:11 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

Feb-01-2021 14:58:11 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Acute appendicitis	Initial Entry
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-01-2021 14:58:11 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-01-2021 14:58:11 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
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090177e19891a03c\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, Locked, Frozen

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

Feb-01-2021 14:58:11 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: YES	Initial Entry
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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Feb-01-2021 14:58:11 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: RECOVERED/RESOLVE D	Initial Entry

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

Date	Location	User	Value	Reason
Feb-01-2021 14:58:11 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Feb-05-2021 08:23:11 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 2021104203	Initial Entry

090177e19891a03c\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, Locked, Frozen

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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
Feb-19-2021 08:50:05 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-19-2021 08:50:05 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-19-2021 08:50:05 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: localized peritonitis, witho ut perforation or gangrene	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
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090177e19891a03c\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, Locked, Frozen

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

Feb-19-2021 08:50:05 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Jan/22/2021 16:00	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-19-2021 08:50:05 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: NO End Date Time: Jan/23/2021 00:01	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-19-2021 08:50:05 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: 4	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

090177e19891a03c\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, Locked, Frozen

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Feb-21-2021 06:33:28 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-19-2021 08:50:05 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	For AE localized peritonitis, without perforation or gangrene : Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-19-2021 08:50:05 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO	Initial Entry

090177e19891a03c\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, Locked, Frozen

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

			<p>Did this serious event require or prolong hospitalization?</p> <p>NO</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>YES</p> <p>Other medically important serious event</p> <p>YES</p>	
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8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Feb-19-2021 08:50:05 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: NO	Initial Entry

090177e19891a03c\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, Locked, Frozen

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-19-2021 08:50:05 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Acute appendicitis	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-19-2021 08:50:05 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-19-2021 08:50:05 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: YES	Initial Entry

090177e19891a03c\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, Locked, Frozen

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-19-2021 08:50:05 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-19-2021 08:50:05 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: RECOVERED/RESOLVE D	Initial Entry

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

Date	Location	User	Value	Reason
Feb-19-2021 08:50:05 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Feb-21-2021 06:33:28	ACV0PF EINFP60	(b) (4), (b) (6)	Data Entry: 2021104203	Initial Entry

090177e19891a03c\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, Locked, Frozen

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-06:00) Central Time (US & Canada)	00	(b) (4), (b) (6)		
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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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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-13-2021 16:02:40 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	Fredrick Okwori (b) (4)	Data Entry: May/12/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
May-13-2021 16:02:40 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	Fredrick Okwori (b) (4)	Data Entry: ASSESS ELIGIBILITY FO R ADDITIONAL VACCIN ATION	Initial Entry

090177e19891a03c\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471281

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
May-19-2021 02:45:22 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
May-17-2021 21:25:04 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
May-17-2021 06:00:00 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly review and complete 'Vaccination, Immunogenicity Nasal Swab and Inclusion/Exclusion Criteria form' at this visit. Thank you.
May-15-2021 04:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: May/14/2021	Initial Entry

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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-15-2021 04:16:17 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	Data Entry: OBTAINED Date Written Consent Obtained May/14/2021	Initial Entry

090177e19891a03c\Final\Final On: 11-Nov-2021 01:20 (GMT)

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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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-15-2021 04:16:52 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: May/14/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
May-15-2021 04:16:52 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
May-15-2021 04:16:52 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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-17-2021 21:23:38 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
May-17-2021 21:23:38 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
May-18-2021 08:16:47 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
May-17-2021 21:23:38 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

				correct as appropriate.
May-17-2021 21:23:38 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: May/14/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
May-18-2021 08:16:47 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BV1K43	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
May-18-2021 08:16:47 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BV1K43	Initial Entry

5.b

Date	Location	User	Value	Reason
May-18-2021 08:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BV1K44	Initial Entry

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

5.b Sample ID

Date	Location	User	Value	Reason
May-18-2021 08:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BV1K44	Initial Entry

5.c

Date	Location	User	Value	Reason
May-18-2021 08:30:52 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BSC42G	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
May-18-2021 08:30:52 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BSC42G	Initial Entry

5.d

Date	Location	User	Value	Reason
May-18-2021 08:34:17 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BSC42V	Initial Entry

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sample ID

Date	Location	User	Value	Reason
May-18-2021 08:34:17 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	Data Entry: BSC42V	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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-17-2021 21:23:57 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
May-17-2021 21:23:57 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
May-18-2021 08:25:49 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
May-17-2021 21:23:57 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

				correct as appropriate.
May-17-2021 21:23:57 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: May/14/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
May-18-2021 08:25:49 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BV1K3D	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
May-18-2021 08:25:49 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BV1K3D	Initial Entry

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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-17-2021 21:24:40 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
May-17-2021 21:24:40 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
May-17-2021 21:24:40 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
May-17-2021 21:24:40 (UTC-06:00) Central	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: May/14/2021 14:36	Initial Entry

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)

5. Anatomical Location:

Date	Location	User	Value	Reason
May-17-2021 21:24:40 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
May-17-2021 21:24:40 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
May-17-2021 21:24:40 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
May-17-2021 21:24:40 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

9. Unit:

Date	Location	User	Value	Reason
May-17-2021 21:24:40 (UTC-06:00) Central 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-17-2021 21:24:40 (UTC-06:00) Central 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-17-2021 21:24:40 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e19891a03c\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471281

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Jun-07-2021 15:24:24 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Jun/3/2021	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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-07-2021 17:00:30 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jun-07-2021 17:00:30 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jun-07-2021 17:00:45 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jun-07-2021 17:00:30 (UTC-06:00) Central 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

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

				appropriate.
Jun-07-2021 17:00:30 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: YES Date of Collection: Jun/3/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jun-07-2021 17:00:45 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Sample ID: BV1K5H	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jun-07-2021 17:00:45 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: BV1K5H	Initial Entry

090177e19891a03c\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1147

Subject No: 11471281

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1147) Ochsner Health System

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
Jun-07-2021 15:25:46 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jun-07-2021 15:25:46 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jun-07-2021 15:25:46 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Jun-07-2021 15:25:46 (UTC-06:00) Central Time (US &	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Jun/3/2021 10:32	Initial Entry

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

Canada)

5. Anatomical Location:

Date	Location	User	Value	Reason
Jun-07-2021 15:25:46 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jun-07-2021 15:25:46 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jun-07-2021 15:25:46 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jun-07-2021 15:25:46 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

9. Unit:

Date	Location	User	Value	Reason
Jun-07-2021 15:25:46 (UTC-06:00) Central 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-07-2021 15:25:46 (UTC-06:00) Central 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-07-2021 15:25:46 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: YES	Initial Entry

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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
Jul-23-2021 03:24:16 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	data updated
Jul-22-2021 00:42:01 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Jul-20-2021 04:59:47 (UTC-06:00) Central 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.
Jul-13-2021 11:03:38 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jul/7/2021	Initial Entry

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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
Jul-13-2021 11:03:59 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Jul-13-2021 11:03:59 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	Data Entry: YES Date of Contact: Jul/7/2021	Initial Entry

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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
Jul-22-2021 00:41:46 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jul/7/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jul-22-2021 00:41:46 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: OPEN LABEL TREATMENT	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jul-22-2021 00:41:46 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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-07-2021 12:48:11 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Dec-13-2020 14:25:50 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Dec-13-2020 14:17:57 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Jun-10-2021 03:14:09 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 3: Closed	Visit was updated
Jun-09-2021 14:37:20 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Query 3: Answered	Visit entered

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

Jun-04-2021 07:27:27 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	Balaji Prabu R (b) (4)	Query 3: Opened	Vaccination 4 is reported in IRT, however, V102_VAX4 is not completed. Please review and enter all CRF in the vaccination visit or explain otherwise.
Feb-15-2021 14:02:53 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-15-2021 11:12:32 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Query 2: Answered	AE CRF updated
Feb-15-2021 05:33:01 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2021104203 localized peritonitis without perforation or gangrene(onset date:22jAN2021)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form
Feb-15-2021 05:32:43	ACV0PF EINFP60	(b) (4), (b) (6)	Query 1: Closed	UPDATE QUERY TEXT

090177e19891a03c\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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-06:00) Central Time (US & Canada)	00	(b) (4), (b) (6)		
Feb-15-2021 05:32:17 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2021104203 cal peritonitis (onset date:22jAN2021)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Feb-07-2021 12:48:11 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Feb/6/2021	Initial Entry
Dec-13-2020 14:25:50 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Dec/12/2020	Initial Entry
Dec-13-2020 14:17:57 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Dec/12/2020	Initial Entry

090177e19891a03c\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, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471281

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
Mar-16-2021 16:24:10 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry