

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Cohort Selection

DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.

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

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/4/2021
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Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10091382]
2.	Birth Date:	(b) (6) 2006
3.	Sex:	FEMALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Jan/4/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable _____
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Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable _____
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090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Screening

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[ANXIETY]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[CELIAC DISEASE]
	Start Date:	UNK/UNK/2013
	Ongoing:	YES

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: HIV STATUS

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

HIV Status

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:29

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Jan/4/2021
2.	Weight:	[156.2]
3.	Unit:	LB
4.	Height:	[63.0]
5.	Unit:	in
6.	Body Mass Index:	[27.7]

Vital Signs Details

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

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:23

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Jan/4/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	NEGATIVE
	Not Done:	

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Jan/4/2021
2.	Randomization Number:	[24808]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR5BNH]
5.b	Sample ID	[BSJ3R2]
5.c	Sample ID	[BR5BNG]

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BGH063]
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090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:26

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/4/2021 16:30
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

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Jan/25/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

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

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 14-Jan-2021 02:22

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Jan/25/2021
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.1]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:23

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Jan/25/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	NEGATIVE
	Not Done:	

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/25/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR9FBK]
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/25/2021 16:17
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

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

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

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

Site No: 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382 **Subject Initials:** ---

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

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Feb/25/2021
2.	Erroneous Visit	

Header Text: c4591001

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

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

Site No: 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382 **Subject Initials:** ---

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

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

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

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

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

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

Site No: 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382 **Subject Initials:** ---

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

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

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

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

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

Site No: 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382 **Subject Initials:** ---

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

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

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

Site No: 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382 **Subject Initials:** ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/25/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR622B]
5.b	Sample ID	[BR6229]
5.c	Sample ID	[BSJ4CV]

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: DATE OF VISIT - ILLNESS ONSET

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: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	May/19/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A
----	-------------------------	---------

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Version: 30-Apr-2021 01:47

Form Status: Data Complete, Not Complete

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	May/19/2021
2.	Date of First Symptom Started:	May/15/2021
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: May/20/2021

Symptoms

4.a	Symptoms:	FEVER
	Was symptom present?	NO
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	NO
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	NO
4.d	Symptoms:	CHILLS
	Was symptom present?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	NO

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Version: 30-Apr-2021 01:47

Form Status: Data Complete, Not Complete

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	YES
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	NO
Symptoms - Other		
5.a	Symptoms - Other Text:	[]
5.b	Symptoms - Other Text:	[]
5.c	Symptoms - Other Text:	[]

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (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: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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[eCRF Audit Trail History](#)

Microbiology Specimen

1.	Actual Date of Collection:	Not Done _____ //	Comments
2.	Specimen Type:	Not Done _____	Comments
3.	Specimen Collection Location:	Not Done _____	Comments
4.	Assay Code and Description:	Not Done _____	Comments
5.	Device Type:	Not Done _____	Comments
6.	Trade Name:	Not Done _____	Comments
7.	Test Result:	Not Done _____	Comments
8.	Comments/Findings /Details:	Not Done _____ []	Comments
9.	Trade Name Other, Specify:	Not Done _____ []	Comments

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021**Form:** ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF**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:** 10091382**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: May/19/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[RR11673]
-----	-----------	-----------

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

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: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001**Visit:** POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021**Form:** HEALTH CARE UTILIZATION**Form Version:** 30-Apr-2021 01:37**Form Status:** Data Complete, Frozen, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family
Clinic South**Subject No:** 10091382**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Health Care Utilization**

1.a	Physician or Healthcare Professional:	SPECIALIST
	Occurrence of Visits or Contacts:	NO
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM
	Occurrence of Visits or Contacts:	NO
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [1]
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	NO
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	NO

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: HEALTH CARE UTILIZATION

Form Version: 30-Apr-2021 01:37

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

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?	NO
----	--	----

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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: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: RESPIRATORY TREATMENT

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: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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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?	

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	NO
3.	Toxicity Grade:	1

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: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.					Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: ILLNESS DETAILS - SEVERE

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: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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Illness Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 10-Dec-2020 02:24

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 10-Dec-2020 02:24

Form Status: Not Started

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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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

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 10-Dec-2020 02:28

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

#	Category f or Lab Tes t	Vendor Nam e (DERIVED)	Collecti on Date :	Specim en Type	Lab Result			Form Instan ce
1.					Sponsor-Defi ned Identifie r	Te st:	Res ult:	Repeating Pages

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 10-Dec-2020 02:28

Form Status: Not Started

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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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

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 10-Dec-2020 02:25

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

#	Date:	Vital Signs Details			Form Instance
1.		Record Identifier:	Systolic:	Diastolic:	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: VITAL SIGNS - COVID

Form Version: 10-Dec-2020 02:25

Form Status: Not Started

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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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: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 10-Dec-2020 02:31

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

#	Date:	Vital Signs Details		Form Instance
1.		Record Identifier:	Oxygen Saturation	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 10-Dec-2020 02:31

Form Status: Not Started

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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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: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.				Repeating Pages

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: OXYGENATION PARAMETERS

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: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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Oxygenation Parameters

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

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: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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Concomitant Medications

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

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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: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: IMAGING

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: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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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_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form: DATE OF VISIT - ILLNESS ONSET

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: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit

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

COVID-19 Illness Visit

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

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form Version: 30-Apr-2021 01:47

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Data Complete

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Jul/2/2021
2.	Date of First Symptom Started:	Jun/29/2021
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Jul/3/2021

Symptoms

4.a	Symptoms:	FEVER
	Was symptom present?	NO
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	YES
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	NO
4.d	Symptoms:	CHILLS
	Was symptom present?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	NO

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Version: 30-Apr-2021 01:47

Form Status: Data Complete

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	YES
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	NO
Symptoms - Other		
5.a	Symptoms - Other Text:	[rhinorrhea]

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

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: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form Version: 06-Jul-2020 21:54

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: MICROBIOLOGY SPECIMEN

Form Status: Data Complete

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

Subject Initials: ---

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

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[Form Comments](#)

[eCRF Audit Trail History](#)

Microbiology Specimen

1.	Actual Date of Collection:	Not Done _____ //	Comments
2.	Specimen Type:	Not Done _____	Comments
3.	Specimen Collection Location:	Not Done _____	Comments
4.	Assay Code and Description:	Not Done _____	Comments
5.	Device Type:	Not Done _____	Comments
6.	Trade Name:	Not Done _____	Comments
7.	Test Result:	Not Done _____	Comments
8.	Comments/Findings /Details:	Not Done _____ []	Comments
9.	Trade Name Other, Specify:	Not Done _____ []	Comments

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1009**Subject No:** 10091382**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF**Form Status:** Data Complete, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family
Clinic South**Subject Initials:** ---**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Jul/8/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[date of collection is more than 4 days after symptom resolution, PD captured]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[RR23599]
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Header Text: c4591001**Visit:** POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021**Form:** ELECTRONIC SAMPLE TRACKING - NASAL
SWAB**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:** 10091382**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001**Visit:** POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021**Form:** HEALTH CARE UTILIZATION**Form Version:** 30-Apr-2021 01:37**Form Status:** Data Complete**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family
Clinic South**Subject No:** 10091382**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Health Care Utilization**

1.a	Physician or Healthcare Professional:	SPECIALIST
	Occurrence of Visits or Contacts:	NO
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM
	Occurrence of Visits or Contacts:	NO
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	NO
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	NO
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	NO

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form: HEALTH CARE UTILIZATION

Form Version: 30-Apr-2021 01:37

Form Status: Data Complete

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

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?	NO
----	--	----

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

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: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form: RESPIRATORY TREATMENT

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: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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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?	

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form Version: 06-Jul-2020 21:52

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: ILLNESS DETAILS

Form Status: Data Complete

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	NO
3.	Toxicity Grade:	1

Header Text: c4591001

Visit: POT_COVID_ILL 2

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: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.					Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form: ILLNESS DETAILS - SEVERE

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: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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Illness Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 10-Dec-2020 02:24

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	Repeating Pages

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 10-Dec-2020 02:24

Form Status: Not Started

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 10-Dec-2020 02:28

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

#	Category f or Lab Tes t	Vendor Nam e (DERIVED)	Collecti on Date :	Specim en Type	Lab Result			Form Instan ce
1.					Sponsor-Defi ned Identifie r	Te st:	Res ult:	Repeating Pages

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 10-Dec-2020 02:28

Form Status: Not Started

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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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

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: VITAL SIGNS - COVID

Form Version: 10-Dec-2020 02:25

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

#	Date:	Vital Signs Details			Form Instance
1.		Record Identifier:	Systolic:	Diastolic:	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form: VITAL SIGNS - COVID

Form Version: 10-Dec-2020 02:25

Form Status: Not Started

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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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:	[]

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 10-Dec-2020 02:31

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

#	Date:	Vital Signs Details		Form Instance
1.		Record Identifier:	Oxygen Saturation	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 10-Dec-2020 02:31

Form Status: Not Started

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

Header Text: c4591001

Visit: POT_COVID_ILL 2

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: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.				Repeating Pages

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form: OXYGENATION PARAMETERS

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: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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Oxygenation Parameters

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

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form Version: 06-Jul-2020 21:55

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

Form Status: Not Started

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

Subject Initials: ---

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

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Concomitant Medications

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

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

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: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form: IMAGING

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: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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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: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	

Header Text: c4591001**Visit:** POT_COVID_CONVA - New
Unscheduled Visit**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family
Clinic South**Subject No:** 10091382**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

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

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

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Repeat Swab		
3.	COVID-19 Repeat Swab:	

Header Text: c4591001**Visit:** POT_COVID_REPEAT_SWAB - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB**Form Version:** 10-Oct-2020 15:57 **Form Status:** Not Started**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject No:** 10091382**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Unplanned - New Unscheduled **Form:** DATE OF VISIT
Visit

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

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit **Form:** UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04 **Form Status:** Not Started

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

Unplanned Assessments

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VITAL SIGNS - TEMP

Form Version: 30-Apr-2021 01:41

Form Status: Not Started

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

Vital Signs

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

Vital Signs Details

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

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001**Visit:** Unplanned Vaccination -
Unscheduled**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Version:** 20-Feb-2021 02:14**Form Status:** Not Started**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family
Clinic South**Subject No:** 10091382**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44**Lab Urinalysis**

1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[]
5.	Specimen Type:	

Lab Result

6.	Sponsor ID:	[]
	Test:	
	Result:	
	Not Done:	

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:** 10091382**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44**Vaccination**

1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

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: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

Contact Outcome

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: CONTACT OUTCOME - MONTH 6

Form Version: 10-Oct-2020 16:01

Form Status: Not Started

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

Contact Outcome

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

Header Text: c4591001

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

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

Site No: 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091382 **Subject Initials:** ---

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

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Informed Consent - Asymptomatic Surveillance

1.	Consent Was:	OBTAINED Date Written Consent Obtained Apr/7/2021
----	--------------	---

Header Text: c4591001**Visit:** V201_SURVEIL_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING -
Unscheduled IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family
Clinic South**Subject No:** 10091382**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR9DND]
5.b	Sample ID	[BR9DNF]
5.c	Sample ID	[BRTSP7]

Header Text: c4591001**Visit:** V201_SURVEIL_CONSENT -
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING - NASAL
SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family
Clinic South**Subject No:** 10091382**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR9DTK]
-----	-----------	----------

Header Text: c4591001

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

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Feb/25/2021
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

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

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

Site No: 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091382 **Subject Initials:** ---

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

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Date of Visit

1.	Date of Visit	May/13/2021
2.	Erroneous Visit	

Header Text: c4591001

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

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

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

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Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

Disposition - Follow-Up

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

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	RIGHT KNEE PAIN	Jan/10/2021 UNK:UNK	NO End Date Time: Jan/25/2021 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	chills	Jun/3/2021 UNK:UNK	NO End Date Time: Jun/3/2021 UNK:UNK	Repeating Pages
3.	ADVERSE EVENT	3	generalized muscle pain	May/15/2021 UNK:UNK	NO End Date Time: May/20/2021 UNK:UNK	Repeating Pages
4. DELETED	ADVERSE EVENT	4	Sore Throat	May/15/2021 UNK:UNK	NO End Date Time: May/20/2021 UNK:UNK	Repeating Pages
5.	ADVERSE EVENT	5	dizziness	May/15/2021 UNK:UNK	NO End Date Time:	Repeating Pages

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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: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
					May/16/2021 UNK:UNK	
6.	ADVERSE EVENT	6	rhinorrhea	May/15/2021 UNK:UNK	NO End Date Time: May/17/2021 UNK:UNK	Repeating Pages
7.	ADVERSE EVENT	7	nausea	May/15/2021 UNK:UNK	NO End Date Time: May/17/2021 UNK:UNK	Repeating Pages
8. DELETED	ADVERSE EVENT	8	headache	Jan/6/2021 14:00	NO End Date Time: Jan/6/2021 17:01	Repeating Pages

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[RIGHT KNEE PAIN]
4.	Start Date Time:	Jan/10/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/25/2021 UNK:UNK
6.	Toxicity Grade:	2

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Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [DANCING OVERUSE]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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Form Status: Data Complete, Locked, Frozen

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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Subject No: 10091382

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

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

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Adverse Event Report

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

Header Text: c4591001

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Site No: 1009

Subject No: 10091382

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): 10-Nov-2021 20:44

7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

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Form Status: Data Complete, Frozen

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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Site No: 1009

Subject No: 10091382

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: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[generalized muscle pain]
4.	Start Date Time:	May/15/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: May/20/2021 UNK:UNK
6.	Toxicity Grade:	1

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Site No: 1009

Subject No: 10091382

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: ---

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7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

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Form Status: Data Complete, Frozen

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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Site No: 1009

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Sore Throat]
4.	Start Date Time:	May/15/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: May/20/2021 UNK:UNK
6.	Toxicity Grade:	‡

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Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

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Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[dizziness]
4.	Start Date Time:	May/15/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: May/16/2021 UNK:UNK
6.	Toxicity Grade:	1

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Form Status: Data Complete, Frozen

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

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Form Status: Data Complete, Frozen

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[6]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[rhinorrhea]
4.	Start Date Time:	May/15/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: May/17/2021 UNK:UNK
6.	Toxicity Grade:	1

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Form Status: Data Complete, Frozen

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

Subject Initials: ---

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7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

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Form Status: Data Complete, Frozen

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[7]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[nausea]
4.	Start Date Time:	May/15/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: May/17/2021 UNK:UNK
6.	Toxicity Grade:	1

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Subject No: 10091382

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: ---

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7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

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Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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

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Site No: 1009

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

Subject No: 10091382

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Generated By: (b) (4)

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[8]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[headache]
4.	Start Date Time:	Jan/6/2021 14:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/6/2021 17:01
6.	Toxicity Grade:	1

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Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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7.	<p>Is the adverse event serious?</p> <p>If Yes, NOTIFY PFIZER IMMEDIATELY.</p> <p>Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).</p>	NO
8.	<p>Is this adverse event the result of a study Medication Error?</p> <p>If Yes, record the type of medication error on the Medication Error Log.</p>	NO
9.	<p>Is this event related to study treatment:</p>	RELATED
10.	<p>Latest Action Taken with Study Treatment:</p>	NOT APPLICABLE
11.	<p>Was a Concomitant Medication given?</p>	YES

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Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

***** THIS REPEATING FORM HAS BEEN DELETED *****

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	[]

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1009

Subject No: 10091382

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): 10-Nov-2021 20:44

[Back to Form](#)

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	[]

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Concomitant Medications

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

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

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: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Concomitant Medications

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

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Radiation Treatment

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

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 -
Unscheduled Visit on Apr/17/2021

Form: DATE OF VISIT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Apr/17/2021
2.	Erroneous Visit	

COVID-19 Surveillance Visit

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

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001**Visit:** V202_SURVEIL_SWAB 1 -
Unscheduled Visit on Apr/17/2021**Form Version:** 10-Oct-2020 15:57**Site No:** 1009**Subject No:** 10091382**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT
SWAB**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family
Clinic South**Subject Initials:** ---**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Apr/17/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[AA45711]
-----	-----------	-----------

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 2 -
Unscheduled Visit on Apr/28/2021

Form: DATE OF VISIT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit

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

COVID-19 Surveillance Visit

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

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001**Visit:** V202_SURVEIL_SWAB 2 -
Unscheduled Visit on Apr/28/2021**Form Version:** 10-Oct-2020 15:57**Site No:** 1009**Subject No:** 10091382**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT
SWAB**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family
Clinic South**Subject Initials:** ---**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Apr/28/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[AA45779]
-----	-----------	-----------

Header Text: c4591001

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

Form: DATE OF VISIT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit

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

COVID-19 Surveillance Visit

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK6
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090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001**Visit:** V202_SURVEIL_SWAB 3 -
Unscheduled Visit on May/12/2021**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT
SWAB**Form Version:** 10-Oct-2020 15:57**Form Status:** Data Complete, Frozen, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family
Clinic South**Subject No:** 10091382**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[AA45780]
-----	-----------	-----------

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 10-Dec-2020 02:27

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Treatment Unblinded

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091382

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): 10-Nov-2021 20:44

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: V101_VAX3

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	May/14/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained May/14/2021
----	--------------	--

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 28-Mar-2021 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation/Death :	May/14/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 30-Apr-2021 01:41

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	May/14/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	NEGATIVE
	Not Done:	

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: May/14/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRTSSS]
5.b	Sample ID	[BTLHCB]
5.c	Sample ID	[BTLHC9]

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001**Visit:** V101_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject No:** 10091382**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: May/14/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BTLH7P]
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Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1009

Subject No: 10091382

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): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	May/14/2021 09:08
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

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

Header Text: c4591001

Visit: V102_VAX4

Form Version: 30-Apr-2021 01:41

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Jun/2/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	NEGATIVE
	Not Done:	

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001**Visit:** V102_VAX4**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject No:** 10091382**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BTLH8Y]
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Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1009

Subject No: 10091382

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): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jun/2/2021 09:54
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091382

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): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

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

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Contact Outcome

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

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091382

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): 10-Nov-2021 20:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

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

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091382

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): 10-Nov-2021 20:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

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

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit:
FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Disposition - Treatment

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Feb/25/2021

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

[Audit Trail](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
------	----------------------	------	------	--------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Version: 10-Oct-2020 16:00

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-04-2021 16:49:21 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
Form	May-21-2021 10:52:11 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
1	May-21-2021 10:52:11 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
2	May-21-2021 10:52:11 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
3	May-21-2021 10:52:11 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
4	May-21-2021 10:52:11 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5	May-21-2021 10:52:11 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
6	May-21-2021 10:52:11 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
7	May-21-2021 10:52:11 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
8	May-21-2021 10:52:11 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
9	May-21-2021 10:52:11 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB - Comments

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: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	May-21-2021 10:52:50 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	
Form	May-20-2021 09:56:23 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

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: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
1	May-21-2021 10:52:50 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	
1	May-20-2021 09:56:23 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

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: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
2	May-21-2021 10:52:50 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	
2	May-20-2021 09:56:23 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

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: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
3	May-21-2021 10:52:50 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	
3	May-20-2021 09:56:23 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

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: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
4	May-21-2021 10:52:50 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	
4	May-20-2021 09:56:23 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Jul-06-2021 08:16:55 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
1	Jul-06-2021 08:16:55 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
2	Jul-06-2021 08:16:55 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form Version: 06-Jul-2020 21:54

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: MICROBIOLOGY SPECIMEN - Comments

Form Status: Data Complete

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
3	Jul-06-2021 08:16:55 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
4	Jul-06-2021 08:16:55 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
5	Jul-06-2021 08:16:55 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
6	Jul-06-2021 08:16:55 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
7	Jul-06-2021 08:16:55 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
8	Jul-06-2021 08:16:55 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
9	Jul-06-2021 08:16:55 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

Form Version: 28-Mar-2021 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	May-14-2021 10:23:08 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Apr-20-2021 09:42:22 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

(b) (6)	Approved	Apr-13-2021 18:55:07 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, (b) (6) verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

(b) (6)	N/A	Apr-07-2021 17:17:29 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

Affidavit:

N/A

(b) (6)	Approved	Mar-11-2021 21:49:21 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, (b) (6) verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Jan-04-2021 16:48:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 01 DEC 2020	Initial Entry

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

Date	Location	User	Value	Reason
Jan-04-2021 16:48:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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1. Consent Was:

Date	Location	User	Value	Reason
Jan-04-2021 16:48:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Jan/4/2021	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 10-Dec-2020 02:26

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Subject ID

Date	Location	User	Value	Reason
Jan-04-2021 16:48:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 10091382	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Jan-04-2021 16:48:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: (b) (6) 2006	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Jan-04-2021 16:49:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Jan-04-2021	ACV0PF	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

16:49:04 (UTC-07:00) Mountain Time (US & Canada)	EINFP60 00	(b) (4), (b) (6)	HISPANIC OR LATINO(A) OR OF SPANISH ORIGI N
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5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Jan-04-2021 16:49:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-04-2021 16:49:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jan/4/2021	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Jan-04-2021 16:49:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jan/4/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-04-2021 16:49:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-04-2021 16:49:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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1.a

Date	Location	User	Value	Reason
Jan-04-2021 16:51:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: ANXIETY Start Date: UNK/UNK /2018 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Jan-04-2021 16:51:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Jan-04-2021 16:51:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: ANXIETY	Initial Entry

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

1.a Start Date:

Date	Location	User	Value	Reason
Jan-04-2021 16:51:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: UNK/UNK/2018	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Jan-04-2021 16:51:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Jan-04-2021 16:55:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Line/MH Num 2 ber: Medical Histor CELIAC DI y Term: SEASE Start Date: UNK/UNK/ 2013 Ongoing: YES	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

1.b Line/MH Number:

Date	Location	User	Value	Reason
Jan-04-2021 16:55:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Jan-05-2021 13:22:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-05-2021 11:09:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	they have not received exclusionary medication
Jan-05-2021 10:25:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	GPD Clin: Please confirm if participant has/has not received systemic corticosteroids or immunosuppressants (eg. azathioprine) for refractory Celiac Disease.

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

Jan-04-2021 16:55:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: CELIAC DISEASE	Initial Entry
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1.b Start Date:

Date	Location	User	Value	Reason
Jan-04-2021 16:55:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: UNK/UNK/2013	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Jan-04-2021 16:55:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Jan-04-2021 16:55:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: The subject is NOT known to be HIV POSITIVE	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date:

Date	Location	User	Value	Reason
Jan-04-2021 16:55:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jan/4/2021	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Jan-04-2021 16:55:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 156.2	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Jan-04-2021 16:55:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: LB	Initial Entry

4. Height:

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jan-04-2021 16:55:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 63.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Jan-04-2021 16:55:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Jan-04-2021 16:55:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 27.7	Initial Entry

7.a

Date	Location	User	Value	Reason
Jan-04-2021 16:55:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Record Identifier::	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)			Temperature: 98.1 Temperature Unit: F Temperature Location:: ORAL CA VITY	
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7.a Record Identifier:

Date	Location	User	Value	Reason
Jan-04-2021 16:55:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Jan-04-2021 16:55:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 98.1	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Jan-04-2021 16:55:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: F	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)

7.a Temperature Location:

Date	Location	User	Value	Reason
Jan-04-2021 16:55:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Jan-04-2021 16:56:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Jan-04-2021 16:56:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-04-2021 16:56:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jan/4/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

Jan-04-2021 16:56:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry
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5. Specimen Type:

Date	Location	User	Value	Reason
Jan-04-2021 16:56:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Jan-04-2021 16:56:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Sponsor-Def 113 ined Identifier: Test:: Choriogonadotropin Beta_PX 113 Result:: NEGATIVE Not Done::	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-04-2021 16:56:03 (UTC-07:00)	ACV0PF EINFP60	auto calc (autocalc)	Data Entry: 113	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

Mountain Time (US
& Canada)

00

6.a Test:

Date	Location	User	Value	Reason
Jan-04-2021 16:56:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_P X113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Jan-04-2021 16:56:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Randomization Date :

Date	Location	User	Value	Reason
Jan-04-2021 16:56:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jan/4/2021	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Jan-04-2021 16:56:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 24808	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Data Origin

Date	Location	User	Value	Reason
Jan-04-2021 16:58:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-04-2021 16:58:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-04-2021 16:58:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-04-2021 16:58:18 (UTC-07:00) Mountain Time (US	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)				entered. Please review and correct as appropriate.
Jan-04-2021 16:58:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/4/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-04-2021 16:58:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BR5BNH	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-04-2021 16:58:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BR5BNH	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

Jan-04-2021 16:58:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BSJ3R2	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Jan-04-2021 16:58:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BSJ3R2	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-04-2021 16:59:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BR5BNG	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

5.c Sample ID

Date	Location	User	Value	Reason
Jan-04-2021 16:59:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: BR5BNG	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Data Origin

Date	Location	User	Value	Reason
Jan-04-2021 16:57:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-04-2021 16:57:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-04-2021 16:57:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-04-2021 16:57:46 (UTC-07:00) Mountain Time (US	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)				entered. Please review and correct as appropriate.
Jan-04-2021 16:57:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/4/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-04-2021 16:57:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BGH063	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-04-2021 16:57:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BGH063	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:26

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-04-2021 16:56:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-04-2021 16:56:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-04-2021 16:56:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Jan-04-2021	ACV0PF	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

16:56:39 (UTC-07:00) Mountain Time (US & Canada)	EINFP60 00	(b) (4), (b) (6)	Jan/4/2021 16:30	
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5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-04-2021 16:56:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jan-25-2021 17:34:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: LEFT	Transcription Error
Jan-04-2021 16:56:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jan-04-2021 16:56:39 (UTC-07:00)	ACV0PF EINFP60	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

Mountain Time (US & Canada)	00			
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10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-04-2021 16:56:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Jan-04-2021 16:56:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Jan-04-2021 16:56:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES - REACTOGENICIT Y E-DIARY COLLECTED FOR THIS SUBJECT	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-25-2021 17:05:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Jan/25/2021	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Jan-25-2021 17:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-25-2021 17:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Symptom:: FE V ER Were fever or systemic N symptoms present on t O he last day the Subject Diary was completed?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Jan-25-2021 17:05:59 (UTC-07:00)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: FEVER	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

Mountain Time (US & Canada)

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

Date	Location	User	Value	Reason
Jan-25-2021 17:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Jan-25-2021 17:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI GU E Were fever or systemic symptoms present on the last day the Subject Diary was completed? NO : :	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

2.b Symptom:

Date	Location	User	Value	Reason
Jan-25-2021 17:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Jan-25-2021 17:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Jan-25-2021 17:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: HE AD AC HE	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Jan-25-2021 17:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Jan-25-2021 17:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Jan-25-2021 17:05:59 (UTC-07:00)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: C HI	Initial Entry

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

Mountain Time (US & Canada)			LL S N O	
Were fever or systemic symptoms present on the last day the Subject Diary was completed?:				

2.d Symptom:

Date	Location	User	Value	Reason
Jan-25-2021 17:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Jan-25-2021 17:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Jan-25-2021 17:05:59	ACV0PF EINFP60	(b) (4), (b) (6)	Data Entry: Symptom:: VO	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-07:00) Mountain Time (US & Canada)	00	(b) (4), (b) (6)	MI TIN G	Were fever or systemi c symptoms present o n the last day the Sub ject Diary was comple ted?:	
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2.e Symptom:

Date	Location	User	Value	Reason
Jan-25-2021 17:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Jan-25-2021 17:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
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090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

Jan-25-2021 17:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: DI AR RH EA Were fever or systemi c symptoms present o n the last day the Subj ect Diary was complet ed?:	Initial Entry
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2.f Symptom:

Date	Location	User	Value	Reason
Jan-25-2021 17:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Jan-25-2021 17:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Feb-01-2021 12:23:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Symptom:: NEW OR WORSENER MUSCLE PAIN</p> <p>Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO</p>	entered DCF to change data. Muscle pain should be entered as an AE of knee pain
Jan-25-2021 17:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Symptom:: NEW OR WORSENER MUSCLE PAIN</p> <p>Were fever or systemic symptoms present on the last day the Subject Diary was completed?: YES Ongoing ? YES</p>	Initial Entry

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

2.g Symptom:

Date	Location	User	Value	Reason
Jan-25-2021 17:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERD MU SCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Feb-02-2021 05:25:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Trial Max data updated.
Feb-01-2021 12:23:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Answered	entered DCF to change data. Muscle pain should be entered as an AE of knee pain
Feb-01-2021 12:23:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	entered DCF to change data. Muscle pain should be entered as an AE of knee pain

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

<p>Feb-01-2021 07:18:53 (UTC-07:00) Mountain Time (US & Canada)</p>	<p>ACV0PF EINFP60 00</p>	<p>(b) (4), (b) (6)</p>	<p>Query 1: Reissued:Opened</p>	<p>eDiary RQ: Per Diary records, MUSCLE PAIN is not ongoing on 25Jan21 which is Day 1 of VAX2. Please reconcile and update as stop date. Else, clarify in query response. Thanks.</p>
<p>Jan-29-2021 14:41:46 (UTC-07:00) Mountain Time (US & Canada)</p>	<p>ACV0PF EINFP60 00</p>	<p>(b) (4), (b) (6)</p>	<p>Query 1: Answered</p>	<p>correct as is. ongoing at visit 2</p>
<p>Jan-27-2021 05:16:49 (UTC-07:00) Mountain Time (US & Canada)</p>	<p>ACV0PF EINFP60 00</p>	<p>(b) (4), (b) (6)</p>	<p>Query 1: Opened</p>	<p>eDiary: Per Diary records, 'NEW OR WORSENER MUSCLE PAIN' reported post Vaccination 1 is not ongoing through Vaccination 2. Please reconcile and consider to update stop date</p>

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

				here. Else, clarify in query response. Thanks.
Jan-25-2021 17:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Ongoing? YES	Initial Entry

2.h

Date	Location	User	Value	Reason
Jan-25-2021 17:13:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: NEW O R WOR SENE JOINT P AIN Were fever or syst NO emic symptoms p resent on the last day the Subject D iary was complete d?:	Initial Entry
Jan-25-2021 17:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: NEW O R WOR SENE	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

			JOINT PAIN	
			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	

2.h Symptom:

Date	Location	User	Value	Reason
Jan-25-2021 17:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR WORSENER JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Jan-25-2021 17:13:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
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090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

Jan-25-2021 17:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry
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4. Injection Site Body Side:

Date	Location	User	Value	Reason
Jan-26-2021 06:35:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-25-2021 17:13:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	correct as is
Jan-25-2021 17:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Opened	Injection Site Body Side entered on this page is not matching with Body Side entered on Vaccination page of VID1VX1L. Please review and update as appropriate.

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

Jan-25-2021 17:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: LEFT	Initial Entry
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5.a

Date	Location	User	Value	Reason
Jan-25-2021 17:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: Injection Site Reaction: RE DN ES S Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Jan-25-2021 17:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
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090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

Jan-25-2021 17:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: NO	Initial Entry
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5.b

Date	Location	User	Value	Reason
Jan-25-2021 17:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Injection Site Reaction: SW ELL ING Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Jan-25-2021 17:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Jan-25-2021 17:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-25-2021 17:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: PAIN AT INJECTION SITE	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Jan-25-2021 17:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Jan-25-2021 17:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 14-Jan-2021 02:22

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date:

Date	Location	User	Value	Reason
Jan-25-2021 17:06:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jan/25/2021	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-25-2021 17:06:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Record Identifier: 1 Temperature: 97.1 Temperature Unit: F Temperature Location: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jan-25-2021 17:06:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 14-Jan-2021 02:22

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

2.a Temperature:

Date	Location	User	Value	Reason
Jan-25-2021 17:06:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: 97.1	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Jan-25-2021 17:06:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Jan-25-2021 17:06:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: ORAL CAVITY	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Jan-25-2021 17:07:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Jan-25-2021 17:07:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-25-2021 17:07:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Jan/25/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

Jan-25-2021 17:07:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry
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5. Specimen Type:

Date	Location	User	Value	Reason
Jan-25-2021 17:07:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Jan-25-2021 17:07:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Sponsor-Def 113 ined Identifier: Test:: Choriogonadotropin Beta_PX 113 Result:: NEGATIVE Not Done::	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-25-2021 17:07:01 (UTC-07:00)	ACV0PF EINFP60	auto calc (autocalc)	Data Entry: 113	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

Mountain Time (US & Canada)	00			
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6.a Test:

Date	Location	User	Value	Reason
Jan-25-2021 17:07:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Choriogonadotropin Beta_P X113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Jan-25-2021 17:07:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: NEGATIVE	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Data Origin

Date	Location	User	Value	Reason
Jan-25-2021 17:09:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-25-2021 17:09:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-25-2021 17:09:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-25-2021 17:09:09 (UTC-07:00) Mountain Time (US	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)				entered. Please review and correct as appropriate.
Jan-25-2021 17:09:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: YES Date of Collection: Jan/25/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-25-2021 17:09:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Sample ID: BR9FBK	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-25-2021 17:09:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: BR9FBK	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-25-2021 17:09:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-25-2021 17:09:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-25-2021 17:09:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Jan-25-2021	ACV0PF	(b) (4), (b) (6) [Redacted]	Data Entry:	Initial Entry

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

17:09:54 (UTC-07:00) Mountain Time (US & Canada)	EINFP60 00	(b) (4), (b) (6)	Jan/25/2021 16:17	
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5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-25-2021 17:09:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jan-25-2021 17:09:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jan-25-2021 17:09:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jan-25-2021 17:09:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Jan-25-2021 17:09:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: YES	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

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

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

Site No: 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382 **Subject Initials:** ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-28-2021 23:48:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-26-2021 14:29:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Feb-26-2021 03:24:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	DM: The treatment period is defined as 1st vaccination visit through the 1-month post vaccination visit after the 2nd vaccination. Please complete treatment disposition CRF and update date of EOT to match date of visit at visit 3.

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

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

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

Site No: 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382 **Subject Initials:** ---

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

Feb-25-2021 16:24:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: Feb/25/2021	Initial Entry
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090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject No:** 10091382**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Feb-25-2021 16:24:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Feb-25-2021 16:24:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: FE V ER Were fever or systemi N c symptoms present o O n the last day the Subj ect Diary was complet ed?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Feb-25-2021 16:24:41	ACV0PF EINFP60	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

Header Text: c4591001

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

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

Site No: 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382 **Subject Initials:** ---

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

(UTC-07:00) Mountain Time (US & Canada)	00	(b) (4), (b) (6)		
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2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-25-2021 16:24:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Feb-25-2021 16:24:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI GU E Were fever or systemi c symptoms present o n the last day the Sub ject Diary was comple ted?: NO	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

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

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

Site No: 1009 Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382 Subject Initials: ---

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

2.b Symptom:

Date	Location	User	Value	Reason
Feb-25-2021 16:24:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(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
Feb-25-2021 16:24:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Feb-25-2021 16:24:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: HE AD AC HE	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

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

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

Site No: 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382 **Subject Initials:** ---

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

			Were fever or system NO ic symptoms present on the last day the Su bject Diary was com pleted?:	
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2.c Symptom:

Date	Location	User	Value	Reason
Feb-25-2021 16:24:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Feb-25-2021 16:24:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Feb-25-2021 16:24:41 (UTC-07:00)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: C HI	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

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

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

Site No: 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382 **Subject Initials:** ---

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

Mountain Time (US & Canada)			LL S N O N O N O	
Were fever or systemic symptoms present on the last day the Subject Diary was completed?:				

2.d Symptom:

Date	Location	User	Value	Reason
Feb-25-2021 16:24:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Feb-25-2021 16:24:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
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090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

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

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

Site No: 1009 Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382 Subject Initials: ---

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

Feb-25-2021 16:24:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: VO MI TIN G Were fever or system NO ic symptoms present on the last day the Su bject Diary was com pleted?:	Initial Entry
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2.e Symptom:

Date	Location	User	Value	Reason
Feb-25-2021 16:24:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Feb-25-2021 16:24:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

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

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

Site No: 1009 Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382 Subject Initials: ---

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

Date	Location	User	Value	Reason
Feb-25-2021 16:24:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: DI AR RH EA Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.f Symptom:

Date	Location	User	Value	Reason
Feb-25-2021 16:24:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Feb-25-2021 16:24:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

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

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

Site No: 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382 **Subject Initials:** ---

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

2.g

Date	Location	User	Value	Reason
Feb-25-2021 16:24:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: NEW O R WOR SENED MUSCL E PAIN Were fever or sy NO stemic symptoms present on the la st day the Subjec t Diary was com pleted?:	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

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

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

Site No: 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382 **Subject Initials:** ---

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

2.g Symptom:

Date	Location	User	Value	Reason
Feb-25-2021 16:24:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERD M USCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Feb-25-2021 16:24:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Feb-25-2021 16:24:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: NEW O R WOR SENERD JOINT PAIN	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

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

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

Site No: 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382 **Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Feb-25-2021 16:24:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR WORSEMENT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Feb-25-2021 16:24:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Feb-25-2021 16:24:41	ACV0PF EINFP60	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

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

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

Site No: 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382 **Subject Initials:** ---

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

(UTC-07:00) Mountain Time (US & Canada)	00			
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4. Injection Site Body Side:

Date	Location	User	Value	Reason
Feb-25-2021 16:24:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-25-2021 16:24:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: RE DN ES S Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
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090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

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

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

Site No: 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382 **Subject Initials:** ---

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

Feb-25-2021 16:24:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry
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5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-25-2021 16:24:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-25-2021 16:24:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: SW ELL ING Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

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

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

Site No: 1009 Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382 Subject Initials: ---

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

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Feb-25-2021 16:24:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Feb-25-2021 16:24:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-25-2021 16:24:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction: PAIN AT INJECTION SITE	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

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

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

Site No: 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382 **Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Feb-25-2021 16:24:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Feb-25-2021 16:24:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

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

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

Site No: 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382 **Subject Initials:** ---

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

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1. Data Origin

Date	Location	User	Value	Reason
Feb-25-2021 16:24:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-25-2021 16:24:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-25-2021 16:26:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-25-2021 16:24:53	ACV0PF EINFP60	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

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

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

Site No: 1009 Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382 Subject Initials: ---

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

(UTC-07:00) Mountain Time (US & Canada)	00			Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-25-2021 16:24:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/25/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-25-2021 16:26:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BR622B	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-25-2021 16:26:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BR622B	Initial Entry

5.b

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

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

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

Site No: 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382 **Subject Initials:** ---

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

Date	Location	User	Value	Reason
Feb-25-2021 16:26:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BR6229	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-25-2021 16:26:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BR6229	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-25-2021 16:26:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BSJ4CV	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

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

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

Site No: 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382 **Subject Initials:** ---

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

5.c Sample ID

Date	Location	User	Value	Reason
Feb-25-2021 16:26:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BSJ4CV	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: DATE OF VISIT - ILLNESS ONSET - 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: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Visit

Date	Location	User	Value	Reason
May-24-2021 03:02:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
May-21-2021 10:52:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 3: Answered	Changed data per query
May-21-2021 04:35:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 3: Opened	DM: Kindly review and complete 'Microbiology Specimen at this visit. Thank you.
May-20-2021 12:12:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
May-20-2021 09:55:27 (UTC-07:00)	ACV0PF EINFP60 00	auto query (autoquery)	Query 2: Deleted	Close Auto Query

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: DATE OF VISIT - ILLNESS ONSET - 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: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

Mountain Time (US & Canada)				
May-20-2021 09:54:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	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.
May-20-2021 09:54:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	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.
May-20-2021 09:54:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: May/19/2021	Initial Entry

3. COVID-19 Illness Visit:

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: DATE OF VISIT - ILLNESS ONSET - 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): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
May-20-2021 09:54:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form Version: 30-Apr-2021 01:47

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Status: Data Complete, Not Complete

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

Subject Initials: ---

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

[Back to Form](#)

1. Date of Assessment:

Date	Location	User	Value	Reason
Jul-20-2021 01:00:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jul-13-2021 15:23:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Jul-05-2021 03:41:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Reissued:Opened	CLINQUERY: Thanks. Please enter NEW OR INCREASED MUSCLE PAIN, Dizziness, Rhinorrhea and Nausea in the AE log. The following should also be deleted from the SOD CRF: Dizziness, Rhinorrhea and Nausea.

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form Version: 30-Apr-2021 01:47

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Status: Data Complete, Not Complete

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

Subject Initials: ---

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

Jun-28-2021 14:32:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Query 1: Answered	Changed data per query
Jun-28-2021 10:59:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Query 1: Reissued:Opened	CLIQUERY: Please retain all other CRF data for this illness visit. Only NEW OR INCREASED SORE THROAT should be captured in the SOD CRF, whereas NEW OR INCREASED MUSCLE PAIN, Dizziness, Rhinorrhea and Nausea should be captured in the AE log.
Jun-25-2021 08:58:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Query 1: Answered	should all crfs be deleted since the symptoms will be captured as AEs?
Jun-21-2021	ACV0PF	(b) (4), (b) (6) [REDACTED]	Query 1: Reissued:Opened	CLIQUERY:

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 30-Apr-2021 01:47

Form Status: Data Complete, Not Complete

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

09:52:51 (UTC-07:00) Mountain Time (US & Canada)	EINFP60 00	(b) (4), (b) (6) [REDACTED]		Since NEW OR INCREASED MUSCLE PAIN, Dizziness, Rhinorrhea and Nausea are related to Vaccine reactogenicity, please report these in the AE log and remove these symptoms from the COVID Illness SOD CRF form.
Jun-15-2021 12:43:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Query 1: Answered	vaccine reactogenicity
Jun-15-2021 02:23:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	CLINQUERY: SOD are reported within 7 days of V101_VAX (14May2021) therefore please confirm if symptoms are related to COV ILL or Vaccine

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 30-Apr-2021 01:47

Form Status: Data Complete, Not Complete

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

				reactogenicity? If considered related to Vaccine reactogenicity please move symptom to AE CRF
May-20-2021 09:55:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: May/19/2021	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
May-20-2021 09:55:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: May/15/2021	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Jun-16-2021 14:16:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
 Unscheduled Visit on May/19/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
 COVID-19 - eCRF Audit Trail History

Form Version: 30-Apr-2021 01:47

Form Status: Data Complete, Not Complete

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

Jun-16-2021 14:16:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Res olved: May/20/2021	Transcription Error
Jun-16-2021 14:16:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Opened	Last Symptom Resolved date is a future date compared to when it was entered. Please correct.
Jun-16-2021 14:16:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Res olved: Jun/20/2021	New Information
May-20-2021 09:55:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.a

Date	Location	User	Value	Reason
May-20-2021 09:55:27 (UTC-07:00)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms: FEVER	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 30-Apr-2021 01:47

Form Status: Data Complete, Not Complete

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

Mountain Time (US & Canada)			Symptom Present: NO	
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4.a Symptoms:

Date	Location	User	Value	Reason
May-20-2021 09:55:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
May-20-2021 09:55:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
May-20-2021 09:55:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCR s: EASED COUGH Symptom NO Present:	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form Version: 30-Apr-2021 01:47

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Status: Data Complete, Not Complete

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

Subject Initials: ---

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

4.b Symptoms:

Date	Location	User	Value	Reason
May-20-2021 09:55:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED CO UGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
May-20-2021 09:55:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
May-20-2021 09:55:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREA SED SHORTNESS OF BREATH Symptom Present: NO	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form Version: 30-Apr-2021 01:47

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Status: Data Complete, Not Complete

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

Subject Initials: ---

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

4.c Symptoms:

Date	Location	User	Value	Reason
May-20-2021 09:55:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SHO RTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
May-20-2021 09:55:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
May-20-2021 09:55:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
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Form: SIGNS AND SYMPTOMS OF POTENTIAL
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Form Status: Data Complete, Not Complete

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

4.d Symptoms:

Date	Location	User	Value	Reason
May-20-2021 09:55:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
May-20-2021 09:55:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Jun-28-2021 14:31:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCR ms: EASED MUSCL E PAIN Symptom NO m Present:	per edc query
May-20-2021 09:55:27	ACV0PF EINFP60	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCR	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

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Form Status: Data Complete, Not Complete

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-07:00) Mountain Time (US & Canada)	00		ms: EASED MUSCL E PAIN	
			Sympto YES m Prese nt:	

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form Version: 30-Apr-2021 01:47

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Status: Data Complete, Not Complete

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

Subject Initials: ---

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

4.e Symptoms:

Date	Location	User	Value	Reason
May-20-2021 09:55:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED MU SCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Jun-28-2021 14:31:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (4), (b) (6)	Data Entry: NO	per edc query
Jun-02-2021 13:18:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jun-02-2021 11:23:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	all symptoms are considered part of the potential covid illness which was captured per investigator discretion. We do not want to split up symptoms and say that some of them are due to vaccine and others are not.

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 30-Apr-2021 01:47

Form Status: Data Complete, Not Complete

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

				We will keep the muscle pain here
May-28-2021 07:57:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Reissued: Opened	CLINQUERY: OK. In this case, NEW OR INCREASED MUSCLE PAIN on this COV ILL SOD CRF can be updated to NO since this symptom considered vaccine related. And then add NEW OR INCREASED MUSCLE PAIN on AE LOG.
May-27-2021 15:59:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	per pi this symptom is most likely vaccine related, however they were instructed to collect a nasal swab due to being seen at their pcp for strep throat
May-27-2021 13:19:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: MUSCLE PAIN reported within 7 days of V101_VAX3(14May2021) therefore please confirm if symptoms are related to COV ILL or Vaccine reactogenicity? If considered related to COV ILL, no updates needed.

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 30-Apr-2021 01:47

Form Status: Data Complete, Not Complete

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

May-20-2021 09:55:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: YES	Initial Entry
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4.f

Date	Location	User	Value	Reason
May-20-2021 09:55:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: Symptoms: NEW LOSS OF TASTE OR SMELL L Symptom Present: NO	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

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Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Status: Data Complete, Not Complete

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

Subject Initials: ---

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

4.f Symptoms:

Date	Location	User	Value	Reason
May-20-2021 09:55:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
May-20-2021 09:55:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
May-20-2021 09:55:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCRE ASED SORE TH ROAT Symptom Present: YES	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form Version: 30-Apr-2021 01:47

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Status: Data Complete, Not Complete

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

Subject Initials: ---

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

4.g Symptoms:

Date	Location	User	Value	Reason
May-20-2021 09:55:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SOR E THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
May-20-2021 09:55:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.h

Date	Location	User	Value	Reason
May-20-2021 09:55:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHE A Symptom Present: NO nt:	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form Version: 30-Apr-2021 01:47

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Status: Data Complete, Not Complete

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

Subject Initials: ---

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

4.h Symptoms:

Date	Location	User	Value	Reason
May-20-2021 09:55:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
May-20-2021 09:55:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
May-20-2021 09:55:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms: VOMITIN G Symptom Present: NO nt:	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 30-Apr-2021 01:47

Form Status: Data Complete, Not Complete

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

4.i Symptoms:

Date	Location	User	Value	Reason
May-20-2021 09:55:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
May-20-2021 09:55:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Jul-13-2021 15:22:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms - Other:	Transcription Error
May-20-2021 09:55:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms - Other: dizziness	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 30-Apr-2021 01:47

Form Status: Data Complete, Not Complete

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Jul-13-2021 15:22:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry:	Transcription Error
May-20-2021 09:55:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: dizziness	Initial Entry

5.b

Date	Location	User	Value	Reason
Jul-13-2021 15:22:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms - Other:	Transcription Error
May-24-2021 08:44:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms - Oth rhinorrhe er: a	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 30-Apr-2021 01:47

Form Status: Data Complete, Not Complete

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

5.b Symptoms - Other Text:

Date	Location	User	Value	Reason
Jul-13-2021 15:22:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry:	Transcription Error
May-24-2021 08:44:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: rhinorrhea	Initial Entry

5.c

Date	Location	User	Value	Reason
Jul-13-2021 15:23:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms - Other:	Transcription Error
May-24-2021 08:44:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms - Other: nausea	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form Version: 30-Apr-2021 01:47

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Status: Data Complete, Not Complete

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

Subject Initials: ---

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

5.c Symptoms - Other Text:

Date	Location	User	Value	Reason
Jul-13-2021 15:23:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry:	Transcription Error
May-24-2021 08:44:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: nausea	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
May-21-2021 10:52:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
May-21-2021 10:52:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
May-21-2021 10:52:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Assay Code and Description:

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
May-21-2021 10:52:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
May-21-2021 10:52:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
May-21-2021 10:52:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
May-21-2021 10:52:11 (UTC-07:00)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

Mountain Time (US
& Canada)

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
May-21-2021 10:52:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
May-21-2021 10:52:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF - 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): 10-Nov-2021 20:44

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1. Data Origin

Date	Location	User	Value	Reason
May-20-2021 12:12:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
May-20-2021 12:12:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
May-20-2021 12:12:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
May-20-2021 12:12:16	ACV0PF EINFP60	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF - 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: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-07:00) Mountain Time (US & Canada)	00			Yes, however no barcodes are entered. Please review and correct as appropriate.
May-20-2021 12:12:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: May/19/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
May-20-2021 12:12:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: RR11673	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
May-20-2021 12:12:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: RR11673	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091382

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): 10-Nov-2021 20:44

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1. Data Origin

Date	Location	User	Value	Reason
May-21-2021 10:53:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry
May-21-2021 10:52:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry:	Initial Entry
May-20-2021 09:56:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
May-21-2021 10:53:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

May-21-2021 10:52:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry:	Initial Entry
May-20-2021 09:56:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
May-22-2021 00:16:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00.InFor mAdapte r.Discrep ancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_BEETRK001_07
May-21-2021 10:53:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Answer ed	Initial Entry
May-21-2021 10:53:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021**Form:** ELECTRONIC SAMPLE TRACKING - NASAL
SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family
Clinic South**Subject No:** 10091382**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44

May-21-2021 10:52:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry:	Initial Entry
May-21-2021 00:26:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00.InFor mAdapte r.Discrep ancy	DMW QUERY (b) (4) [REDACTED]	Query 1: Opened	DMW9472663;Sample Collected is not expected to be Not Done. If the sample was not collected then please mark 'Sample collected' as 'NO' and provide the reason sample was not done in field 'If no sample was collected.....' of this page. Thank you.
May-20-2021 09:56:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

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

Date	Location	User	Value	Reason
May-21-2021 10:53:14 (UTC-07:00) Mountain Time (US	ACV0PF EINFP60 00	(b) [REDACTED] (4), [REDACTED] (b) (6) [REDACTED]	Data Entry: self swab collected	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)				
May-21-2021 10:52:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry:	Initial Entry
May-20-2021 09:56:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021**Form Version:** 30-Apr-2021 01:37**Site No:** 1009**Subject No:** 10091382**Generated By:** (b) (4)**Form:** HEALTH CARE UTILIZATION - 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):** 10-Nov-2021 20:44[Back to Form](#)*1.a*

Date	Location	User	Value	Reason
May-20-2021 09:57:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry
May-20-2021 09:57:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts:	Initial Entry

1.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
May-20-2021 09:57:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: SPECIALIST	Initial Entry

1.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
May-20-2021	ACV0PF	(b) (4), (b) (6) [REDACTED]	Data Entry:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 30-Apr-2021 01:37

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

09:57:34 (UTC-07:00) Mountain Time (US & Canada)	EINFP60 00	(b) (4), (b) (6)	NO	
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1.b

Date	Location	User	Value	Reason
May-20-2021 09:57:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Type of Practitioner: EMERGE NCY ROOM Occurrence of Visits or Contacts: NO	Initial Entry
May-20-2021 09:57:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Type of Practitioner: EMERGE NCY ROOM Occurrence of Visits or Contacts:	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 30-Apr-2021 01:37

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
May-20-2021 09:57:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: EMERGENCY ROOM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
May-20-2021 09:57:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.c

Date	Location	User	Value	Reason
May-20-2021 09:57:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Type of Prac PRIMARY C itioner: ARE PHYSIC IAN Occurrence YES of Visits or C <i>Number of V</i> ontacts: <i>isits or Cont</i> <i>acts:</i> 1	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 30-Apr-2021 01:37

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
May-20-2021 09:57:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PHYSICI AN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
May-20-2021 09:57:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES <i>Number of Visits or Contact s:</i> 1	Initial Entry

1.d

Date	Location	User	Value	Reason
May-20-2021 09:57:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Type of Practitio URGEN ner: T CARE Occurrence of Vi NO sits or Contacts:	Initial Entry
May-20-2021 09:57:20 (UTC-07:00)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Type of Practitio URGEN ner: T CARE	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 30-Apr-2021 01:37

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

Mountain Time (US & Canada)			Occurrence of Visits or Contacts:	
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1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
May-20-2021 09:57:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
May-20-2021 09:57:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
May-20-2021 09:57:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 30-Apr-2021 01:37

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

May-20-2021 09:57:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHON E CONSULT ATION Occurrence of Visits or Contacts:	Initial Entry
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I.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
May-20-2021 09:57:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTATI ON	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
May-20-2021 09:57:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.f

Date	Location	User	Value	Reason
May-20-2021 09:57:34	ACV0PF EINFP60	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTH	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 30-Apr-2021 01:37

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-07:00) Mountain Time (US & Canada)	00	(b) (4), (b) (6)	ER Occurrence of Visits or Contacts: NO	
May-20-2021 09:57:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTH ER Occurrence of Visits or Contacts:	Initial Entry

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
May-20-2021 09:57:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
May-20-2021 09:57:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
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090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form Version: 30-Apr-2021 01:37

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: HEALTH CARE UTILIZATION - 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): 10-Nov-2021 20:44

May-20-2021 09:57:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry
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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
May-20-2021 09:57:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILL NESS	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Jun-02-2021 13:12:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jun-02-2021 11:24:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	no, strep test was negative
May-28-2021 07:58:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Per prior site response, subject seen at PCP for strep throat. Was there a diagnosis

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on May/19/2021

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

				made in relation to symptoms reported on SOD CRF?
May-20-2021 09:57:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
May-20-2021 09:57:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: 1	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: DATE OF VISIT - ILLNESS ONSET - 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): 10-Nov-2021 20:44

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1. Date of Visit

Date	Location	User	Value	Reason
Jul-06-2021 08:18:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jul-06-2021 08:16:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Jul-06-2021 08:10:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	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.
Jul-06-2021 08:10:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form: DATE OF VISIT - ILLNESS ONSET - 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: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

				missing. Please review and update as appropriate.
Jul-06-2021 08:10:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jul/2/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Jul-06-2021 08:10:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: COVID_B	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 30-Apr-2021 01:47

Form Status: Data Complete

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Assessment:

Date	Location	User	Value	Reason
Jul-06-2021 08:16:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jul/2/2021	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Jul-06-2021 08:16:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jun/29/2021	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Aug-31-2021 00:26:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-30-2021 16:24:19 (UTC-07:00) Mountain Time (US	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Answered	New Information

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 30-Apr-2021 01:47

Form Status: Data Complete

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)				
Aug-30-2021 16:24:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: NO Date of Last Symptom R esolved: Jul/3/2021	New Information
Aug-30-2021 01:53:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED] [REDACTED]	Query 1: Opened	60 days have passed since the Date of First Symptom Started and Ongoing is YES. Please confirm if symptoms are truly ongoing. Else, please enter Date of Last Symptom Resolved.
Jul-06-2021 08:16:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: YES	Initial Entry

4.a

Date	Location	User	Value	Reason
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090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form Version: 30-Apr-2021 01:47

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

Jul-06-2021 08:16:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry
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4.a Symptoms:

Date	Location	User	Value	Reason
Jul-06-2021 08:16:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Jul-06-2021 08:16:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Jul-06-2021 08:16:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCR s: EASED COUGH Symptom YES Present:	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 30-Apr-2021 01:47

Form Status: Data Complete

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

4.b Symptoms:

Date	Location	User	Value	Reason
Jul-06-2021 08:16:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED CO UGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Jul-06-2021 08:16:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.c

Date	Location	User	Value	Reason
Jul-06-2021 08:16:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom Present: NEW OR INCREA SED SHORTNESS OF BREATH Symptom Present: NO	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form Version: 30-Apr-2021 01:47

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

4.c Symptoms:

Date	Location	User	Value	Reason
Jul-06-2021 08:16:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SH ORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Jul-06-2021 08:16:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Jul-06-2021 08:16:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms: CHILL S Symptom Present NO :	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form Version: 30-Apr-2021 01:47

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

4.d Symptoms:

Date	Location	User	Value	Reason
Jul-06-2021 08:16:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Jul-06-2021 08:16:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Jul-06-2021 08:16:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED MUSCLE PAIN Symptom Present: NO	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 30-Apr-2021 01:47

Form Status: Data Complete

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

4.e Symptoms:

Date	Location	User	Value	Reason
Jul-06-2021 08:16:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED MU SCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Jul-06-2021 08:16:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Jul-06-2021 08:16:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom: NEW LOSS OF TASTE OR SWEET TASTE Symptom Present: NO	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 30-Apr-2021 01:47

Form Status: Data Complete

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

4.f Symptoms:

Date	Location	User	Value	Reason
Jul-06-2021 08:16:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Jul-06-2021 08:16:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Jul-06-2021 08:16:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED SORE THROAT Symptom Present: YES	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 30-Apr-2021 01:47

Form Status: Data Complete

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

4.g Symptoms:

Date	Location	User	Value	Reason
Jul-06-2021 08:16:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SO RE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Jul-06-2021 08:16:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.h

Date	Location	User	Value	Reason
Jul-06-2021 08:16:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHE A Symptom Prese nt: NO	Initial Entry

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 30-Apr-2021 01:47

Form Status: Data Complete

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

4.h Symptoms:

Date	Location	User	Value	Reason
Jul-06-2021 08:16:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Jul-06-2021 08:16:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Jul-06-2021 08:16:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms: VOMITIN G Symptom Prese nt: NO	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 30-Apr-2021 01:47

Form Status: Data Complete

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

4.i Symptoms:

Date	Location	User	Value	Reason
Jul-06-2021 08:16:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Jul-06-2021 08:16:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Jul-06-2021 08:16:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms - Other rhinorrhea	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Jul-06-2021 08:16:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: rhinorrhea	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form Version: 06-Jul-2020 21:54

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Jul-06-2021 08:16:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jul-06-2021 08:16:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Jul-06-2021 08:16:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Jul-06-2021 08:16:55	ACV0PF	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-07:00) Mountain Time (US & Canada)	EINFP60 00	(b) (4), (b) (6)	Not Done	
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5. Device Type:

Date	Location	User	Value	Reason
Jul-06-2021 08:16:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Jul-06-2021 08:16:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Jul-06-2021 08:16:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
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090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form Version: 06-Jul-2020 21:54

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

Jul-06-2021 08:16:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Jul-06-2021 08:16:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF - 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): 10-Nov-2021 20:44

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1. Data Origin

Date	Location	User	Value	Reason
Jul-06-2021 08:18:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jul-06-2021 08:18:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-02-2021 16:14:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Sep-02-2021 08:05:29 (UTC-07:00) Mountain Time (US	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Answered	Changed data per query

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)				
Sep-01-2021 05:07:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM1: Please also add the reason to the specify field as well. Thank you.
Aug-31-2021 11:49:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Answered	PD will be captured
Aug-30-2021 16:24:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 2: Opened	Date of Collection is more than 4 days after Date of Last Symptom Resolved on the Signs and Symptoms form in the same visit. Please review and update as appropriate.
Jul-08-2021 12:13:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jul/8/2021	Transcription Error

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1009**Subject No:** 10091382**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF - 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):** 10-Nov-2021 20:44

Jul-08-2021 12:13:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jul-06-2021 08:18:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jul-06-2021 08:18:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: YES Date of Collection: Jul/2/2021	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2021 08:05:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) [REDACTED] (4), [REDACTED] (b) (6) [REDACTED]	Data Entry: date of collection is more than 4 days after symptom resolution, PD captured	Initial Entry

5.a

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF - 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): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Jul-08-2021 12:13:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: RR23599	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jul-08-2021 12:13:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: RR23599	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091382

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): 10-Nov-2021 20:44

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1. Data Origin

Date	Location	User	Value	Reason
Jul-06-2021 08:18:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jul-06-2021 08:18:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jul-06-2021 08:18:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
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090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091382

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): 10-Nov-2021 20:44

Jul-06-2021 08:18:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: self swab collected	Initial Entry
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Header Text: c4591001**Visit:** POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021**Form Version:** 30-Apr-2021 01:37**Site No:** 1009**Subject No:** 10091382**Generated By:** (b) (4)**Form:** HEALTH CARE UTILIZATION - eCRF Audit
Trail History**Form Status:** Data Complete**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family
Clinic South**Subject Initials:** ---**Generated Time (GMT):** 10-Nov-2021 20:44[Back to Form](#)*1.a*

Date	Location	User	Value	Reason
Jul-06-2021 08:19:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

1.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jul-06-2021 08:19:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

1.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jul-06-2021 08:19:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.b

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 30-Apr-2021 01:37

Form Status: Data Complete

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

Jul-06-2021 08:19:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Type of Practitioner: EMERGE NCY ROO M Occurrence of Visits or Contacts: NO	Initial Entry
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1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jul-06-2021 08:19:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: EMERGENCY ROOM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jul-06-2021 08:19:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.c

Date	Location	User	Value	Reason
Jul-06-2021 08:19:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY C ARE PHYSI CIAN	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 30-Apr-2021 01:37

Form Status: Data Complete

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

			Occurrence of NO f Visits or Co ntacts:	
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1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jul-06-2021 08:19:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PHYSICI AN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jul-06-2021 08:19:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.d

Date	Location	User	Value	Reason
Jul-06-2021 08:19:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Type of Practitio URGEN ner: T CARE Occurrence of Vi NO sits or Contacts:	Initial Entry

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 30-Apr-2021 01:37

Form Status: Data Complete

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jul-06-2021 08:19:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jul-06-2021 08:19:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Jul-06-2021 08:19:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHON E CONSULT ATION Occurrence of Visits or Co ntacts: NO	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 30-Apr-2021 01:37

Form Status: Data Complete

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

I.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jul-06-2021 08:19:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTAT ION	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jul-06-2021 08:19:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.f

Date	Location	User	Value	Reason
Jul-06-2021 08:19:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTH ER Occurrence of Visits NO or Contacts:	Initial Entry
Jul-06-2021 08:19:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTH ER Occurrence of Visits or Contacts:	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 30-Apr-2021 01:37

Form Status: Data Complete

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jul-06-2021 08:19:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jul-06-2021 08:19:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-06-2021 08:19:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jul/02/2021

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Jul-06-2021 08:19:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILL NESS	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Jul-06-2021 08:19:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Jul-06-2021 08:19:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - **Form:** DATE OF VISIT - eCRF Audit Trail History
Unscheduled

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

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Visit

Date	Location	User	Value	Reason
Apr-07-2021 17:17:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	Data Entry: Apr/7/2021	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC
SURVEILLANCE - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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1. Consent Was:

Date	Location	User	Value	Reason
Apr-07-2021 17:17:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtai ned Apr/7/2021	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History
Unscheduled

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: 10091382 **Subject Initials:** ---

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

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1. Data Origin

Date	Location	User	Value	Reason
Apr-07-2021 17:17:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Apr-07-2021 17:17:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Apr-07-2021 17:22:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Apr-07-2021 17:17:51	ACV0PF EINFP60	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-07:00) Mountain Time (US & Canada)	00			Yes, however no barcodes are entered. Please review and correct as appropriate.
Apr-07-2021 17:17:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Apr/7/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Apr-07-2021 17:22:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BR9DND	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Apr-07-2021 17:22:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BR9DND	Initial Entry

5.b

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History
Unscheduled

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: 10091382 **Subject Initials:** ---

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

Date	Location	User	Value	Reason
Apr-07-2021 17:22:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: Sample ID: BR9DNF	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Apr-07-2021 17:22:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: BR9DNF	Initial Entry

5.c

Date	Location	User	Value	Reason
Apr-07-2021 17:23:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: Sample ID: BRTSP7	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sample ID

Date	Location	User	Value	Reason
Apr-07-2021 17:23:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: BRTSP7	Initial Entry

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Apr-07-2021 17:18:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Apr-07-2021 17:18:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Apr-07-2021 17:22:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Apr-07-2021 17:18:09	ACV0PF EINFP60	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-07:00) Mountain Time (US & Canada)	00			Yes, however no barcodes are entered. Please review and correct as appropriate.
Apr-07-2021 17:18:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Apr/7/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Apr-07-2021 17:22:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BR9DTK	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Apr-07-2021 17:22:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BR9DTK	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

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

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

Site No: 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382 **Subject Initials:** ---

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Feb-26-2021 14:29:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Feb/25/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-26-2021 14:29:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Feb-26-2021 14:29:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT - eCRF Audit Trail History
Unscheduled

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

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Visit

Date	Location	User	Value	Reason
May-13-2021 14:43:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: May/13/2021	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

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

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

Site No: 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091382 **Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
May-13-2021 14:44:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
May-13-2021 14:43:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
May-13-2021 14:43:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091382

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): 10-Nov-2021 20:44

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Date	Location	User	Value	Reason
Feb-01-2021 15:12:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Jun-10-2021 09:58:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Jul-13-2021 15:09:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

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Date	Location	User	Value	Reason
Jul-21-2021 08:36:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	removed per query
Jul-13-2021 15:13:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Jul-13-2021 15:14:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Jul-13-2021 15:16:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Jul-13-2021 15:17:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

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Date	Location	User	Value	Reason
Jul-16-2021 12:56:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	captured in ediary therefore removing ae. thank you.
Jul-13-2021 15:20:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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1. Category:

Date	Location	User	Value	Reason
Feb-01-2021 15:12:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-01-2021 15:12:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-01-2021 15:12:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: RIGHT KNEE PAIN	Initial Entry

4. Start Date Time:

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Feb-01-2021 15:12:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jan/10/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-10-2021 03:24:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Mar-08-2021 15:08:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 2: Answered	Changed Information
Mar-08-2021 15:08:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/25/2021 UNK:UNK	Changed Information
Mar-08-2021 10:37:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Opened	Per source knee pain ended 25Jan2021. Please confirm and update if

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

				applicable.
Mar-08-2021 10:36:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Query to be reworded.
Mar-08-2021 10:34:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	Per visit 3 note, knee pain has resolved. Please confirm and update EDC if applicable.
Feb-01-2021 15:12:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-01-2021 15:12:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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
Feb-01-2021 15:12:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Feb-01-2021 15:12:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-01-2021 15:12:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to :	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

			OTHER <i>If Other, specify:</i> DANCING OVERUS E	
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-01-2021 15:12:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-01-2021 15:12:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-01-2021 15:12:13 (UTC-07:00)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: NO	Initial Entry

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

Mountain Time (US & Canada)

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

Date	Location	User	Value	Reason
Mar-08-2021 15:08:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-08-2021 15:08:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Changed Information
Mar-08-2021 15:08:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Opened	For AE RIGHT KNEE PAIN: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Feb-01-2021 15:12:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Feb-01-2021 15:12:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1009

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

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Category:

Date	Location	User	Value	Reason
Jun-10-2021 09:58:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jun-10-2021 09:58:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jun-10-2021 09:58:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: chills	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
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090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Jun-10-2021 09:58:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jun/3/2021 UNK:UNK	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jun-15-2021 12:42:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jun/3/2021 UNK:UNK	Transcription Error
Jun-10-2021 09:58:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jun-10-2021 09:58:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

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090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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
Jun-10-2021 09:58:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Jun-10-2021 09:58:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jun-10-2021 09:58:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jun-10-2021 09:58:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jun-10-2021 09:58:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jun-10-2021 09:58:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
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090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Jun-15-2021 21:29:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00.InFor mAdapte r.Discrep ancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_AE001_35
Jun-15-2021 12:42:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Jun-11-2021 11:51:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00.InFor mAdapte r.Discrep ancy	DMW QUERY (b) (4)	Query 1: Opened	DMW9802848;Response to "What was the outcome of this adverse event?" is 'Recovered/Resolved' or 'Recovered/Resolved with Sequelae' but End Date/Time is missing. Please review and update as appropriate.
Jun-10-2021 09:58:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: RECOVERED/ RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
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090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Jun-10-2021 09:58:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Category:

Date	Location	User	Value	Reason
Jul-13-2021 15:09:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jul-13-2021 15:09:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jul-13-2021 15:09:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: generalized muscle pain	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
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090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Jul-13-2021 15:09:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: May/15/2021 UNK:UNK	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jul-13-2021 15:09:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO End Date Time: May/20/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jul-13-2021 15:09:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
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090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Jul-13-2021 15:09:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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**8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.**

Date	Location	User	Value	Reason
Jul-13-2021 15:09:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jul-13-2021 15:09:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jul-13-2021 15:09:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Jul-13-2021 15:09:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jul-13-2021 15:09:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Jul-13-2021 15:09:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Jul-13-2021 15:09:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

***** THIS REPEATING FORM HAS BEEN DELETED *****

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Jul-13-2021 15:13:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jul-13-2021 15:13:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jul-21-2021 18:14:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Jul-21-2021 08:36:26	ACV0PF EINFP60	auto query (autoquery)	Query 1: Answered	removed per query

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

(UTC-07:00) Mountain Time (US & Canada)	00			
Jul-19-2021 09:56:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	Salim Bouguermouh (b) (4)	Query 4: Closed	Response satisfies query
Jul-19-2021 09:56:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	Salim Bouguermouh (b) (4)	Query 3: Closed	Response satisfies query
Jul-19-2021 09:55:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	Salim Bouguermouh (b) (4)	Query 2: Closed	Response satisfies query
Jul-19-2021 09:55:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	Salim Bouguermouh (b) (4)	Query 1: Reissued:Opened	Pfizer medical monitor: This not correct. Please remove SORE THROAT from the AE page. SORE THROAT is already captured on the SOD form and please should not be captured a second time on the AE page. please review the protocol. Thank you.
Jul-16-2021 12:53:33 (UTC-07:00) Mountain Time (US	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 4: Answered	vaccine was received 5.14.21, symptoms

& Canada)				captured per protocol.
Jul-16-2021 12:53:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) [REDACTED] (4), [REDACTED] (b) (6) [REDACTED]	Query 3: Answered	vaccine was received 5.14.21, symptoms captured per protocol.
Jul-16-2021 12:53:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) [REDACTED] (4), [REDACTED] (b) (6) [REDACTED]	Query 2: Answered	vaccine was received 5.14.21, symptoms captured per protocol.
Jul-16-2021 12:53:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) [REDACTED] (4), [REDACTED] (b) (6) [REDACTED]	Query 1: Answered	vaccine was received 5.14.21, symptoms captured per protocol.
Jul-14-2021 16:23:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	Salim Bouguermouh (b) (4) [REDACTED]	Query 4: Opened	Clin: After 7 days following vaccination, potential COVID-19 symptoms (i.e., fever, chills, new or increased muscle pain, diarrhea, vomiting, cough, shortness of breath, loss of taste/smell, sore throat) should trigger a COVID-19 Visit
Jul-14-2021 16:21:29	ACV0PF EINFP60	Salim Bouguermouh	Query 3: Opened	Clin: During 7 days following

(UTC-07:00) Mountain Time (US & Canada)	00	(b) (4)		vaccination, potential COVID-19 symptoms that do not overlap with specific systemic events (i.e., cough; shortness of breath, loss of taste/smell, sore throat) should trigger a potential COVID-19 illness visit.
Jul-14-2021 16:20:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	Salim Bouguermouh (b) (4)	Query 2: Opened	Clin: During 7 days following vaccination, potential COVID-19 symptoms that overlap with specific systemic events (i.e., fever, chills, new or increased muscle pain, diarrhea, vomiting) should not trigger a COVID-19 Visit unless investigator decision
Jul-14-2021 16:11:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	Salim Bouguermouh (b) (4)	Query 1: Reissued:Opened	Clin: Per Prot Sect 8.1., SORE THROAT do not overlap with specific

				systemic events (ie, fever, chills, new or increased muscle pain, diarrhea, vomiting) and should be captured ONLY on the potential COVID-19 CRF SOD form. Thank you
Jul-14-2021 11:16:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Query 1: Answered	all reactions deemed related to vaccination
Jul-14-2021 09:17:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	Salim Bouguermouh (b) (4) [REDACTED]	Query 1: Opened	Clin: Per Prot Sect 8.3.8., COVID-19 listed symptoms SORE THROAT does not qualify as AE and please should be documented ONLY on the COVID-19 Illness CRF SOD form (already entered on COVID_A Visit) and should not be captured on the AE CRF page. Thank you
Jul-13-2021 15:13:03 (UTC-07:00)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: Sore Throat	Initial Entry

Mountain Time (US & Canada)				
4. Start Date Time:				
Date	Location	User	Value	Reason
Jul-13-2021 15:13:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) [REDACTED] (4), [REDACTED] (b) (6) [REDACTED]	Data Entry: May/15/2021 UNK:UNK	Initial Entry
5. Is the adverse event still ongoing?				
Date	Location	User	Value	Reason
Jul-13-2021 15:13:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) [REDACTED] (4), [REDACTED] (b) (6) [REDACTED]	Data Entry: NO End Date Time: May/20/2021 UNK:UNK	Initial Entry
6. Toxicity Grade:				
Date	Location	User	Value	Reason
Jul-13-2021 15:13:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) [REDACTED] (4), [REDACTED] (b) (6) [REDACTED]	Data Entry: 1	Initial Entry
7. Is the adverse event serious?				
If Yes, NOTIFY PFIZER IMMEDIATELY.				
Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).				
Date	Location	User	Value	Reason
Jul-13-2021 15:13:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) [REDACTED] (4), [REDACTED] (b) (6) [REDACTED]	Data Entry: NO	Initial Entry

& Canada)				
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**8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.**

Date	Location	User	Value	Reason
Jul-13-2021 15:13:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) [redacted] (4), [redacted] (b) (6) [redacted]	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jul-13-2021 15:13:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) [redacted] (4), [redacted] (b) (6) [redacted]	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jul-13-2021 15:13:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) [redacted] (4), [redacted] (b) (6) [redacted]	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jul-13-2021 15:13:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) [redacted] (4), [redacted] (b) (6) [redacted]	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jul-13-2021 15:13:03 (UTC-07:00)	ACV0PF EINFP60	(b) (4), (b) (6) [redacted]	Data Entry: NO	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Mountain Time (US & Canada)	00	(b) (4), (b) (6)		
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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Jul-13-2021 15:13:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Jul-13-2021 15:13:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Category:

Date	Location	User	Value	Reason
Jul-13-2021 15:14:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jul-13-2021 15:14:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 5	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jul-13-2021 15:14:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: dizziness	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
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090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Jul-13-2021 15:14:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: May/15/2021 UNK:UNK	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jul-13-2021 15:14:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO End Date Time: May/16/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jul-13-2021 15:14:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
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090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Jul-13-2021 15:14:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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**8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.**

Date	Location	User	Value	Reason
Jul-13-2021 15:14:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jul-13-2021 15:14:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jul-13-2021 15:14:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Jul-13-2021 15:14:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jul-13-2021 15:14:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Jul-13-2021 15:14:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Jul-13-2021 15:14:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Category:

Date	Location	User	Value	Reason
Jul-13-2021 15:16:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jul-13-2021 15:16:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 6	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jul-19-2021 09:57:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	Salim Bouguermouh (b) (4)	Query 2: Closed	Response satisfies query
Jul-16-2021 12:57:25 (UTC-07:00)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Answered	symptom is also related to reactogenicity per

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Mountain Time (US & Canada)				pi therefore ae, not on SOD page.
Jul-14-2021 16:30:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	Salim Bouguermouh (b) (4)	Query 2: Opened	Pfizer Medical monitor: Part of the query was incorrect - apologies for this misunderstanding. Please move RINORRHEA to back to the potential COVID-19 Visit SOD form. Thank you
Jul-14-2021 16:27:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Jul-14-2021 16:16:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	Salim Bouguermouh (b) (4)	Query 1: Reissued:Opened	Pfizer Medical monitor: The query was incorrect - apologies. Please move RINORRHEA to back to the potential COVID-19 Visit SOD form. Thank

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

				you
Jul-14-2021 11:18:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Query 1: Answered	this was originally captured on SOD but was changed to an AE per query on the SOD crf
Jul-14-2021 09:27:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	Salim Bouguermouh (b) (4) [REDACTED]	Query 1: Opened	Clin: Since RINORRHEA is one of the CDC-defined symptoms of COVID-19 (Prot Sect 8.1), please consider whether this symptom, could have been due to COVID-19 and should be added (has been removed) to the COVID_A Visit SOD CRF Form. Thank you
Jul-13-2021 15:16:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: rhinorrhea	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

4. Start Date Time:

Date	Location	User	Value	Reason
Jul-13-2021 15:16:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: May/15/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jul-13-2021 15:16:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO End Date Time: May/17/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jul-13-2021 15:16:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Jul-13-2021 15:16:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Jul-13-2021 15:16:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jul-13-2021 15:16:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jul-13-2021 15:16:26 (UTC-07:00)	ACV0PF EINFP60	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Mountain Time (US & Canada)	00	(b) (4), (b) (6)		
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jul-13-2021 15:16:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jul-13-2021 15:16:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Jul-13-2021 15:16:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
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090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Jul-13-2021 15:16:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

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Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Category:

Date	Location	User	Value	Reason
Jul-13-2021 15:17:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jul-13-2021 15:17:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 7	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jul-19-2021 09:57:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Jul-16-2021 12:55:14 (UTC-07:00)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	related to reactogenicity therefore ae not

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Mountain Time (US & Canada)				on SOD page. thank you
Jul-14-2021 16:27:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	Salim Bouguermouh (b) (4)	Query 1: Reissued:Opened	Clin: Please confirm NAUSEA is considered related to reactogenicity and not considered related to potential COVID-19 Illness. If considered related to potential COVID-19 it should be entered on the SOD form only. Thank you
Jul-14-2021 11:20:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	captured as AE per query: CLIQUERY: Since NEW OR INCREASED MUSCLE PAIN, Dizziness, Rhinorrhea and Nausea are related to

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

				Vaccine reactogenicity, please report these in the AE log and remove these symptoms from the COVID Illness SOD CRF form.
Jul-14-2021 09:26:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: Since NAUSEA is one of the CDC-defined symptoms of COVID-19 (Prot Sect 8.1), please consider whether this symptom, could have been due to COVID-19 and should be added (has been removed) to the COVID_A Visit SOD CRF Form. Thank you
Jul-13-2021 15:17:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: nausea	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

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Form Status: Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

4. Start Date Time:

Date	Location	User	Value	Reason
Jul-13-2021 15:17:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: May/15/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jul-13-2021 15:17:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO End Date Time: May/17/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jul-13-2021 15:17:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Jul-13-2021 15:17:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

**8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.**

Date	Location	User	Value	Reason
Jul-13-2021 15:17:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jul-13-2021 15:17:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jul-13-2021 15:17:54 (UTC-07:00)	ACV0PF EINFP60	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Mountain Time (US & Canada)	00	(b) (4), (b) (6)		
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jul-13-2021 15:17:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jul-13-2021 15:17:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Jul-13-2021 15:17:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
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090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Jul-13-2021 15:17:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

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1. Category:

Date	Location	User	Value	Reason
Jul-13-2021 15:20:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jul-13-2021 15:20:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 8	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jul-19-2021 04:07:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Data deleted by site.
Jul-16-2021 12:56:06	ACV0PF EINFP60	(b) (4), (b) (6)	Query 1: Answered	in ed diary will remove ae.

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

(UTC-07:00) Mountain Time (US & Canada)	00			thank you.
Jul-14-2021 23:20:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00.InFor mAdapte r.Discrep ancy	PFE SDQ PROD (b) (4)	Query 1: Opened	eDiary: AE Headache reported with start date 06-Jan-2021 and End Date 06-Jan-2021 seems to be same as e-Diary occurrence Headache reported on 06-Jan-2021 . Please reconcile or confirm in the query response as appropriate (b) (4)
Jul-13-2021 15:20:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: headache	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jul-13-2021 15:20:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jan/6/2021 14:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jul-13-2021 15:20:27 (UTC-07:00)	ACV0PF EINFP60	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Mountain Time (US & Canada)	00	(b) (4), (b) (6)	End Date Time: Jan/6/2021 17:01
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6. Toxicity Grade:

Date	Location	User	Value	Reason
Jul-13-2021 15:20:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Jul-13-2021 15:20:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Jul-13-2021 15:20:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jul-13-2021 15:20:27 (UTC-07:00)	ACV0PF EINFP60	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

Mountain Time (US & Canada)	00	(b) (4), (b) (6)		
-----------------------------	----	------------------	--	--

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jul-13-2021 15:20:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jul-13-2021 15:20:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jul-13-2021 15:20:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Jul-13-2021 15:20:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Jul-13-2021 15:20:27 (UTC-07:00)	ACV0PF EINFP60	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Mountain Time (US
& Canada)

00

(b) (4), (b) (6)

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 -
Unscheduled Visit on Apr/17/2021

Form Version: 14-Jan-2021 02:22

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: DATE OF VISIT - ASYMPTOMATIC
SURVEILLANCE - 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): 10-Nov-2021 20:44

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1. Date of Visit

Date	Location	User	Value	Reason
Apr-20-2021 09:42:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: Apr/17/2021	Initial Entry

3. COVID-19 Surveillance Visit:

Date	Location	User	Value	Reason
Apr-20-2021 09:42:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: SSWAB_WEEK2	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 -
Unscheduled Visit on Apr/17/2021

Form Version: 10-Oct-2020 15:57

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - REPEAT
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): 10-Nov-2021 20:44

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1. Data Origin

Date	Location	User	Value	Reason
Apr-20-2021 09:42:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Apr-20-2021 09:42:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Apr-20-2021 09:43:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Apr-20-2021 09:42:40	ACV0PF EINFP60	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 -
Unscheduled Visit on Apr/17/2021

Form Version: 10-Oct-2020 15:57

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - REPEAT
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): 10-Nov-2021 20:44

(UTC-07:00) Mountain Time (US & Canada)	00			Yes, however no barcodes are entered. Please review and correct as appropriate.
Apr-20-2021 09:42:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: YES Date of Collection: Apr/17/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Apr-20-2021 09:43:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: Sample ID: AA45711	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Apr-20-2021 09:43:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: AA45711	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 2 -
Unscheduled Visit on Apr/28/2021

Form Version: 14-Jan-2021 02:22

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: DATE OF VISIT - ASYMPTOMATIC
SURVEILLANCE - 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): 10-Nov-2021 20:44

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1. Date of Visit

Date	Location	User	Value	Reason
Apr-30-2021 09:13:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Apr/28/2021	Initial Entry

3. COVID-19 Surveillance Visit:

Date	Location	User	Value	Reason
Apr-30-2021 09:13:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: SSWAB_WEEK4	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 2 -
Unscheduled Visit on Apr/28/2021

Form Version: 10-Oct-2020 15:57

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - REPEAT
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): 10-Nov-2021 20:44

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1. Data Origin

Date	Location	User	Value	Reason
Apr-30-2021 09:13:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Apr-30-2021 09:13:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Apr-30-2021 09:14:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Apr-30-2021 09:13:36	ACV0PF EINFP60	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 2 -
Unscheduled Visit on Apr/28/2021

Form: ELECTRONIC SAMPLE TRACKING - REPEAT
SWAB - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-07:00) Mountain Time (US & Canada)	00			Yes, however no barcodes are entered. Please review and correct as appropriate.
Apr-30-2021 09:13:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Apr/28/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Apr-30-2021 09:14:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: AA45779	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Apr-30-2021 09:14:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: AA45779	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 3 -
Unscheduled Visit on May/12/2021

Form Version: 14-Jan-2021 02:22

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: DATE OF VISIT - ASYMPTOMATIC
SURVEILLANCE - 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): 10-Nov-2021 20:44

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1. Date of Visit

Date	Location	User	Value	Reason
May-13-2021 11:39:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: May/12/2021	Initial Entry

3. COVID-19 Surveillance Visit:

Date	Location	User	Value	Reason
May-13-2021 11:39:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: SSWAB_WEEK6	Initial Entry

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 3 -
Unscheduled Visit on May/12/2021

Form Version: 10-Oct-2020 15:57

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - REPEAT
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): 10-Nov-2021 20:44

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1. Data Origin

Date	Location	User	Value	Reason
May-13-2021 11:39:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
May-13-2021 11:39:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
May-13-2021 11:39:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
May-13-2021 11:39:22	ACV0PF EINFP60	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 3 -
Unscheduled Visit on May/12/2021

Form: ELECTRONIC SAMPLE TRACKING - REPEAT
SWAB - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-07:00) Mountain Time (US & Canada)	00			Yes, however no barcodes are entered. Please review and correct as appropriate.
May-13-2021 11:39:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: May/12/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
May-13-2021 11:39:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: AA45780	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
May-13-2021 11:39:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: AA45780	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:27

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
May-13-2021 14:44:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: May/13/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
May-13-2021 14:44:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FO R ADDITIONAL VACCINA TION	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091382

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): 10-Nov-2021 20:44

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1. Date of Visit

Date	Location	User	Value	Reason
May-14-2021 10:21:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: May/14/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER
VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Consent Was:

Date	Location	User	Value	Reason
May-14-2021 10:22:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained May/14/2021	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
May-14-2021 10:23:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: May/14/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
May-14-2021 10:23:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
May-14-2021 10:23:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Apr-2021 01:41

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Lab Panel:

Date	Location	User	Value	Reason
May-14-2021 10:23:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
May-14-2021 10:23:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
May-14-2021 10:23:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: May/14/2021	Initial Entry

4. Laboratory Name and Address (Derived)

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Apr-2021 01:41

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
May-14-2021 10:23:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
May-14-2021 10:23:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
May-14-2021 10:23:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX 113 Result:: NEGATIVE Not Done::	Initial Entry

6.a Sponsor ID:

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 30-Apr-2021 01:41

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
May-14-2021 10:23:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
May-14-2021 10:23:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_P X113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
May-14-2021 10:23:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091382

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): 10-Nov-2021 20:44

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1. Data Origin

Date	Location	User	Value	Reason
May-14-2021 10:23:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
May-14-2021 10:23:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
May-14-2021 10:28:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
May-14-2021 10:23:51	ACV0PF EINFP60	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-07:00) Mountain Time (US & Canada)	00			Yes, however no barcodes are entered. Please review and correct as appropriate.
May-14-2021 10:23:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: May/14/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
May-14-2021 10:28:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BRTSSS	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
May-14-2021 10:28:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BRTSSS	Initial Entry

5.b

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
May-14-2021 10:29:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BTLHCB	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
May-14-2021 10:29:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BTLHCB	Initial Entry

5.c

Date	Location	User	Value	Reason
May-14-2021 10:29:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BTLHC9	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

5.c Sample ID

Date	Location	User	Value	Reason
May-14-2021 10:29:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: BTLHC9	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Data Origin

Date	Location	User	Value	Reason
May-14-2021 10:24:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
May-14-2021 10:24:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
May-14-2021 10:29:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
May-14-2021 10:24:06	ACV0PF EINFP60	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-07:00) Mountain Time (US & Canada)	00			Yes, however no barcodes are entered. Please review and correct as appropriate.
May-14-2021 10:24:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: May/14/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
May-14-2021 10:29:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BTLH7P	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
May-14-2021 10:29:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BTLH7P	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1009

Subject No: 10091382

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): 10-Nov-2021 20:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
May-14-2021 10:24:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
May-14-2021 10:24:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
May-14-2021 10:24:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
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090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

May-14-2021 10:24:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: May/14/2021 09:08	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
May-14-2021 10:24:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
May-14-2021 10:24:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
May-14-2021 10:24:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

8. Actual Dose:

Date	Location	User	Value	Reason
May-14-2021 10:24:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
May-14-2021 10:24:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
May-14-2021 10:24:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
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090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

May-14-2021 10:24:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: YES	Initial Entry
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Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091382

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): 10-Nov-2021 20:44

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1. Date of Visit

Date	Location	User	Value	Reason
Jun-02-2021 09:33:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	Madison Ellis (b) (4)	Data Entry: Jun/2/2021	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Apr-2021 01:41

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Lab Panel:

Date	Location	User	Value	Reason
Jun-02-2021 09:33:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Jun-02-2021 09:33:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jun-02-2021 09:33:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	Madison Ellis (b) (4)	Data Entry: Jun/2/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Apr-2021 01:41

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Jun-02-2021 09:33:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry
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5. Specimen Type:

Date	Location	User	Value	Reason
Jun-02-2021 09:33:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Jun-02-2021 09:33:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Sponsor-Def 113 ined Identifier: Test:: Choriogonadot ropin Beta_PX 113 Result:: NEGATIVE Not Done::	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Jun-02-2021 09:33:27 (UTC-07:00)	ACV0PF EINFP60	auto calc (autocalc)	Data Entry: 113	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 30-Apr-2021 01:41

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Mountain Time (US & Canada)	00			
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6.a Test:

Date	Location	User	Value	Reason
Jun-02-2021 09:33:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	Madison Ellis (b) (4)	Data Entry: Choriogonadotropin Beta_PX 113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Jun-02-2021 09:33:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	Madison Ellis (b) (4)	Data Entry: NEGATIVE	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Data Origin

Date	Location	User	Value	Reason
Jun-02-2021 09:34:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jun-02-2021 09:34:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jun-02-2021 09:35:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jun-02-2021 09:34:48 (UTC-07:00) Mountain Time (US	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

& Canada)				entered. Please review and correct as appropriate.
Jun-02-2021 09:34:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	Madison Ellis (b) (4)	Data Entry: YES Date of Collection: Jun/2/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jun-02-2021 09:35:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	Madison Ellis (b) (4)	Data Entry: Sample ID: BTLH8Y	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jun-02-2021 09:35:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	Madison Ellis (b) (4)	Data Entry: BTLH8Y	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1009

Subject No: 10091382

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): 10-Nov-2021 20:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jun-02-2021 10:02:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	Madison Ellis (b) (4)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jun-02-2021 10:02:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jun-02-2021 10:02:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Jun-02-2021	ACV0PF	Madison	Data Entry:	Initial Entry

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

10:02:09 (UTC-07:00) Mountain Time (US & Canada)	EINFP60 00	Ellis (b) (4)	Jun/2/2021 09:54	
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5. Anatomical Location:

Date	Location	User	Value	Reason
Jun-02-2021 10:02:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jun-02-2021 10:02:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	Madison Ellis (b) (4)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jun-02-2021 10:02:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Jun-02-2021 10:02:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jun-02-2021 10:02:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jun-02-2021 10:02:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Jun-02-2021 10:02:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	Madison Ellis (b) (4)	Data Entry: YES	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091382

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): 10-Nov-2021 20:44

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1. Date of Visit

Date	Location	User	Value	Reason
Jul-06-2021 08:08:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jul/2/2021	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form: CONTACT OUTCOME - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Contact Type:

Date	Location	User	Value	Reason
Jul-06-2021 08:08:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Jul-06-2021 08:08:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Contact: Jul/2/2021	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit:
FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit
Trail History

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Jul-06-2021 08:09:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jul/2/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jul-06-2021 08:09:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: OPEN LABEL TREATMENT	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jul-06-2021 08:09:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Subject Status

Date	Location	User	Value	Reason
Feb-26-2021 14:29:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Jan-04-2021 16:56:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Jan-04-2021 16:49:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Feb-26-2021 14:29:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Feb/25/2021	Initial Entry
Jan-04-2021 16:56:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Jan/4/2021	Initial Entry

090177e19891a03fFinalFinal On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091382

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

& Canada)				
Jan-04-2021 16:49:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Jan/4/2021	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1009

Subject No: 10091382

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - 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): 10-Nov-2021 20:44

[Back to Form](#)

1. Casebook Signature

Date	Location	User	Value	Reason
Mar-10-2021 17:10:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry

090177e19891a03f\Final\Final On: 11-Nov-2021 01:20 (GMT)