

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 10-Oct-2020 16:01

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** COHORT\_SELECTION

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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

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<b>Header Text:</b> c4591001	
<b>Visit:</b> COHORT_SELECTION	<b>Form:</b> MAIN INFORMED CONSENT
<b>Form Version:</b> 22-Apr-2020 21:02	<b>Form Status:</b> Data Complete, Frozen, Verified
<b>Site No:</b> 1009	<b>Site Name:</b> (1009) J. Lewis Research, Inc. Foothill Family Clinic South
<b>Subject No:</b> 10091231	<b>Subject Initials:</b> ---
<b>Generated By:</b> (b) (4)	<b>Generated Time (GMT):</b> 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Oct/20/2020
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 15-Sep-2020 21:54

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** DEMOGRAPHY

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[10091231]
2.	Birth Date:	(b) (6) 2005
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	ASIAN
6.	Racial Designation:	

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Oct/20/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 10-Oct-2020 16:00

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**Form Comments**

**Inclusion Criteria Not Met**

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

**Exclusion Criteria Met**

2.	Description of Exclusion Criterion Met	Not Applicable
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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 15-Sep-2020 21:52

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** DISPOSITION - SCREENING

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation/Death	Oct/20/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**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 _____ _____

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 15-Sep-2020 21:57

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** HIV STATUS

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**HIV Status**

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



**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 10-Oct-2020 16:04**Site No:** 1009**Subject No:** 10091231**Generated By:** (b) (4)**Form:** VITAL SIGNS - BASELINE**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12**eCRF Audit Trail History****Vital Signs**

1.	Date:	Oct/20/2020
2.	Weight:	[127.2]
3.	Unit:	LB
4.	Height:	[66.0]
5.	Unit:	in
6.	Body Mass Index:	[20.5]

**Vital Signs Details**

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

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** RANDOMIZATION

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Oct/20/2020
2.	Randomization Number:	[20210]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**eCRF Audit Trail History**

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/20/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BR9FMZ]
5.b	Sample ID	[BR9FN0]
5.c	Sample ID	[BKYCYB]

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**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1009**Subject No:** 10091231**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12**eCRF Audit Trail History****Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/20/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP9GCS]
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**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:04**Site No:** 1009**Subject No:** 10091231**Generated By:** (b) (4)**Form:** VACCINATION**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12**eCRF Audit Trail History****Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/20/2020 18:16
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

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** REACTOGENICITY DIARY

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Nov/9/2020
2.	Erroneous Visit	

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Oct-2020 16:03

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[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
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

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Oct-2020 16:03

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Oct-2020 16:01

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - TEMP

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Nov/9/2020
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**Vital Signs Details**

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

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1009**Subject No:** 10091231**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12**eCRF Audit Trail History****Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Nov/9/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BGGZY5]
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**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 22-Apr-2020 21:04**Site No:** 1009**Subject No:** 10091231**Generated By:** (b) (4)**Form:** VACCINATION**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12**eCRF Audit Trail History****Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Nov/9/2020 15:56
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

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Dec/10/2020
2.	Erroneous Visit	

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**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES**Form Version:** 10-Oct-2020 16:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject No:** 10091231**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12[eCRF Audit Trail History](#)**Vaccination Symptoms Diary - Symptom Resolved Dates**

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	YES Ongoing? NO Stop Date: Nov/13/2020
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	YES Ongoing? NO Stop Date: Nov/12/2020
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 10-Oct-2020 16:03

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	YES Ongoing? NO Stop Date: Nov/14/2020
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	YES Ongoing? NO Stop Date: Nov/13/2020
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	YES Ongoing? NO Stop Date: Nov/12/2020

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**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 10-Oct-2020 16:03

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

5.c

Injection Site Reaction:

PAIN AT INJECTION SITE

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

YES

Ongoing?

NO

Stop Date:

Nov/14/2020



**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**eCRF Audit Trail History**

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/10/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BR5BG8]
5.b	Sample ID	[BR5BG7]
5.c	Sample ID	[BSJ3LD]

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**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**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	[ ]
----	-----------	-----

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET  
on Nov/11/2020

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091231

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Nov/11/2020
2.	Erroneous Visit	ERRONEOUS VISIT

**COVID-19 Illness Visit**

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

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19  
on Nov/11/2020

**Form Version:** 20-Feb-2021 02:17

**Form Status:** Not Started

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091231

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 04:12

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

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** MICROBIOLOGY SPECIMEN

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091231

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 04:12

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN  
on Nov/11/2020

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Not Started

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091231

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 04:12

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**Microbiology Specimen**

1.	Actual Date of Collection:	//
2.	Specimen Type:	
3.	Specimen Collection Location:	
4.	Assay Code and Description:	
5.	Device Type:	
6.	Trade Name:	
7.	Test Result:	
8.	Comments/Findings/Details:	[ ]
9.	Trade Name Other, Specify:	[ ]

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Nov/11/2020

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091231

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 04:12

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB  
on Nov/11/2020

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091231

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 04:12

**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	[ ]
----	-----------	-----

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION  
on Nov/11/2020

**Form Version:** 20-Feb-2021 02:19

**Form Status:** Not Started

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091231

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 04:12

**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?	
----	--	--

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** RESPIRATORY TREATMENT

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091231

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 04:12

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.	[ ]			[ ]		<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT  
on Nov/11/2020

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Not Started

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091231

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 04:12

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**Respiratory Treatment**

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



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS  
on Nov/11/2020

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Not Started

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091231

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 04:12

**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\_ILL 1

**Form:** ILLNESS DETAILS - SEVERE

**Form Version:** 17-Jul-2020 21:55

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091231

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 04:12

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.					<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE  
on Nov/11/2020

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Not Started

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091231

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 04:12

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**Illness Details**

1.	Category of Clinical Event:	
2.	Subcategory of Clinical Event:	
3.	Was a diagnosis obtained?	
4.	Toxicity Grade:	

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form Version:** 10-Oct-2020 15:58

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Nov/11/2020

**Form Version:** 10-Oct-2020 15:58

**Form Status:** Not Started

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091231

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 04:12

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**Lab Chemistry Details**

1.	Lab Panel:	
2.	Laboratory Name and Address	[ ]
3.	Collection Date:	//
4.	Specimen Type:	

**Lab Result**

5.	Sponsor ID:	[ ]
	Test:	
	Result:	[ ]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form Version:** 10-Oct-2020 16:02

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

#	Category for Lab Test	Vendor Name (DE RIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
on Nov/11/2020

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Not Started

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091231

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 04:12

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**Laboratory Data Hematology**

1.	Lab Panel:	
2.	Laboratory Name and Address	[ ]
3.	Collection Date:	//
4.	Specimen Type:	

**Lab Result**

5.	Sponsor ID:	[ ]
	Test:	
	Result:	[ ]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form Version:** 10-Oct-2020 15:59

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - COVID

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

#	Date:	Vital Signs Details			Form Instance
1.		Record Identifier:	Systolic:	Diastolic:	<a href="#">Repeating Pages</a>



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID  
on Nov/11/2020

**Form Version:** 10-Oct-2020 15:59

**Form Status:** Not Started

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091231

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 04:12

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**Vital Signs**

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

**Vital Signs Details**

2.	Record Identifier:	
	Systolic:	[ ]
	Diastolic:	[ ]
	Respiratory Rate in respirations/minute:	[ ]
	Heart Rate in beats/minute:	[ ]

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form Version:** 10-Oct-2020 16:04

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - PULSE OX ROOM AIR

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

#	Date:	Vital Signs Details		Form Instance
1.		Record Identifier:	Oxygen Saturation	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** VITAL SIGNS - PULSE OX ROOM AIR  
on Nov/11/2020

**Form Version:** 10-Oct-2020 16:04

**Form Status:** Not Started

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091231

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 04:12

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**Vital Signs**

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

**Vital Signs Details**

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[ ]

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** OXYGENATION PARAMETERS

**Form Version:** 06-Jul-2020 21:52

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091231

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 04:12

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.				<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS  
on Nov/11/2020

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Not Started

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091231

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 04:12

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**Oxygenation Parameters**

1.	Date Time of Assessment:	//
2.	Arterial Blood Gases PaO2 (mmHg):	[ ]
3.	FiO2 (Fraction of Inhaled Oxygen):	[ ]

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form Version:** 06-Jul-2020 21:55

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS  
on Nov/11/2020

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Not Started

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091231

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 04:12

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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.	Start Date:	//
6.	Ongoing?	

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** IMAGING

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091231

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 04:12

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					<a href="#">Repeating Pages</a>



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** IMAGING  
on Nov/11/2020

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Not Started

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091231

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 04:12

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**Imaging**

1.	Date of Assessment:	//
2.	Location of Assessment:	
3.	Type of Imaging Exam:	
4.	Assessment:	

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA - New  
Unscheduled Visit

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - ILLNESS CONVALESCENT

**Form Status:** Not Started

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Visit:** POT\_COVID\_CONVA - New  
Unscheduled Visit

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**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	[ ]
----	-----------	-----

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New  
Unscheduled Visit

**Form:** DATE OF VISIT - REPEAT SWAB

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091231

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 04:12

**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:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091231

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 04:12

**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	[ ]
----	-----------	-----

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091231

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 04:12

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	left swollen axillary lymph node	Nov/10/2020 UNK:UNK	NO End Date Time:  Nov/10/2020 UNK:UNK	<a href="#">Repeating Pages</a>

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1009**Subject No:** 10091231**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Frozen**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12

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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)	[left swollen axillary lymph node]
4.	Start Date Time:	Nov/10/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/10/2020 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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



**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091231

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 04:12

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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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	[ ]

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - NON STUDY  
VACCINATIONS

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091231

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 04:12

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** CONCOMITANT MEDICATIONS - NON STUDY  
VACCINATIONS

**Form Status:** Not Started

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[Back to Form](#)

**Concomitant Medications**

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

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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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?	

**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091231

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 04:12

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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**Radiation Treatment**

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



**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091231

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 04:12

#	Transfusion Type	Date of Transfusion	Form Instance
1.			<a href="#">Repeating Pages</a>

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Nov/11/2020

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091231

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Nov/11/2020
2.	Erroneous Visit	

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Nov/11/2020

**Form:** UNPLANNED VISIT

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091231

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Unplanned Assessments**

1.	Assessments	CONTACT OUTCOME
----	-------------	-----------------

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Nov/11/2020

**Form:** CONTACT OUTCOME - UNPLANNED

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091231

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Contact Outcome**

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Nov/11/2020  Contact Outcome: VISIT ARRANGED
3.	Comments:	[ ]

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Nov/11/2020

**Form:** VITAL SIGNS - TEMP

**Form Version:** 10-Oct-2020 16:01

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091231

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Nov/11/2020
----	-------	-------------

**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[98.4]
	Unit:	F
	Temperature Location:	ORAL CAVITY

**Header Text:** c4591001**Visit:** Unplanned 1 - Unscheduled Visit on Nov/11/2020**Form Version:** 10-Oct-2020 15:57**Site No:** 1009**Subject No:** 10091231**Generated By:** (b) (4)**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12[eCRF Audit Trail History](#)**Unplanned Assessment Of Local Reaction**

1.	Date of Assessment:	Nov/11/2020
2.	Injection Site Location	DELTOID MUSCLE
3.	Injection Site Body Side:	LEFT

**Reaction**

4.a	Reaction:	REDNESS
	Reaction Present:	YES Maximum Diameter (cm): [8.0]  Minimum Diameter (cm): [6.0]  Meets Grade 4 Reaction Criteria: NO
4.b	Reaction:	SWELLING
	Reaction Present:	YES Maximum Diameter (cm): [6.0]  Minimum Diameter (cm): [4.0]  Meets Grade 4 Reaction Criteria: NO

**Symptom**

5.a	Symptom:	PAIN AT INJECTION SITE
	Symptom Present:	YES Symptom Grade: 1  Event related to Study Treatment? YES

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Nov/11/2020

**Form Version:** 10-Oct-2020 15:57

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION -  
SYSTEMIC EVENT

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

5.b	Symptom:	FATIGUE/TIREDNESS
	Symptom Present:	NO
5.c	Symptom:	HEADACHE
	Symptom Present:	NO
5.d	Symptom:	VOMITING
	Symptom Present:	NO
5.e	Symptom:	DIARRHEA
	Symptom Present:	NO
5.f	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Symptom Present:	YES Symptom Grade: 1  Event related to Study Treatment? YES
5.g	Symptom:	NEW OR WORSENERED JOINT PAIN
	Symptom Present:	YES Symptom Grade: 1  Event related to Study Treatment? YES
5.h	Symptom:	CHILLS
	Symptom Present:	YES Symptom Grade: 1  Event related to Study Treatment? YES

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)



**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form Version:** 20-Feb-2021 02:16

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - TEMP

**Form Status:** Not Started

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**Vital Signs**

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

**Vital Signs Details**

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

**Header Text:** c4591001**Visit:** Unplanned Vaccination - Unscheduled**Form:** VACCINATION**Form Version:** 10-Dec-2020 02:26**Form Status:** Not Started**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject No:** 10091231**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12**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?	

**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:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject No:** 10091231**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form Version:** 10-Oct-2020 16:01

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** CONTACT OUTCOME - MONTH 6

**Form Status:** Not Started

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form Version:** 14-Jan-2021 02:29

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

**Form Status:** Not Started

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**Informed Consent - Asymptomatic Surveillance**

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

**Header Text:** c4591001**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1009**Subject No:** 10091231**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Status:** Not Started**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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



**Header Text:** c4591001**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1009**Subject No:** 10091231**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Status:** Not Started**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form Version:** 10-Dec-2020 02:29

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** DISPOSITION - TREATMENT

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation/Death :	Dec/10/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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**Date of Visit**

1.	Date of Visit	Feb/19/2021	<a href="#">Comments</a>
2.	Erroneous Visit	ERRONEOUS VISIT	

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form Version:** 10-Dec-2020 02:25

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** FURTHER VACCINATION CONFIRMATION

**Form Status:** Not Started

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**Further Vaccination Confirmation**

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	
----	---	--

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

**Form Version:** 15-Sep-2020 21:53

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**Disposition - Follow-Up**

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

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001**Visit:** Disposition - Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1009**Subject No:** 10091231**Generated By:** (b) (4)**Form:** TREATMENT UNBLINDED**Form Status:** Not Started**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12**Treatment Unblinded**

1.	Date Treatment Unblinded :	//
2.	Primary Reason for Unblinding:	

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Not Started

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**Withdrawal Of Consent**

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

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** DEATH DETAILS CODED

**Form Status:** Not Started

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**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 Version:** 22-Apr-2020 21:03

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Dec/10/2020

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** CASEBOOK SIGNATURE FORM

**Form Status:** Data Complete, Signed, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** CASEBOOK SIGNATURE FORM

**Form Status:** Data Complete, Signed, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[Audit Trail](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Shane Christensen	Approved	Mar-09-2021 21:40:03 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed

**Affidavit:**

By my dated signature below, I, ShaneChristensen, 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.

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 10-Oct-2020 16:00

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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Item	Date	User	Comment
Form	Oct-22-2020 20:59:02 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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Item	Date	User	Comment
Form	Oct-22-2020 20:59:35 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001**Visit:** Potential ReVax Initial Contact**Form Version:** 22-Apr-2020 21:02**Site No:** 1009**Subject No:** 10091231**Generated By:** (b) (4)**Form:** DATE OF VISIT - Comments**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)

Item	Date	User	Comment
1	Feb-22-2021 16:40:00 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not completed. Entry error.

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** CASEBOOK SIGNATURE FORM - Signature History

**Form Status:** Data Complete, Signed, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Shane Christensen	Approved	Mar-09-2021 21:40:03 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed

**Affidavit:**

By my dated signature below, I, ShaneChristensen, 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.

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 10-Oct-2020 16:01

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** COHORT SELECTION - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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**1. Select appropriate response - Protocol version**

Date	Location	User	Value	Reason
Oct-22-2020 20:57:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 06 OCT 2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-22-2020 20:57:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry



**Header Text:** c4591001**Visit:** COHORT\_SELECTION**Form Version:** 22-Apr-2020 21:02**Site No:** 1009**Subject No:** 10091231**Generated By:** (b) (4)**Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**I. Consent Was:**

Date	Location	User	Value	Reason
Oct-22-2020 21:03:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-22-2020 20:58:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date Informed Consent Obtained is not the same as the Date of Visit. Please correct as necessary.
Oct-22-2020 20:58:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Oct/20/2020	Transcription Error
Oct-22-2020 20:57:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Oct/22/2020	Initial Entry

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 15-Sep-2020 21:54

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** DEMOGRAPHY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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**1. Subject ID**

Date	Location	User	Value	Reason
Oct-22-2020 20:57:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10091231	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Oct-22-2020 20:56:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6) 2005	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Oct-22-2020 20:58:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> MALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Oct-22-2020 20:58:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-22-2020 20:58:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASIAN	Initial Entry

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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***1. Date of Visit***

Date	Location	User	Value	Reason
Oct-22-2020 21:03:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b><u>Data Entry:</u></b> Oct/20/2020	Transcription Error
Oct-22-2020 20:58:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b><u>Data Entry:</u></b> Oct/22/2020	Initial Entry

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 15-Sep-2020 21:52

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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**1. Date of Completion/Discontinuation/Death**

Date	Location	User	Value	Reason
Oct-22-2020 20:59:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/20/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-22-2020 20:59:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-22-2020 20:59:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 15-Sep-2020 21:57

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** HIV STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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

Date	Location	User	Value	Reason
Oct-22-2020 20:59:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> The subject is NOT known to be HIV POSITIVE	Initial Entry

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 10-Oct-2020 16:04

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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**1. Date:**

Date	Location	User	Value	Reason
Oct-22-2020 21:00:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/20/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Oct-22-2020 21:00:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 127.2	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Oct-22-2020 21:00:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LB	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Oct-22-2020 21:00:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 66.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Oct-22-2020 21:00:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> in	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Oct-22-2020 21:00:14 (UTC-07:00) Mountain	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 20.5	Initial Entry

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 10-Oct-2020 16:04

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

Time (US & Canada)

**7.a**

Date	Location	User	Value	Reason
Oct-22-2020 21:00:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> 1 : <b>Temperature:</b> 98.3 <b>Temperature Unit</b> F : <b>Temperature Location:</b> ORAL CAVITY	Initial Entry

**7.a Record Identifier:**

Date	Location	User	Value	Reason
Oct-22-2020 21:00:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**7.a Temperature:**

Date	Location	User	Value	Reason
Oct-22-2020 21:00:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 98.3	Initial Entry

**7.a Unit:**

Date	Location	User	Value	Reason
Oct-22-2020 21:00:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

**7.a Temperature Location:**

Date	Location	User	Value	Reason
Oct-22-2020 21:00:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** RANDOMIZATION - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Oct-22-2020 21:03:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-22-2020 21:00:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Randomization Date 20/Oct/2020 is before or more than 1 day after corresponding Date of Visit 22/Oct/2020. Please review and update as appropriate.
Oct-22-2020 21:00:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/20/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Oct-22-2020 21:03:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 20210	Transcription Error
Oct-22-2020 21:00:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 10091231	Initial Entry

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)



**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1009**Subject No:** 10091231**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-22-2020 21:00:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-22-2020 21:00:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-22-2020 21:02:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-22-2020 21:00:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-22-2020 21:00:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/20/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-22-2020 21:02:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BR9FMZ	Initial Entry

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-22-2020 21:02:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u><b>Data Entry:</b></u> BR9FMZ	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Oct-22-2020 21:02:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u><b>Data Entry:</b></u> <b>Sample ID:</b> BR9FN0	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Oct-22-2020 21:02:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u><b>Data Entry:</b></u> BR9FN0	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Nov-20-2020 07:43:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u><b>Data Entry:</b></u> <b>Sample ID:</b> BKYCYB	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Nov-20-2020 07:43:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u><b>Data Entry:</b></u> BKYCYB	Initial Entry

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1009**Subject No:** 10091231**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-22-2020 21:01:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-22-2020 21:01:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-22-2020 21:02:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-22-2020 21:02:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/20/2020	Transcription Error
Oct-22-2020 21:01:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-22-2020 21:01:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/22/2020	Initial Entry

**5.a**

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

Date	Location	User	Value	Reason
Oct-22-2020 21:02:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP9GCS	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-22-2020 21:02:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP9GCS	Initial Entry

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Oct-22-2020 21:04:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Oct-22-2020 21:04:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Oct-22-2020 21:04:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Oct-22-2020 21:04:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/20/2020 18:16	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Oct-22-2020 21:04:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Oct-22-2020 21:04:37 (UTC-07:00) Mountain	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

Time (US & Canada)

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

**7. Route:**

Date	Location	User	Value	Reason
Oct-22-2020 21:04:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Oct-22-2020 21:04:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Oct-22-2020 21:04:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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***1. Select appropriate response - Reactogenicity diary collection***

Date	Location	User	Value	Reason
Oct-22-2020 21:08:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b><u>Data Entry:</u></b> YES - REACTOGENICITY E-DI ARY COLLECTED FOR THIS S UBJECT	Initial Entry

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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*1. Date of Visit*

Date	Location	User	Value	Reason
Nov-09-2020 16:14:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/9/2020	Initial Entry



**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 10-Oct-2020 16:03**Site No:** 1009**Subject No:** 10091231**Generated By:** (b) (4)**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12[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
Nov-09-2020 16:15:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Nov-09-2020 16:15:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FE VE R  <b>Were fever or systemic sym N ptoms present on the last d O ay the Subject Diary was co mpleted?:</b>	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
Nov-09-2020 16:15:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Nov-09-2020 16:15:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
Nov-09-2020 16:15:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FA TIG	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Oct-2020 16:03

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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

Date	Location	User	Value	Reason
Nov-09-2020 16:15:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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
Nov-09-2020 16:15:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**2.c**

Date	Location	User	Value	Reason
Nov-09-2020 16:15:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject No:** 10091231**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12**2.c Symptom:**

Date	Location	User	Value	Reason
Nov-09-2020 16:15:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Nov-09-2020 16:15:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.d**

Date	Location	User	Value	Reason
Nov-09-2020 16:15:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> CH IL LS  <b>Were fever or systemic sym NO</b> <b>ptoms present on the last d</b> <b>ay the Subject Diary was co</b> <b>mpleted?:</b>	Initial Entry

**2.d Symptom:**

Date	Location	User	Value	Reason
Nov-09-2020 16:15:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Nov-09-2020 16:15:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.e**

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Oct-2020 16:03

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

Date	Location	User	Value	Reason
Nov-09-2020 16:15:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> VO MIT ING  <b>Were fever or systemic sy NO mptoms present on the las t day the Subject Diary wa s completed?:</b>	Initial Entry

**2.e Symptom:**

Date	Location	User	Value	Reason
Nov-09-2020 16:15:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Nov-09-2020 16:15:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.f**

Date	Location	User	Value	Reason
Nov-09-2020 16:15:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DIA RR HE A  <b>Were fever or systemic sy NO mptoms present on the las t day the Subject Diary wa s completed?:</b>	Initial Entry

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 10-Oct-2020 16:03

Site No: 1009

Subject No: 10091231

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

**2.f Symptom:**

Date	Location	User	Value	Reason
Nov-09-2020 16:15:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Nov-09-2020 16:15:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.g**

Date	Location	User	Value	Reason
Nov-09-2020 16:15:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE NED MUS CLE PAI N  <b>Were fever or system NO ic symptoms present on the last day the S ubject Diary was co mpleted?:</b>	Initial Entry

**2.g Symptom:**

Date	Location	User	Value	Reason
Nov-09-2020 16:15:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSE NED MUSCL E 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
Nov-09-2020 16:15:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Oct-2020 16:03

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**2.h**

Date	Location	User	Value	Reason
Nov-09-2020 16:15:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE NED JOI NT PAIN  <b>Were fever or systemi NO c symptoms present o n the last day the Sub ject Diary was compl eted?:</b>	Initial Entry

**2.h Symptom:**

Date	Location	User	Value	Reason
Nov-09-2020 16:15:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSE NED JOI NT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Nov-09-2020 16:15:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**3. Injection Site Location:**

Date	Location	User	Value	Reason
Nov-09-2020 16:15:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**4. Injection Site Body Side:**

Date	Location	User	Value	Reason
Nov-09-2020 16:15:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Oct-2020 16:03

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**5.a**

Date	Location	User	Value	Reason
Nov-09-2020 16:15:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> RE DN ESS  <b>Were injection site reactio ns present on the last day t he Subject Diary was com pleted?:</b> NO	Initial Entry

**5.a Injection Site Reaction:**

Date	Location	User	Value	Reason
Nov-09-2020 16:15:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Nov-09-2020 16:15:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Nov-09-2020 16:15:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> SWE LLI NG  <b>Were injection site reactio ns present on the last day the Subject Diary was co mpleted?:</b> NO	Initial Entry

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Oct-2020 16:03

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**5.b Injection Site Reaction:**

Date	Location	User	Value	Reason
Nov-09-2020 16:15:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Nov-09-2020 16:15:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Nov-09-2020 16:15:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction</b> PAIN A :: T INJE CTION SITE  <b>Were injection site rea</b> NO <b>ctions present on the la</b> <b>st day the Subject Diar</b> <b>y was completed?:</b>	Initial Entry

**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Nov-09-2020 16:15:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Nov-09-2020 16:15:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)



**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 10-Oct-2020 16:01**Site No:** 1009**Subject No:** 10091231**Generated By:** (b) (4)**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Nov-09-2020 16:15:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/9/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Nov-09-2020 16:15:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 98.3 <b>Temperature Unit:</b> F <b>Temperature Location::</b> ORAL CAV ITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Nov-09-2020 16:15:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Nov-09-2020 16:15:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 98.3	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Nov-09-2020 16:15:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

**2.a Temperature Location:**

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Oct-2020 16:01

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

Date	Location	User	Value	Reason
Nov-09-2020 16:15:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b><u>Data Entry:</u></b> ORAL CAVITY	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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**1. Data Origin**

Date	Location	User	Value	Reason
Nov-09-2020 16:15:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-09-2020 16:15:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-11-2020 19:19:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-10-2020 03:33:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-09-2020 16:15:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-09-2020 16:15:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Nov/9/2020	Initial Entry

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**5.a**

Date	Location	User	Value	Reason
Nov-11-2020 19:19:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BGGZY5	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Nov-11-2020 19:19:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BGGZY5	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Nov-09-2020 16:58:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Nov-09-2020 16:58:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Nov-09-2020 16:58:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Nov-09-2020 16:58:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/9/2020 15:56	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Nov-09-2020 16:58:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Nov-09-2020 16:58:32 (UTC-07:00) Mountain	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

Time (US & Canada)

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

**7. Route:**

Date	Location	User	Value	Reason
Nov-09-2020 16:58:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Nov-09-2020 16:58:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Nov-09-2020 16:58:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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*1. Date of Visit*

Date	Location	User	Value	Reason
Dec-10-2020 15:34:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u><b>Data Entry:</b></u> Dec/10/2020	Initial Entry

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form Version:** 10-Oct-2020 16:03**Site No:** 1009**Subject No:** 10091231**Generated By:** (b) (4)**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12[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
Dec-10-2020 15:40:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Dec-10-2020 15:40:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FE VE R  Were fever or systemic sy N mptoms present on the las O t day the Subject Diary w as completed?:	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
Dec-10-2020 15:40:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Dec-10-2020 15:40:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
Dec-10-2020 15:40:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FATIGUE	Initial Entry



**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form Version:** 10-Oct-2020 16:03**Site No:** 1009**Subject No:** 10091231**Generated By:** (b) (4)**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12

			<b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> YES Ongoing ? NO Stop Date: No v/1 3/2 020	
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**2.b Symptom:**

Date	Location	User	Value	Reason
Dec-10-2020 15:40:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Dec-10-2020 15:40:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Ongoing? NO Stop Date: Nov/13/2020	Initial Entry

**2.c**

Date	Location	User	Value	Reason
Dec-10-2020 15:40:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> HE AD AC HE	Initial Entry

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject No:** 10091231**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12

			<b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	
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**2.c Symptom:**

Date	Location	User	Value	Reason
Dec-10-2020 15:40:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Dec-10-2020 15:40:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.d**

Date	Location	User	Value	Reason
Dec-10-2020 15:40:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> CHILLS <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> YES Ongoing ? NO  Stop Date:  No v/1 2/2 020	Initial Entry

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 10-Oct-2020 16:03

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**2.d Symptom:**

Date	Location	User	Value	Reason
Dec-10-2020 15:40:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Dec-10-2020 15:40:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Ongoing?  NO  Stop Date:  Nov/12/2020	Initial Entry

**2.e**

Date	Location	User	Value	Reason
Dec-10-2020 15:40:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> VO MIT ING  <b>Were fever or systemic s NO</b> <b>ymptoms present on the</b> <b>last day the Subject Diar</b> <b>y was completed?:</b>	Initial Entry

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 10-Oct-2020 16:03

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**2.e Symptom:**

Date	Location	User	Value	Reason
Dec-10-2020 15:40:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Dec-10-2020 15:40:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.f**

Date	Location	User	Value	Reason
Dec-10-2020 15:40:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DIA RR HE A  <b>Were fever or systemic s NO</b> <b>ymptoms present on the l</b> <b>ast day the Subject Diary</b> <b>was completed?:</b>	Initial Entry

**2.f Symptom:**

Date	Location	User	Value	Reason
Dec-10-2020 15:40:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Dec-10-2020 15:40:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form Version:** 10-Oct-2020 16:03**Site No:** 1009**Subject No:** 10091231**Generated By:** (b) (4)**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12**2.g**

Date	Location	User	Value	Reason
Dec-10-2020 15:40:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR W ORSENERED MUSCLE P AIN  <b>Were fever or sys</b> YES <b>temic symptoms</b> Ongoing? <b>present on the las</b> <b>t day the Subject</b> NO <b>Diary was compl</b> <b>eted?:</b> Stop Dat e:  Nov/1 4/2020	Initial Entry

**2.g Symptom:**

Date	Location	User	Value	Reason
Dec-10-2020 15:40:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENERED MUSC LE 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
Dec-10-2020 15:40:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Ongoing?  NO  Stop Date:  Nov/14/2020	Initial Entry

**2.h**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 10-Oct-2020 16:03

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

Dec-10-2020 15:40:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR W ORSENE J OINT PAIN  <b>Were fever or sys temic symptoms present on the las t day the Subject Diary was comple ted?:</b> YES Ongoing?  NO  Stop Da te:  Nov/1 3/2020	Initial Entry
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**2.h Symptom:**

Date	Location	User	Value	Reason
Dec-10-2020 15:40:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Dec-10-2020 15:40:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Ongoing?  NO  Stop Date:  Nov/13/2020	Initial Entry

**3. Injection Site Location:**

Date	Location	User	Value	Reason
Dec-10-2020 15:40:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**4. Injection Site Body Side:**

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject No:** 10091231**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12

Date	Location	User	Value	Reason
Dec-10-2020 15:40:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-20-2020 12:00:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> RE DN ESS  <b>Were injection site reactio NO ns present on the last day the Subject Diary was co mpleted?:</b>	changed per query
Dec-10-2020 15:40:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reacti REDNES on::</b> S  <b>Were injection site r YES eactions present on Ongoing the last day the Subj ? ect Diary was compl eted?:</b> NO  Stop Date:  No v/1 2/2 020	Initial Entry

**5.a Injection Site Reaction:**

Date	Location	User	Value	Reason
Dec-10-2020 15:40:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> REDNESS	Initial Entry

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

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject No:** 10091231**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12

Date	Location	User	Value	Reason
Dec-21-2020 01:35:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-20-2020 12:00:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	changed per query
Dec-20-2020 12:00:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	changed per query
Dec-18-2020 14:05:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	As per protocol, grade 1 redness is considered as 5 to 10 measuring device units, therefore, "4" is not considered as a graded reaction. Please update response to NO.
Dec-16-2020 21:59:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	In candidate/ site not able to update data as per instructions. Site needs to update the event as No. Added to eDiary log.
Dec-16-2020 18:35:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	in trial max it shows that the patient marked a redness of 4 on the last day diary was completed, this means the redness was ongoing. entered correctly as is.
Dec-15-2020 21:29:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	eDiary RQ2: Thanks for your response. Redness



**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject No:** 10091231**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12

				greater than 4 caliper units on the last day is considered as Grade 1. Per e-Diary records, Redness is not reported. However, Last day in Inform is marked as 'Yes'. Please review and update as appropriate.
Dec-15-2020 13:42:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	last day of entry was 11nov2020. pt reports resolved 12nov2020
Dec-14-2020 00:22:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	eDiary RQ: Per protocol, Redness from 5 to 10 units on the last day is considered as Grade 1. Per e-Diary records, Redness is not reported. However, Last day in Inform is marked as 'Yes'. Please review and update as appropriate. Thanks
Dec-13-2020 12:56:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	redness measurement 4 is reported on day 3
Dec-11-2020 02:22:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	eDiary: Per diary records, Day 3 is the last day reported on 11Nov20 & REDNESS not present on Last day however inform is

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject No:** 10091231**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12

				entered with 'Yes' for the same. Please verify and update. Else, clarify. Thanks
Dec-10-2020 15:40:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Ongoing?  NO  Stop Date:  Nov/12/2020	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Dec-10-2020 15:40:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> SWELLING <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> YES Ongoing? ? NO  Stop Date:  No v/1 2/2 020	Initial Entry

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 10-Oct-2020 16:03

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**5.b Injection Site Reaction:**

Date	Location	User	Value	Reason
Dec-10-2020 15:40:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Dec-10-2020 15:40:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Ongoing?  NO  Stop Date:  Nov/12/2020	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Dec-10-2020 15:40:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> PAIN AT INJECTION SITE <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> YES Ongoing? NO Stop Date: Nov/14/2020	Initial Entry

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 10-Oct-2020 16:03

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Dec-10-2020 15:40:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Dec-10-2020 15:40:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Ongoing?  NO  Stop Date:  Nov/14/2020	Initial Entry

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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**1. Data Origin**

Date	Location	User	Value	Reason
Dec-10-2020 15:41:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Dec-10-2020 15:41:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-22-2021 09:08:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Jan-21-2021 16:39:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Changed data per query
Jan-12-2021 13:06:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	HOLDS: For Visit 3, serum barcode BSJ3LD was received by the lab; however, the barcode has not been recorded. Please review and update as appropriate. Otherwise please clarify.
Dec-10-2020 15:42:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject No:** 10091231**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12

Dec-10-2020 15:41:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-10-2020 15:41:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Dec/10/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-13-2020 12:53:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BR5BG8	Transcription Error
Dec-10-2020 15:42:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BR5BG9	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Dec-15-2020 13:44:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Clo sed	Auto closed by Validation Check: VC_BEETRK001_06
Dec-13-2020 19:18:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Rei ssued: Candi date	Reopening discrepancy due to primary column value change
Dec-13-2020 12:53:59 (UTC-07:00) Mountain	ACV0PFEINFP6000	auto query (autoquery)	Query 1: An swere d	Transcription Error

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject No:** 10091231**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12

Time (US & Canada)				
Dec-13-2020 12:53:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR5BG8	Transcription Error
Dec-10-2020 22:47:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6433526;The barcode BR5BG9 is recorded for two subjects 10091231 and 10091321, please review and update as appropriate.
Dec-10-2020 15:42:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR5BG9	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Dec-13-2020 12:54:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BR5BG7	Transcription Error
Dec-10-2020 15:42:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BR5BGB	Initial Entry

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject No:** 10091231**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12**5.b Sample ID**

Date	Location	User	Value	Reason
Dec-15-2020 13:44:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Clo sed	Auto closed by Validation Check: VC_BEETRK001_06
Dec-13-2020 19:18:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Rei ssued: Candi date	Reopening discrepancy due to primary column value change
Dec-13-2020 12:54:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: An swere d	Transcription Error
Dec-13-2020 12:54:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : BR5B G7	Transcription Error
Dec-10-2020 22:47:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW6433527;The barcode BR5BGB is recorded for two subjects 10091231 and 10091321, please review and update as appropriate.
Dec-10-2020 15:42:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : BR5B GB	Initial Entry

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**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**5.c**

Date	Location	User	Value	Reason
Jan-21-2021 16:39:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> <b>Sample ID:</b> BSJ3LD	Transcription Error
Dec-10-2020 15:42:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> <b>Sample ID:</b> BSJ3LF	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Jan-21-2021 16:39:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> BSJ3LD	Transcription Error
Dec-10-2020 15:42:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> BSJ3LF	Initial Entry

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Nov/11/2020

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091231

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 04:12

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***I. Date of Visit***

Date	Location	User	Value	Reason
Nov-11-2020 19:31:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Deleted	Query is invalid or does not apply
Nov-11-2020 19:30:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Deleted	Query is invalid or does not apply
Nov-11-2020 19:30:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query can be addressed internally
Nov-11-2020 19:20:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this visit.
Nov-11-2020 19:20:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Nov-11-2020 19:20:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Nov/11/2020

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091231

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 04:12

Nov-11-2020 19:20:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/11/2020	Initial Entry
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**2. Erroneous Visit**

Date	Location	User	Value	Reason
Nov-11-2020 19:20:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ERRONEOUS VISIT	Initial Entry

**3. COVID-19 Illness Visit:**

Date	Location	User	Value	Reason
Nov-11-2020 19:20:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> COVID_A	Initial Entry

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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Date	Location	User	Value	Reason
Nov-11-2020 19:26:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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**1. Category:**

Date	Location	User	Value	Reason
Nov-11-2020 19:26:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Nov-11-2020 19:26:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Nov-11-2020 19:26:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> left swollen axillary lymph node	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Nov-11-2020 19:26:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/10/2020 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Dec-18-2020 07:39:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 2: Closed	Response satisfies query
Dec-15-2020 13:40:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Dec-15-2020 13:40:44 (UTC-07:00) Mountain	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Transcription Error

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1009**Subject No:** 10091231**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12

Time (US & Canada)		(b) (4), (b) (6)	End Date Time:  Nov/10/2020 UNK:UNK	
Dec-14-2020 04:43:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 2: Opened	Clin: Participant attended Visit 3 on 10th Dec please confirm if AE is still ongoing
Dec-09-2020 09:41:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 1: Closed	Response satisfies query
Dec-07-2020 08:44:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	unknown, we will ask about it at the next visit
Dec-07-2020 06:33:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 1: Opened	Clin: Please confirm if the AE is still ongoing
Nov-11-2020 19:26:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Nov-11-2020 19:26:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**7. Is the adverse event serious?****If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

Date	Location	User	Value	Reason
Nov-11-2020 19:26:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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

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

Date	Location	User	Value	Reason
Nov-11-2020 19:26:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Nov-11-2020 19:26:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RELATED	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Nov-11-2020 19:26:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Nov-11-2020 19:26:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Nov-11-2020 19:26:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Dec-15-2020 13:40:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

Dec-15-2020 13:40:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Transcription Error
Dec-15-2020 13:40:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE left swollen axillary lymph node: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Nov-11-2020 19:26:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RECOVERED/NOT RES OLVED	Initial Entry

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

Date	Location	User	Value	Reason
Nov-11-2020 19:26:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)



**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Nov/11/2020

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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*1. Date of Visit*

Date	Location	User	Value	Reason
Nov-11-2020 19:21:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/11/2020	Initial Entry

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001**Visit:** Unplanned 1 - Unscheduled Visit on Nov/11/2020**Form Version:** 22-Apr-2020 21:04**Site No:** 1009**Subject No:** 10091231**Generated By:** (b) (4)**Form:** UNPLANNED VISIT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)***I. Assessments***

Date	Location	User	Value	Reason
Nov-11-2020 19:21:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-11-2020 19:21:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Nov-11-2020 19:21:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b><u>Data Entry:</u></b> CONTACT OUTCOME	Initial Entry

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Nov/11/2020

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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**1. Contact Type:**

Date	Location	User	Value	Reason
Nov-11-2020 19:21:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> TELEPHONE VISIT	Initial Entry

**2. Was contact made?**

Date	Location	User	Value	Reason
Nov-11-2020 19:24:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-11-2020 19:21:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Contact Outcome' is selected as 'VISIT ARRANGED' but no 'VITAL SIGNS' and/or 'UNPLANNED ASSESSMENT OF LOCAL REACTION' form(s) is/are entered. Please review and update as appropriate.
Nov-11-2020 19:21:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Contact:  Nov/11/2020  Contact Outcome:  VISIT ARRANGED	Initial Entry

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001**Visit:** Unplanned 1 - Unscheduled Visit on  
Nov/11/2020**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:01**Form Status:** Data Complete, Frozen, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject No:** 10091231**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Nov-11-2020 19:21:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/11/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Nov-11-2020 19:21:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> 1 : <b>Temperature:</b> 98.4 <b>Temperature Unit</b> F : <b>Temperature Location:</b> ORAL CAV <b>ity:</b> ITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Nov-11-2020 19:21:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Nov-11-2020 19:21:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 98.4	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Nov-11-2020 19:21:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Nov/11/2020

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:01

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091231

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 04:12

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Nov-11-2020 19:21:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

**Header Text:** c4591001**Visit:** Unplanned 1 - Unscheduled Visit on Nov/11/2020**Form Version:** 10-Oct-2020 15:57**Site No:** 1009**Subject No:** 10091231**Generated By:** (b) (4)**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Nov-11-2020 19:24:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/11/2020	Initial Entry

**2. Injection Site Location**

Date	Location	User	Value	Reason
Nov-11-2020 19:24:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**3. Injection Site Body Side:**

Date	Location	User	Value	Reason
Nov-11-2020 19:24:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**4.a**

Date	Location	User	Value	Reason
Nov-11-2020 19:24:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Reaction:: REDNESS</b>	Initial Entry

**Header Text:** c4591001**Visit:** Unplanned 1 - Unscheduled Visit on Nov/11/2020**Form Version:** 10-Oct-2020 15:57**Site No:** 1009**Subject No:** 10091231**Generated By:** (b) (4)**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12

			<b>Reaction P YES</b> <b>resent::</b> <i>Maximum Diameter (cm):</i>  8.0  <i>Minimum Diameter (cm):</i>  6.0  Meets Grade 4 Reaction Criteria:  NO	
--	--	--	---	--

**4.a Reaction:**

Date	Location	User	Value	Reason
Nov-11-2020 19:24:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> REDNESS	Initial Entry

**4.a Reaction Present:**

Date	Location	User	Value	Reason
Nov-11-2020 19:24:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Maximum Diameter (cm):</i>  8.0  <i>Minimum Diameter (cm):</i>  6.0  Meets Grade 4 Reaction Criteria :  NO	Initial Entry

**4.b**

Date	Location	User	Value	Reason
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**Header Text:** c4591001**Visit:** Unplanned 1 - Unscheduled Visit on Nov/11/2020**Form Version:** 10-Oct-2020 15:57**Site No:** 1009**Subject No:** 10091231**Generated By:** (b) (4)**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12

Nov-11-2020 19:24:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Reaction::</b> SWELLING <b>Reaction P YES</b> <b>resent::</b> <i>Maximum Diameter (cm):</i>  6.0  <i>Minimum Diameter (cm):</i>  4.0  Meets Grade 4 Reaction Criteria:  NO	Initial Entry
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**4.b Reaction:**

Date	Location	User	Value	Reason
Nov-11-2020 19:24:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWELLING	Initial Entry

**4.b Reaction Present:**

Date	Location	User	Value	Reason
Nov-11-2020 19:24:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Maximum Diameter (cm):</i>  6.0  <i>Minimum Diameter (cm):</i>  4.0  Meets Grade 4 Reaction Criteria :  NO	Initial Entry



**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Nov/11/2020

**Form Version:** 10-Oct-2020 15:57

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION -  
SYSTEMIC EVENT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**5.a**

Date	Location	User	Value	Reason
Nov-11-2020 19:24:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> PAIN AT INJECTIO N SITE <b>Symptom</b> YES <b>Present::</b> Symptom Grade:  1  Event related to St udy Treatment?  YES	Initial Entry

**5.a Symptom:**

Date	Location	User	Value	Reason
Nov-11-2020 19:24:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

**5.a Symptom Present:**

Date	Location	User	Value	Reason
Nov-11-2020 19:24:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Symptom Grade:  1  Event related to Study Treatment ?  YES	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Nov-11-2020 19:24:37 (UTC-07:00) Mountain	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FATIGUE/TIRE	Initial Entry

**Header Text:** c4591001**Visit:** Unplanned 1 - Unscheduled Visit on Nov/11/2020**Form Version:** 10-Oct-2020 15:57**Site No:** 1009**Subject No:** 10091231**Generated By:** (b) (4)**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12

Time (US & Canada)		(b) (4), (b) (6)	DNESS	
			<b>Symptom Pre sent::</b> NO	

**5.b Symptom:**

Date	Location	User	Value	Reason
Nov-11-2020 19:24:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FATIGUE/TIREDNESS	Initial Entry

**5.b Symptom Present:**

Date	Location	User	Value	Reason
Nov-11-2020 19:24:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Nov-11-2020 19:24:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> HEADACH E <b>Symptom Present:</b> NO :	Initial Entry

**5.c Symptom:**

Date	Location	User	Value	Reason
Nov-11-2020 19:24:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HEADACHE	Initial Entry

**5.c Symptom Present:**

Date	Location	User	Value	Reason
Nov-11-2020 19:24:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Nov/11/2020

**Form Version:** 10-Oct-2020 15:57

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION -  
SYSTEMIC EVENT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**5.d**

Date	Location	User	Value	Reason
Nov-11-2020 19:24:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> VOMITIN G <b>Symptom Present:</b> NO :	Initial Entry

**5.d Symptom:**

Date	Location	User	Value	Reason
Nov-11-2020 19:24:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

**5.d Symptom Present:**

Date	Location	User	Value	Reason
Nov-11-2020 19:24:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Nov-11-2020 19:24:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DIARRHE A <b>Symptom Present:</b> NO :	Initial Entry

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Nov/11/2020

**Form Version:** 10-Oct-2020 15:57

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION -  
SYSTEMIC EVENT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**5.e Symptom:**

Date	Location	User	Value	Reason
Nov-11-2020 19:24:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

**5.e Symptom Present:**

Date	Location	User	Value	Reason
Nov-11-2020 19:24:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.f**

Date	Location	User	Value	Reason
Nov-11-2020 19:24:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom</b> NEW OR WORSEN <b>::</b> ED MUSCLE PAIN <b>Symptom</b> YES <b>Present::</b> Symptom Grade:  1  Event related to Stu dy Treament?  YES	Initial Entry

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Nov/11/2020

**Form Version:** 10-Oct-2020 15:57

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION -  
SYSTEMIC EVENT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**5.f Symptom:**

Date	Location	User	Value	Reason
Nov-11-2020 19:24:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENE D MUSCLE PAIN	Initial Entry

**5.f Symptom Present:**

Date	Location	User	Value	Reason
Nov-11-2020 19:24:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Symptom Grade:  1  Event related to Study Treatment ?  YES	Initial Entry

**5.g**

Date	Location	User	Value	Reason
Nov-11-2020 19:24:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom:</b> NEW OR WORSENE D JOINT PAIN <b>Symptom Present::</b> YES Symptom Grade:  1  Event related to Study Treatment?  YES	Initial Entry

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001**Visit:** Unplanned 1 - Unscheduled Visit on Nov/11/2020**Form Version:** 10-Oct-2020 15:57**Site No:** 1009**Subject No:** 10091231**Generated By:** (b) (4)**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12**5.g Symptom:**

Date	Location	User	Value	Reason
Nov-11-2020 19:24:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENERD JOINT PAIN	Initial Entry

**5.g Symptom Present:**

Date	Location	User	Value	Reason
Nov-11-2020 19:24:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Symptom Grade:  1  Event related to Study Treatment?  YES	Initial Entry

**5.h**

Date	Location	User	Value	Reason
Nov-11-2020 19:24:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> CHILLS <b>Symptom Present::</b> YES Symptom Grade:  1  Event related to Study Treatment?  YES	Initial Entry

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Nov/11/2020

**Form Version:** 10-Oct-2020 15:57

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION -  
SYSTEMIC EVENT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**5.h Symptom:**

Date	Location	User	Value	Reason
Nov-11-2020 19:24:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

**5.h Symptom Present:**

Date	Location	User	Value	Reason
Nov-11-2020 19:24:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Symptom Grade:  1  Event related to Study Treatment ?  YES	Initial Entry

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form Version:** 10-Dec-2020 02:29

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Dec-10-2020 15:43:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/10/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Dec-10-2020 15:43:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Dec-10-2020 15:43:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)



**Header Text:** c4591001**Visit:** Potential ReVax Initial Contact -  
Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1009**Subject No:** 10091231**Generated By:** (b) (4)**Form:** DATE OF VISIT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**I. Date of Visit**

Date	Location	User	Value	Reason
Feb-24-2021 04:37:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Deleted	Query is invalid or does not apply
Feb-24-2021 02:20:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-23-2021 16:30:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	entered in error, marked erroneous
Feb-23-2021 16:30:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark any forms containing data within this visit as Not Done/Not Applicable at the form level.
Feb-22-2021 23:44:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM1: Thanks for response. If visit is entered in error then please review and mark erroneous visit. Else,clarify.
Feb-22-2021 16:39:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Entry error, visit not completed. Please remove.
Feb-22-2021 03:57:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly consider to update missing REVAX CONF form or else

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

				clarify. Thank you.
Feb-19-2021 13:27:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/19/2021	Initial Entry

**2. Erroneous Visit**

Date	Location	User	Value	Reason
Feb-23-2021 16:30:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ERRONEOUS VISIT	Initial Entry

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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**1. Subject Status**

Date	Location	User	Value	Reason
Dec-10-2020 15:43:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Oct-22-2020 21:00:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Oct-22-2020 20:59:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Dec-10-2020 15:43:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Dec/10/2020	Initial Entry
Oct-22-2020 21:00:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/20/2020	Initial Entry
Oct-22-2020 20:59:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/20/2020	Initial Entry

090177e196ae30a2\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1009

**Subject No:** 10091231

**Generated By:** (b) (4)

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

**Form Status:** Data Complete, Signed, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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***I. Casebook Signature***

Date	Location	User	Value	Reason
Mar-09-2021 17:20:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry