

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: 11471327

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

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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/5/2021
----	--------------	---

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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11471327]
2.	Birth Date:	(b) (6) 2006
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:	

090177e19891a03b\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471327

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/5/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1147

Subject No: 11471327

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

090177e19891a03b\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1147

Subject No: 11471327

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	Jan/5/2021
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471327

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

Medical History Details

1.	Line/MH Number:	Not Applicable _____ []
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	Not Applicable _____ []
	Start Date:	Not Applicable _____ //
	Ongoing:	Not Applicable _____

090177e19891a03b\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1147

Subject No: 11471327

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
----	--	---

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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Jan/5/2021
2.	Weight:	[167.2]
3.	Unit:	LB
4.	Height:	[66.0]
5.	Unit:	in
6.	Body Mass Index:	[27.0]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[98.5]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e19891a03b\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: 11471327

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 :	Jan/5/2021
2.	Randomization Number:	[25570]
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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/5/2021
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	[BP8HFV]
5.b	Sample ID	[BP8HFW]
5.c	Sample ID	[BSGV0P]

090177e19891a03b\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: 11471327

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/5/2021
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	[BP8HFG]
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090177e19891a03b\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: 11471327

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/5/2021 17:10
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

090177e19891a03b\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: 11471327

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
----	---	--

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: 11471327

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/27/2021
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: 11471327

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

090177e19891a03b\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: 11471327

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

090177e19891a03b\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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

4.	Injection Site Body Side:	LEFT	Comments
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	

090177e19891a03b\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP

Form Version: 14-Jan-2021 02:22

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Jan/27/2021
----	-------	-------------

Vital Signs Details

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

090177e19891a03b\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: 11471327

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/27/2021
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	[BR5J0P]
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090177e19891a03b\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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	Not Applicable _____	Comments
2.	Treatment Name	Not Applicable _____ []	Comments
3.	Formulation:	Not Applicable _____	Comments
4.	Dose Date Time:	Not Applicable _____ //	Comments
5.	Anatomical Location:	Not Applicable _____	Comments
6.	Body Side:	Not Applicable _____	Comments
7.	Route:	Not Applicable _____	Comments
8.	Actual Dose:	Not Applicable _____ []	Comments
9.	Unit:	Not Applicable _____	Comments
10.	Timeframe Subject Was Observed	Not Applicable _____	Comments

090177e19891a03b\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: 11471327

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?	Not Applicable	Comments
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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: 11471327 **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/25/2021
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: 11471327 **Subject Initials:** ---

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

[Form Comments](#)

[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?	Not Applicable	Comments
2.a	Symptom:	FEVER	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	Comments
2.b	Symptom:	FATIGUE	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	Comments
2.c	Symptom:	HEADACHE	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	Comments

090177e19891a03b\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: 11471327 **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?	Not Applicable	Comments
2.e	Symptom:	VOMITING	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	Comments
2.f	Symptom:	DIARRHEA	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	Comments
2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	Comments
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	Comments

090177e19891a03b\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: 11471327 **Subject Initials:** ---

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

3.	Injection Site Location:	Not Applicable _____	Comments
4.	Injection Site Body Side:	Not Applicable _____	Comments
5.a	Injection Site Reaction:	REDNESS	
	Were injection site reactions present on the last day the Subject Diary was completed?	Not Applicable _____	Comments
5.b	Injection Site Reaction:	SWELLING	
	Were injection site reactions present on the last day the Subject Diary was completed?	Not Applicable _____	Comments
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE	
	Were injection site reactions present on the last day the Subject Diary was completed?	Not Applicable _____	Comments

090177e19891a03b\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: 11471327 **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/25/2021
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	[BR7X56]
5.b	Sample ID	[BRZXLD]

090177e19891a03b\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471327

Generated By: (b) (4)

Form: DATE OF VISIT

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](#)

Date of Visit

1.	Date of Visit	Jul/28/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

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: 11471327

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: Jul/28/2021
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	[BS2D9K]
5.b	Sample ID	[BRND2G]

090177e19891a03b\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471327

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: V5_MONTH12_L

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: 11471327

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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090177e19891a03b\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471327

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: V6_MONTH24_L

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: 11471327

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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090177e19891a03b\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: 11471327

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: 11471327

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

090177e19891a03b\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: 11471327

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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090177e19891a03b\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: 11471327

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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090177e19891a03b\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: 11471327

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?	
----	--	--

090177e19891a03b\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: 11471327

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: 11471327

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: 11471327

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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090177e19891a03b\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: 11471327

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: 11471327 **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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090177e19891a03b\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled
Visit on Jan/06/2021

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: 11471327

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/6/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled
Visit on Jan/06/2021

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Unplanned Assessments

1.	Assessments	CONTACT OUTCOME
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Header Text: c4591001

Visit: Unplanned 1 - Unscheduled
Visit on Jan/06/2021

Form: CONTACT OUTCOME - UNPLANNED

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471327

Subject Initials: ---

Generated By: (b) (4)

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: Jan/6/2021 Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISION
3.	Comments:	[]

090177e19891a03b\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471327

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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

Vital Signs

1.	Date:	//
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Vital Signs Details

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471327

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?	

090177e19891a03b\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: 11471327

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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

Contact Outcome

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

Header Text: c4591001

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

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

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

Subject No: 11471327 **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: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

Informed Consent - Asymptomatic Surveillance

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471327

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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Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471327

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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090177e19891a03b\Final\Final On: 11-Nov-2021 01:20 (GMT)

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: 11471327

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 :	Jan/8/2021
2.	Phase of Disposition:	VACCINATION
3.	Status:	ADVERSE EVENT
4.	Specify Status:	[]

Header Text: c4591001

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

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

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

Subject No: 11471327 **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/6/2021
2.	Erroneous Visit	

Header Text: c4591001

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

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

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

Subject No: 11471327 **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 and NOT 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: 11471327

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: 11471327

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	Fever (104.7)	Jan/6/2021 19:30	NO End Date Time: Jan/8/2021 UNK:UNK	Repeating Pages

090177e19891a03b\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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

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[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Fever (104.7)]
4.	Start Date Time:	Jan/6/2021 19:30
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/8/2021 UNK:UNK
6.	Toxicity Grade:	4

090177e19891a03b\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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	DRUG WITHDRAWN
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO

090177e19891a03b\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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471327

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: 11471327

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	[]

090177e19891a03b\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: 11471327

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.	1	VACCINATIONS	NO	BNT162b2 Dose #1 IM/once	May/7/2021	Repeating Pages
2.	2	VACCINATIONS	NO	BNT162b2 Dose #2 IM/once	Jun/4/2021	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471327

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?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[BNT162b2 Dose #1 IM/once]
5.	Date:	May/7/2021

090177e19891a03b\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471327

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]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[BNT162b2 Dose #2 IM/once]
5.	Date:	Jun/4/2021

090177e19891a03b\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: 11471327

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: 11471327

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?	

090177e19891a03b\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: 11471327

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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Radiation Treatment

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

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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e19891a03b\Final\Final On: 11-Nov-2021 01:20 (GMT)

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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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

Header Text: c4591001

Visit:
UNPLANNED_BOOSTER_CONTACT
- 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: 11471327

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_BOOSTER_CONTACT
- Unscheduled

Form: BOOSTER DOSE TRIGGER FORM

Form Version: 13-Apr-2021 01:26

Form Status: Not Started

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

Booster Dose Trigger Form

- | | | |
|----|--|--|
| 1. | Select appropriate response
- Will the participant return
for consent/eligibility
assessment for the booster
dose visit? | |
|----|--|--|

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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Treatment Unblinded

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471327

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: 11471327

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: 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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Jan/8/2021

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: 11471327

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: 11471327

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
------	----------------------	------	------	--------

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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Jan-06-2021 16:41:22 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	not applicable Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - Comments

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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Jan-06-2021 16:42:20 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	not applicable <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
4	Mar-02-2021 14:43:57 (UTC-06:00) Central Time (US & Canada)	James McMullen (b) (4)	
4	Jan-28-2021 00:20:22 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	n/a <hr/> Not Applicable

090177e19891a03b\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - Comments

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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Jan-28-2021 00:17:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	n/a <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - Comments

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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
1	Jan-28-2021 00:17:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	n/a <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - Comments

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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
2	Jan-28-2021 00:17:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	n/a
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - Comments

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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
3	Jan-28-2021 00:17:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	n/a
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - Comments

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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
4	Jan-28-2021 00:17:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	n/a <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - Comments

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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5	Jan-28-2021 00:17:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	n/a
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - Comments

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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
6	Jan-28-2021 00:17:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	n/a <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - Comments

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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
7	Jan-28-2021 00:17:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	n/a
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - Comments

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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
8	Jan-28-2021 00:17:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	n/a
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - Comments

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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
9	Jan-28-2021 00:17:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	n/a
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - Comments

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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
10	Jan-28-2021 00:17:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	n/a
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - Comments

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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
11	Jan-28-2021 00:17:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	n/a
			Not Applicable

Header Text: c4591001

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

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: 11471327 **Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	James McMullen (b) (4)	Subject discontinued from study treatment. Did not receive Vaccination 2 <hr/> Not Applicable

Header Text: c4591001

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

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: 11471327 **Subject Initials:** ---

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

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Item	Date	User	Comment
1	Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	James McMullen (b) (4)	Subject discontinued from study treatment. Did not receive Vaccination 2 <hr/> Not Applicable

Header Text: c4591001

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

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: 11471327 **Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
2.a	Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	James McMullen (b) (4)	Subject discontinued from study treatment. Did not receive Vaccination 2 <hr/> Not Applicable

Header Text: c4591001

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

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: 11471327 **Subject Initials:** ---

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

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Item	Date	User	Comment
2.b	Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	James McMullen (b) (4)	Subject discontinued from study treatment. Did not receive Vaccination 2 <hr/> Not Applicable

Header Text: c4591001

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

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: 11471327 **Subject Initials:** ---

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

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Item	Date	User	Comment
2.c	Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	James McMullen (b) (4)	Subject discontinued from study treatment. Did not receive Vaccination 2 <hr/> Not Applicable

Header Text: c4591001

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

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: 11471327 **Subject Initials:** ---

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

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Item	Date	User	Comment
2.d	Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	James McMullen (b) (4)	Subject discontinued from study treatment. Did not receive Vaccination 2 <hr/> Not Applicable

Header Text: c4591001

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

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: 11471327 **Subject Initials:** ---

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

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Item	Date	User	Comment
2.e	Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	James McMullen (b) (4)	Subject discontinued from study treatment. Did not receive Vaccination 2 <hr/> Not Applicable

Header Text: c4591001

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

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: 11471327 **Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
2.f	Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	James McMullen (b) (4)	Subject discontinued from study treatment. Did not receive Vaccination 2 <hr/> Not Applicable

Header Text: c4591001

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

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: 11471327 **Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
2.g	Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	James McMullen (b) (4)	Subject discontinued from study treatment. Did not receive Vaccination 2
			Not Applicable

Header Text: c4591001

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

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: 11471327 **Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
2.h	Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	James McMullen (b) (4)	Subject discontinued from study treatment. Did not receive Vaccination 2 <hr/> Not Applicable

Header Text: c4591001

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

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: 11471327 **Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
3	Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	James McMullen (b) (4)	Subject discontinued from study treatment. Did not receive Vaccination 2 <hr/> Not Applicable

Header Text: c4591001

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

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: 11471327 **Subject Initials:** ---

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

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Item	Date	User	Comment
4	Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	James McMullen (b) (4)	Subject discontinued from study treatment. Did not receive Vaccination 2 <hr/> Not Applicable

Header Text: c4591001

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

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: 11471327 **Subject Initials:** ---

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

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Item	Date	User	Comment
5.a	Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	James McMullen (b) (4)	Subject discontinued from study treatment. Did not receive Vaccination 2 <hr/> Not Applicable

Header Text: c4591001

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

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: 11471327 **Subject Initials:** ---

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

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Item	Date	User	Comment
5.b	Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	James McMullen (b) (4)	Subject discontinued from study treatment. Did not receive Vaccination 2 <hr/> Not Applicable

Header Text: c4591001

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

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: 11471327 **Subject Initials:** ---

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

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Item	Date	User	Comment
5.c	Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	James McMullen (b) (4)	Subject discontinued from study treatment. Did not receive Vaccination 2 <hr/> 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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
Fredrick Okwori	N/A	May-14-2021 09:57:49 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

Julia Garcia-Diaz	Approved	Mar-18-2021 21:42:13 (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.

090177e19891a03b\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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Jan-06-2021 16:39:14 (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
Jan-06-2021 16:39:14 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e19891a03b\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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

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1. Consent Was:

Date	Location	User	Value	Reason
Jan-06-2021 16:39:33 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Jan/5/2021	Initial Entry

090177e19891a03b\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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

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1. Subject ID

Date	Location	User	Value	Reason
Jan-06-2021 16:38:51 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 11471327	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Jan-06-2021 16:35:30 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: (b) (6) 2006	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Jan-06-2021 16:40:38 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Jan-07-2021 08:21:02 (UTC-06:00) Central Time (US &	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATI NO(A) OR OF SPANISH ORIGIN	Initial Entry

090177e19891a03b\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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

Canada)

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

Date	Location	User	Value	Reason
Jan-07-2021 08:21:02 (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-27-2021 01:17:52 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-26-2021 20:27:16 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00.InFor mAdapte r.Discrep ancy	DMW QUERY (b) (4)	Query 2: Closed	Auto closed by Validation Check: VC_DM001_09
Jan-26-2021 13:49:21 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 2: Answered	Changed Information
Jan-26-2021 13:49:21	ACV0PF EINFP60	auto query (autoquery)	Query 1: Answered	Changed Information

090177e19891a03b\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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-06:00) Central Time (US & Canada)	00			
Jan-26-2021 13:49:21 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry:	Changed Information
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	DMW6938178;Racial Designation is updated, however Race is not ASIAN. Please review and update appropriately or clarify.
Jan-21-2021 09:49:50 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00.InFor mAdapte r.Discrep ancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6938178;Racial Designation is updated, however Race is not ASIAN. Please review and update appropriately or clarify.
Jan-06-2021 16:40:38 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

090177e19891a03b\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: 11471327

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
Jan-06-2021 16:40:58 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	Data Entry: Jan/5/2021	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471327

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
Jan-06-2021 16:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jan/5/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-06-2021 16:41:49 (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
Jan-06-2021 16:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e19891a03b\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1147

Subject No: 11471327

Generated By: (b) (4)

Form: HIV STATUS - 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 - What is the subject HIV status?

Date	Location	User	Value	Reason
Jan-06-2021 16:43:02 (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

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: 11471327

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-06-2021 16:47:10 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jan/5/2021	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Jan-06-2021 16:47:10 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 167.2	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Jan-06-2021 16:47:10 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
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090177e19891a03b\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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

Jan-06-2021 16:47:10 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 66.0	Initial Entry
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5. Unit:

Date	Location	User	Value	Reason
Jan-06-2021 16:47:10 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Jan-06-2021 16:47:10 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 27.0	Initial Entry

7.a

Date	Location	User	Value	Reason
Jan-06-2021 16:47:10 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Record Identifier:: Temperature: 98.5 Temperature F Unit:	Initial Entry

090177e19891a03b\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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

			Temperature Location::	ORAL C AVITY
--	--	--	-------------------------------	-----------------

7.a Record Identifier:

Date	Location	User	Value	Reason
Jan-06-2021 16:47:10 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Jan-06-2021 16:47:10 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 98.5	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Jan-06-2021 16:47:10 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: F	Initial Entry

7.a Temperature Location:

090177e19891a03b\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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jan-06-2021 16:47:10 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> ORAL CAVITY	Initial Entry

090177e19891a03b\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: 11471327

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
Jan-06-2021 16:44:58 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jan/5/2021	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Jan-06-2021 16:44:58 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 25570	Initial Entry

090177e19891a03b\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: 11471327

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: ---

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

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1. Data Origin

Date	Location	User	Value	Reason
Jan-06-2021 16:45:34 (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-06-2021 16:45:34 (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
Jan-07-2021 05:22:14 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-06-2021 16:45:34 (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

090177e19891a03b\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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

				appropriate.
Jan-06-2021 16:45:34 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/5/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-07-2021 05:22:14 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BP8HFV	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-07-2021 05:22:14 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BP8HFV	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-07-2021 05:23:18 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BP8HFW	Initial Entry

090177e19891a03b\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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

Canada)

5.b Sample ID

Date	Location	User	Value	Reason
Jan-07-2021 05:23:18 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BP8HFW	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-07-2021 05:47:16 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BSGV0P	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-07-2021 05:47:16 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BSGV0P	Initial Entry

090177e19891a03b\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: 11471327

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-06-2021 16:46:00 (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
Jan-06-2021 16:46:00 (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-07-2021 06:10:03 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-06-2021 16:46:00 (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

090177e19891a03b\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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

				appropriate.
Jan-06-2021 16:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/5/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-07-2021 06:10:03 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BP8HFG	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-07-2021 06:10:03 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BP8HFG	Initial Entry

090177e19891a03b\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:26

Site No: 1147

Subject No: 11471327

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-06-2021 16:44:18 (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-06-2021 16:44:18 (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-06-2021 16:44:18 (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-06-2021 16:44:18 (UTC-06:00) Central Time (US &	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jan/5/2021 17:10	Initial Entry

090177e19891a03b\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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

Canada)

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-06-2021 16:44:18 (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-06-2021 16:44:18 (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-06-2021 16:44:18 (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-06-2021 16:44:18 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIE D OBSERVATION PERIOD	Initial Entry

090177e19891a03b\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: 11471327

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-06-2021 16:44:18 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e19891a03b\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Jan-06-2021 16:44:27 (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

090177e19891a03b\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: 11471327

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
Jan-28-2021 00:13:33 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	Data Entry: Jan/27/2021	Initial Entry

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: 11471327

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
Jan-28-2021 00:20:03 (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-28-2021 00:20:03 (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-28-2021 00:20:03	ACV0PF EINFP60	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

090177e19891a03b\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: 11471327

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

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (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-28-2021 00:20:03 (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

090177e19891a03b\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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

2.b Symptom:

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (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-28-2021 00:20:03 (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-28-2021 00:20:03 (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

090177e19891a03b\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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

2.c Symptom:

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (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-28-2021 00:20:03 (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-28-2021 00:20:03 (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

090177e19891a03b\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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

2.d Symptom:

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (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-28-2021 00:20:03 (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-28-2021 00:20:03 (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

090177e19891a03b\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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

2.e Symptom:

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (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-28-2021 00:20:03 (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-28-2021 00:20:03 (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

090177e19891a03b\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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

2.f Symptom:

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: NEW O R WOR SENED MUSCL E PAIN	Initial Entry

090177e19891a03b\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: 11471327

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-28-2021 00:20:03 (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-28-2021 00:20:03 (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-28-2021 00:20:03 (UTC-06:00)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: NEW OR WOR	Initial Entry

090177e19891a03b\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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

Central Time (US & Canada)			SENE JOINT PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	
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2.h Symptom:

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR WORSENE JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (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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090177e19891a03b\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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

Jan-28-2021 00:20:03 (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
Mar-02-2021 23:12:11 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-02-2021 14:44:15 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Answered	Initial Entry
Mar-02-2021 14:44:15 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: LEFT	Initial Entry
Mar-02-2021 14:43:57 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry:	Initial Entry
Mar-02-2021 14:33:21 (UTC-06:00)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	Subject received Vax 1 so NOT APPLICABLE

090177e19891a03b\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: 11471327
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 10-Nov-2021 20:44

Central Time (US & Canada)				is not an acceptable response for INJECTION SITE BODY SIDE in this CRF. Please update INJECTION SITE BODY SIDE in this CRF (based on Vax 1 injection site laterality) as data point is required.
Jan-28-2021 00:20:22 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: RE DN ES S	Initial Entry

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: 11471327

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.a Injection Site Reaction:

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (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
Jan-28-2021 00:20:03 (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
Jan-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction: SWELLING	Initial Entry

090177e19891a03b\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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> 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-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction: PAIN AT INJECTION	Initial Entry

090177e19891a03b\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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

Canada)			ON SITE	
			Were injection site reactions present on the last day the Subject Diary was completed?:	NO

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINF6000	(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-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINF6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e19891a03b\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 14-Jan-2021 02:22

Site No: 1147

Subject No: 11471327

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - 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:

Date	Location	User	Value	Reason
Jan-28-2021 00:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jan/27/2021	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-28-2021 00:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Record Identifier:: Temperature: 98.6 Temperature F Unit: Temperature ORAL C Location:: AVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jan-28-2021 00:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e19891a03b\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:22

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

2.a Temperature:

Date	Location	User	Value	Reason
Jan-28-2021 00:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 98.6	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Jan-28-2021 00:14:40 (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-28-2021 00:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e19891a03b\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: 11471327

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-28-2021 00:15:03 (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-28-2021 00:15:03 (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-28-2021 07:55:42 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-28-2021 03:12:39 (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 review and correct as

090177e19891a03b\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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

				appropriate.
Jan-28-2021 00:15:03 (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.
Jan-28-2021 00:15:03 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/27/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-28-2021 07:55:42 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BR5J0P	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-28-2021 07:55:42 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BR5J0P	Initial Entry

090177e19891a03b\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1147

Subject No: 11471327

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
Feb-01-2021 00:03:59 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-29-2021 11:27:30 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	subject discontinued
Jan-29-2021 02:20:06 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00.InFormAdapt er.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7042935;Temp Delay is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Jan-28-2021 00:17:40 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
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090177e19891a03b\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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

Jan-28-2021 00:17:40 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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3. Formulation:

Date	Location	User	Value	Reason
Jan-28-2021 00:17:40 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Feb-01-2021 05:06:34 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00.InFor mAdapte r.Discrep ancy	DMW QUERY (b) (4)	Query 1: Closed	Confirmed As-Is
Jan-29-2021 11:27:54 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	Subject discontinued
Jan-29-2021 02:22:01 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00.InFor mAdapte	DMW QUERY (b) (4)	Query 1: Opened	DMW7042957;Dose Date is not expected to be Unknown or Not Applicable.

090177e19891a03b\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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)	r.Discrepancy			Please review and update appropriately or clarify
Jan-28-2021 00:17:40 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-28-2021 00:17:40 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jan-28-2021 00:17:40 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jan-28-2021 00:17:40 (UTC-06:00)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e19891a03b\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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

Central Time (US & Canada)

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-28-2021 00:17:40 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-28-2021 00:17:40 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-28-2021 00:17:40 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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

090177e19891a03b\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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jan-28-2021 00:17:40 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e19891a03b\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: 11471327 **Subject Initials:** ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-26-2021 17:21:07 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	Data Entry: Feb/25/2021	Initial Entry

090177e19891a03b\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: 11471327 **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
Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Not Applicable	Initial Entry
Mar-01-2021 12:20:36 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry:	Changed Information
Feb-26-2021 17:23:22 (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
Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Symptom:: FE VE R	Initial Entry

090177e19891a03b\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: 11471327 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?:	Not Applicable
Mar-01-2021 12:20:44 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Symptom:: Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	FE V E R Information
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	FE V E R N O Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
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090177e19891a03b\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: 11471327 **Subject Initials:** ---

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

Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry
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2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Not Applicable	Initial Entry
Mar-01-2021 12:20:44 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry:	Changed Information
Feb-26-2021 17:23:22 (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
Mar-01-2021 12:22:25 (UTC-06:00)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Symptom:: FAT	Initial Entry

090177e19891a03b\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: 11471327 **Subject Initials:** ---

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

Central Time (US & Canada)			IG UE Were fever or systemic symptoms present on the last day of the Subject Diary was completed?:	
Mar-01-2021 12:20:51 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Symptom:: FA TI G UE Were fever or systemic symptoms present on the last day of the Subject Diary was completed?:	Changed Information
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI G UE Were fever or systemic symptoms present on the last day of the Subject Diary was completed?:	Initial Entry

090177e19891a03b\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: 11471327 Subject Initials: ---

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

2.b Symptom:

Date	Location	User	Value	Reason
Feb-26-2021 17:23:22 (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
Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Not Applicable	Initial Entry
Mar-01-2021 12:20:51 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry:	Changed Information
Feb-26-2021 17:23:22 (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
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090177e19891a03b\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: 11471327 Subject Initials: ---

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

Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: Not Applicable	Initial Entry
Mar-01-2021 12:21:00 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Changed Information
Feb-26-2021 17:23:22 (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

090177e19891a03b\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: 11471327 Subject Initials: ---

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

2.c Symptom:

Date	Location	User	Value	Reason
Feb-26-2021 17:23:22 (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
Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Not Applicable	Initial Entry
Mar-01-2021 12:21:00 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry:	Changed Information
Feb-26-2021 17:23:22 (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
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090177e19891a03b\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: 11471327 Subject Initials: ---

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

Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Symptom:: CHI LL S Were fever or systemic symptoms present on the last day the Subject Diary was completed?: Not Applicable	Initial Entry
Mar-01-2021 12:21:08 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Symptom:: C HI LL S Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Changed Information
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: C HI LL S Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e19891a03b\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: 11471327 Subject Initials: ---

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

2.d Symptom:

Date	Location	User	Value	Reason
Feb-26-2021 17:23:22 (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
Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Not Applicable	Initial Entry
Mar-01-2021 12:21:08 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry:	Changed Information
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
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090177e19891a03b\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: 11471327 Subject Initials: ---

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

Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Symptom:: VO MIT ING Were fever or syste mic symptoms pres ent on the last day the Subject Diary was completed?:	Initial Entry
Mar-01-2021 12:21:15 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Symptom:: VO MI TIN G Were fever or syste mic symptoms pres ent on the last day t he Subject Diary w as completed?:	Changed Information
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: VO MI TIN G Were fever or syste mic symptoms pres ent on the last day t he Subject Diary w as completed?:	Initial Entry

090177e19891a03b\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: 11471327 Subject Initials: ---

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

2.e Symptom:

Date	Location	User	Value	Reason
Feb-26-2021 17:23:22 (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
Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Not Applicable	Initial Entry
Mar-01-2021 12:21:15 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry:	Changed Information
Feb-26-2021 17:23:22 (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
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090177e19891a03b\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: 11471327 Subject Initials: ---

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

Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Symptom:: DI AR RH EA Were fever or systemic symptoms present on the last day the Subject Diary was completed?: Not Applicable	Initial Entry
Mar-01-2021 12:21:23 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Symptom:: DI AR RH EA Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Changed Information
Feb-26-2021 17:23:22 (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

090177e19891a03b\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: 11471327 Subject Initials: ---

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

2.f Symptom:

Date	Location	User	Value	Reason
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Not Applicable	Initial Entry
Mar-01-2021 12:21:23 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry:	Changed Information
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
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090177e19891a03b\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: 11471327 Subject Initials: ---

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

<p>Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)</p>	<p>ACV0PF EINFP60 00</p>	<p>James McMullen (b) (4)</p>	<p>Data Entry: Symptom:: NEW O R WOR SENE MUSC LE PAI N Were fever or s ystemic sympto ms present on t he last day the Subject Diary was completed? :</p>	<p>Initial Entry</p>
<p>Mar-01-2021 12:21:31 (UTC-06:00) Central Time (US & Canada)</p>	<p>ACV0PF EINFP60 00</p>	<p>James McMullen (b) (4)</p>	<p>Data Entry: Symptom:: NEW O R WOR SENE MUSC LE PAI N Were fever or s ystemic sympto ms present on t he last day the Subject Diary was completed? :</p>	<p>Changed Information</p>
<p>Feb-26-2021 17:23:22 (UTC-06:00)</p>	<p>ACV0PF EINFP60 00</p>	<p>(b) (4), (b) (6)</p>	<p>Data Entry: Symptom:: NEW O R WOR</p>	<p>Initial Entry</p>

090177e19891a03b\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: 11471327 **Subject Initials:** ---

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

Central Time (US & Canada)			SENE MUSC LE PAI N Were fever or s ystemic sympto ms present on t he last day the Subject Diary was completed? :	
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090177e19891a03b\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: 11471327 Subject Initials: ---

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

2.g Symptom:

Date	Location	User	Value	Reason
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERD M USCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Not Applicable	Initial Entry
Mar-01-2021 12:21:31 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry:	Changed Information
Feb-26-2021 17:23:22 (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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090177e19891a03b\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: 11471327 **Subject Initials:** ---

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

Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Symptom:: NEW OR W ORSE NED J OINT P AIN Were fever or sy Not Ap stemic symptom plicable s present on the last day the Sub ject Diary was c ompleted?:	Initial Entry
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090177e19891a03b\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: 11471327 Subject Initials: ---

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

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2.h

Date	Location	User	Value	Reason
Mar-01-2021 12:21:39 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Symptom:: NEW OR W ORSE NED J OINT P AIN Were fever or systemic symptoms present on the last day the Subject Diary was completed? :	Changed Information
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR W ORSE NED J OINT P AIN	Initial Entry

090177e19891a03b\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: 11471327 **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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090177e19891a03b\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: 11471327 Subject Initials: ---

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

2.h Symptom:

Date	Location	User	Value	Reason
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR WORSENE J OINT 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
Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Not Applicable	Initial Entry
Mar-01-2021 12:21:39 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry:	Changed Information
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

090177e19891a03b\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: 11471327 Subject Initials: ---

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

Date	Location	User	Value	Reason
Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Mar-01-2021 12:20:36 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry:	Changed Information
Feb-26-2021 17:23:22 (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
Mar-02-2021 05:04:42 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-01-2021 12:22:50 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Query 1: Answered	Subject discontinued from study treatment
Mar-01-2021 12:22:25	ACV0PF EINFP60	James McMullen	Data Entry: Not Applicable	Initial Entry

090177e19891a03b\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: 11471327 Subject Initials: ---

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

(UTC-06:00) Central Time (US & Canada)	00	(b) (4)		
Mar-01-2021 02:26:57 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	DM: Please complete this item. Thank you.

5.a

Date	Location	User	Value	Reason
Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Injection Site Reaction: RE DN ESS Were injection site reactions present on the last day the subject Diary was completed?: Not Applicable	Initial Entry
Mar-01-2021 12:21:48 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Injection Site Reaction: RE DN ES S	Changed Information

090177e19891a03b\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: 11471327 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?:	
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: 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
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Mar-01-2021 12:22:25	ACV0PF EINFP60	James McMullen	Data Entry: Not Applicable	Initial Entry

090177e19891a03b\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: 11471327 Subject Initials: ---

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

(UTC-06:00) Central Time (US & Canada)	00	(b) (4)		
Mar-01-2021 12:21:48 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry:	Changed Information
Feb-26-2021 17:23:22 (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
Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Injection Site Reaction: SW ELL ING Were injection site reactions present on the last day the Subject Diary was completed?: Not App licab le	Initial Entry
Mar-01-2021 12:21:56 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Injection Site Reaction: SW EL	Changed Information

090177e19891a03b\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: 11471327 **Subject Initials:** ---

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

Canada)			LIN G Were injection site reactions present on the last day the Subject Diary was completed?:	
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: SW EL LIN G Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e19891a03b\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: 11471327 Subject Initials: ---

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

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Feb-26-2021 17:23:22 (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
Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Not Applicable	Initial Entry
Mar-01-2021 12:21:56 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry:	Changed Information
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

090177e19891a03b\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: 11471327 Subject Initials: ---

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

Date	Location	User	Value	Reason
Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Injection Site Reaction: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?:	Initial Entry
Mar-01-2021 12:22:04 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Injection Site Reaction: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?:	Changed Information
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: PAIN AT INJECTION SITE	Initial Entry

090177e19891a03b\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: 11471327 Subject Initials: ---

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

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SIT E	Initial Entry

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

Date	Location	User	Value	Reason
Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Not Applicable	Initial Entry
Mar-01-2021 12:22:04 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry:	Changed Information
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e19891a03b\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: 11471327 **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-26-2021 07:59:30 (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-26-2021 07:59:30 (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-26-2021 08:00:08 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-26-2021 07:59:30 (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

090177e19891a03b\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: 11471327 Subject Initials: ---

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

				review and correct as appropriate.
Feb-26-2021 07:59:30 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/25/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-26-2021 08:00:08 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BR7X56	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-26-2021 08:00:08 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BR7X56	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-26-2021 08:28:35	ACV0PF EINFP60	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e19891a03b\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: 11471327 **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: BRZXLD	
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5.b Sample ID

Date	Location	User	Value	Reason
Feb-26-2021 08:28:35 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINF60 00	(b) (4), (b) (6)	Data Entry: BRZXLD	Initial Entry

090177e19891a03b\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471327

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
Aug-09-2021 14:13:44 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-09-2021 12:51:48 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	Katherine Downs (b) (4)	Query 1: Answered	Changed data per query
Aug-05-2021 15:18:33 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	Per source documentation, subject received non study vaccine on 07May2021 and 04Jun2021. Please update Concomitant Vaccine Log.
Jul-28-2021 23:33:53 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jul/28/2021	Initial Entry

090177e19891a03b\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471327

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
Jul-28-2021 23:34:10 (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
Jul-28-2021 23:34:10 (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
Jul-29-2021 06:57:26 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jul-28-2021 23:34:10 (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

090177e19891a03b\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

				appropriate.
Jul-28-2021 23:34:10 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jul/28/2021	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Jul-29-2021 06:58:25 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	Katherine Downs (b) (4)	Data Entry:	Initial Entry

5.a

Date	Location	User	Value	Reason
Jul-29-2021 06:57:26 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	Katherine Downs (b) (4)	Data Entry: Sample ID: BS2D9K	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jul-29-2021 06:57:26 (UTC-06:00) Central	ACV0PF EINFP60 00	Katherine Downs (b) (4)	Data Entry: BS2D9K	Initial Entry

090177e19891a03b\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)				
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5.b

Date	Location	User	Value	Reason
Jul-29-2021 06:58:32 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	Katherine Downs (b) (4)	Data Entry: Sample ID: BRND2G	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jul-29-2021 06:58:32 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	Katherine Downs (b) (4)	Data Entry: BRND2G	Initial Entry

090177e19891a03b\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled
Visit on Jan/06/2021

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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-07-2021 10:30:27 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Jan/6/2021	Initial Entry

090177e19891a03b\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Jan/06/2021

Form Version: 22-Apr-2020 21:04

Site No: 1147

Subject No: 11471327

Generated By: (b) (4)

Form: UNPLANNED 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. Assessments

Date	Location	User	Value	Reason
Jan-07-2021 10:31:11 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-07-2021 10:30:35 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Jan-07-2021 10:30:35 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: CONTACT OUTCOME	Initial Entry

090177e19891a03b\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Jan/06/2021

Form Version: 22-Apr-2020 21:04

Site No: 1147

Subject No: 11471327

Generated By: (b) (4)

Form: CONTACT OUTCOME - UNPLANNED - 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. Contact Type:

Date	Location	User	Value	Reason
Jan-07-2021 10:30:46 (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
Jan-07-2021 10:31:11 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-07-2021 10:31:11 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: YES Date of Contact: Jan/6/2021 Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISION	Changed Information
Jan-07-2021 10:30:46 (UTC-06:00)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Opened	Response to "Date of Contact" is

090177e19891a03b\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled
Visit on Jan/06/2021

Form Version: 22-Apr-2020 21:04

Site No: 1147

Subject No: 11471327

Generated By: (b) (4)

Form: CONTACT OUTCOME - UNPLANNED - 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

Central Time (US & Canada)				missing.
Jan-07-2021 10:30:46 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: YES Contact Outcome: VISIT NOT REQUIRE D, INVESTIGATOR D ECISION	Initial Entry

090177e19891a03b\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: 11471327

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
Mar-03-2021 11:18:35 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Jan/8/2021	Changed Information
Jan-28-2021 08:47:59 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Jan/9/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-28-2021 08:47:59 (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
Mar-04-2021 09:18:33 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query

090177e19891a03b\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: 11471327 **Subject Initials:** ---

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

Mar-03-2021 15:56:14 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 2: Closed	Close Auto Query
Mar-03-2021 15:55:54 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 2: Opened	Response to "Status" is ADVERSE EVENT but "Specify Status" is Provided.
Mar-03-2021 15:55:54 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Answered	Changed Information
Mar-03-2021 15:55:54 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: ADVERSE EVENT	Changed Information
Mar-03-2021 15:25:49 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	Hayley Wyper (b) (4)	Query 1: Reissued:Opened	CLINQUERY: Comment and AE log reports 'fever' as event leading to treatment discontinuation. Please match status selection to this event

090177e19891a03b\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: 11471327 **Subject Initials:** ---

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

				(status ADVERSE EVENT)
Mar-03-2021 11:19:27 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Query 1: Answered	Reason updated. Please unfreeze DOV for visit 2
Mar-03-2021 00:59:12 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: EOT date and status should match to reason why Vax 2 was not given. Please review and update. Current entry is inadequate for reporting end of treatment
Mar-02-2021 07:55:21 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	Hayley Wyper (b) (4)	Query 1: Candidate	CLINQUERY: EOT date and status should match to reason why Vax 2 was not given. Please review and update. Current entry is inadequate for reporting end of treatment

090177e19891a03b\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: 11471327 **Subject Initials:** ---

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

Jan-28-2021 08:47:59 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: OTHER	Initial Entry
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4. Specify Status:

Date	Location	User	Value	Reason
Mar-03-2021 15:56:14 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry:	Changed Information
Mar-03-2021 15:26:18 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Mar-03-2021 12:57:22 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Query 1: Answered	AE leading to treatment discontinuation captured in AE log
Mar-03-2021 12:33:55 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: Fever is reported leading to treatment discontinuation. However, an AE entry has not been reported.

090177e19891a03b\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: 11471327 **Subject Initials:** ---

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

				Please review - any event leading to discontinuation should be reported even if captured in ed diary
Mar-03-2021 11:19:04 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Treatment discontinued due to fever of 104.7	Changed Information
Mar-03-2021 11:16:23 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Treatment discontinued due to COVID Illness	Changed Information
Jan-28-2021 08:47:59 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Treatment discontinued	Initial Entry

090177e19891a03b\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: 11471327 **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-14-2021 09:57:49 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	Fredrick Okwori (b) (4)	Data Entry: May/6/2021	Initial Entry

Header Text: c4591001

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

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

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

Subject No: 11471327 **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-14-2021 09:58:40 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
May-14-2021 09:58:16 (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-14-2021 09:58:16 (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 and NOT confirmed to have received on ly placebo at Vaccination 1/2	Initial Entry

090177e19891a03b\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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Mar-03-2021 12:56:50 (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: 11471327

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
Mar-03-2021 12:56:50 (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
Mar-03-2021 12:56:50 (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
Mar-03-2021 12:56:50 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: Fever (104.7)	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-03-2021	ACV0PF	James	Data Entry:	Initial Entry

090177e19891a03b\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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

12:56:50 (UTC-06:00) Central Time (US & Canada)	EINFP60 00	McMullen (b) (4)	Jan/6/2021 19:30	
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-03-2021 12:56:50 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: NO End Date Time: Jan/8/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-11-2021 13:35:13 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-11-2021 07:41:40 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Query 1: Answered	Per Table 3, a fever >104.0F is a grade 4.
Mar-11-2021 07:21:47 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	GPD Clin: Fever alone may not typically be considered life

090177e19891a03b\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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

				threatening AE. Please review and confirm if toxicity grade assignment appropriate and provide rationale in query response.
Mar-03-2021 12:56:50 (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).

Date	Location	User	Value	Reason
Mar-03-2021 12:56:50 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: NO	Initial Entry

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

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

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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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Mar-03-2021 12:56:50 (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
Mar-03-2021 12:56:50 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-03-2021 12:56:50 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: DRUG WITHDRAWN	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-03-2021 12:56:50 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: YES	Initial Entry

090177e19891a03b\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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

Canada)

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-03-2021 12:56:50 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Mar-03-2021 12:56:50 (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
Mar-03-2021 12:56:50 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	James McMullen (b) (4)	Data Entry: NO	Initial Entry

090177e19891a03b\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON
STUDY VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Aug-09-2021 12:50:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Downs (b) (4)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON
STUDY VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Aug-09-2021 12:51:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Downs (b) (4)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Aug-09-2021 12:50:41 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Aug-09-2021 12:50:41 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Aug-09-2021 12:50:41 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
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090177e19891a03b\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

Aug-09-2021 12:50:41 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	Katherine Downs (b) (4)	Data Entry: BNT162b2 Dose #1 IM/onc e	Initial Entry
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5. Date:

Date	Location	User	Value	Reason
Aug-09-2021 12:50:41 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	Katherine Downs (b) (4)	Data Entry: May/7/2021	Initial Entry

090177e19891a03b\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. What is the medication identifier?

Date	Location	User	Value	Reason
Aug-09-2021 12:51:07 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 2	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Aug-09-2021 12:51:07 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Aug-09-2021 12:51:07 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

090177e19891a03b\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Aug-09-2021 12:51:07 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	Katherine Downs (b) (4)	Data Entry: BNT162b2 Dose #2 IM/onc e	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Aug-09-2021 12:51:07 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	Katherine Downs (b) (4)	Data Entry: Jun/4/2021	Initial Entry

090177e19891a03b\Final\Final On: 11-Nov-2021 01:20 (GMT)

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: 11471327

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-14-2021 09:58:40 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	Fredrick Okwori (b) (4)	Data Entry: May/13/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
May-14-2021 09:58:40 (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

090177e19891a03b\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: 11471327

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
Mar-03-2021 15:55:54 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: DISCONTINUED	Changed Information
Jan-28-2021 08:47:59 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: DISCONTINUED	Initial Entry
Jan-06-2021 16:44:58 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Jan-06-2021 16:41:49 (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
Mar-03-2021 15:55:54 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Jan/8/2021	Changed Information
Mar-03-2021 11:18:35 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Jan/8/2021	Changed Information

090177e19891a03b\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: 11471327

Subject Initials: ---

Generated By: (b) (4)

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

Jan-28-2021 08:47:59 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Jan/9/2021	Initial Entry
Jan-06-2021 16:44:58 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Jan/5/2021	Initial Entry
Jan-06-2021 16:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Jan/5/2021	Initial Entry

090177e19891a03b\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: 11471327

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 16:00:19 (UTC-06:00) Central Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry