

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT\_SELECTION

**Form Version:** 30-Jul-2020 21:29

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

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Cohort Selection**

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

1.	Select appropriate response - Protocol version	24 JUL 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** MAIN INFORMED CONSENT

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

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

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/31/2020
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

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

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

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[10091135]
2.	Birth Date:	(b) (6) 1957
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**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):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Aug/31/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levisse

**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):** 29-Mar-2021 04:12

**Form Comments**

**Inclusion Criteria Not Met**

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

**Exclusion Criteria Met**

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

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

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levisse

**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):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation/Death	Aug/31/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**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):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HYSTERECTOMY]
	Start Date:	UNK/UNK/1986
	Ongoing:	NO End Date: UNK/UNK/1986
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[ENVIRONMENTAL ALLERGIES]
	Start Date:	UNK/UNK/1958
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[MILD ASTHMA]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[OSTEOARTHRITIS (GENERALIZED)]
	Start Date:	Jun/UNK/2019
	Ongoing:	YES

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**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**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):** 29-Mar-2021 04:12

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HYPOTHYROIDISM]
	Start Date:	Jun/UNK/2011
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[DEPRESSION]
	Start Date:	Jun/UNK/2011
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[ANXIETY]
	Start Date:	Jun/UNK/2011
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[MTHFR GENE MUTATION]
	Start Date:	(b) (6) /1957
	Ongoing:	YES
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[ASPIRIN INTOLERANCE]
	Start Date:	UNK/UNK/1986
	Ongoing:	YES

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**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**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):** 29-Mar-2021 04:12

1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[GLUTEN INTOLERANCE]
	Start Date:	UNK/UNK/2003
	Ongoing:	YES
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[LACTOSE INTOLERANCE]
	Start Date:	UNK/UNK/1970
	Ongoing:	YES
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[MORPHINE INTOLERANCE]
	Start Date:	UNK/UNK/1986
	Ongoing:	YES

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**Header Text:** c4591001

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

**Form:** VITAL SIGNS - BASELINE

**Form Version:** 21-Aug-2020 02:51

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

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Aug/31/2020
2.	Weight:	[243.2]
3.	Unit:	LB
4.	Height:	[64.0]
5.	Unit:	in
6.	Body Mass Index:	[41.7]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[97.9]
	Unit:	F
	Temperature Location:	ORAL CAVITY

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**Header Text:** c4591001

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

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**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):** 29-Mar-2021 04:12

[Form Comments](#)

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	Not Applicable _____	<a href="#">Comments</a>
2.	Lab Sub-Panel:	Not Applicable _____	<a href="#">Comments</a>
3.	Collection Date:	Not Applicable _____ //	<a href="#">Comments</a>
4.	Laboratory Name and Address (Derived)	Not Applicable _____ [ ]	<a href="#">Comments</a>
5.	Specimen Type:	Not Applicable _____	<a href="#">Comments</a>

**Lab Result**

6.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>

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**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levisse

**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):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Aug/31/2020
2.	Randomization Number:	[244646]
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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/31/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP9GKG]
5.b	Sample ID	[BP9GKH]
5.c	Sample ID	[BP9GKJ]
5.d	Sample ID	[BPR980]
5.e	Sample ID	[BPR981]

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**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/31/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP9G29]
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090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.lewissc

**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):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/31/2020 13:44
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**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):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT 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:** 10091135

**Generated By:** pfe.levissc

**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):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Sep/22/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levisse

**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):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/22/2020
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**Vital Signs Details**

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

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 21-Aug-2020 02:49**Site No:** 1009**Subject No:** 10091135**Generated By:** pfe.levissc**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):** 29-Mar-2021 04:12[Form Comments](#)[eCRF Audit Trail History](#)**Lab Urinalysis**

1.	Lab Panel:	Not Applicable _____	<a href="#">Comments</a>
2.	Lab Sub-Panel:	Not Applicable _____	<a href="#">Comments</a>
3.	Collection Date:	Not Applicable _____ //	<a href="#">Comments</a>
4.	Laboratory Name and Address (Derived)	Not Applicable _____ [ ]	<a href="#">Comments</a>
5.	Specimen Type:	Not Applicable _____	<a href="#">Comments</a>

**Lab Result**

6.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/22/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP9G84]
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**Form:** VACCINATION

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/22/2020 16:22
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

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**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):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Oct/21/2020
2.	Erroneous Visit	

**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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/21/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BR9FNH]
5.b	Sample ID	[BKCYM]
5.c	Sample ID	[BKYCVC]

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**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

**Form:** 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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

**Form:** 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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

**Form:** 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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020

**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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Oct/28/2020
2.	Erroneous Visit	ERRONEOUS VISIT

**COVID-19 Illness Visit**

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

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

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

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

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Form Comments](#)  
[eCRF Audit Trail History](#)

**Signs and Symptoms**

1.	Date of Assessment:	Not Applicable _____ //	<a href="#">Comments</a>
2.	Date of First Symptom Started:	Not Applicable _____ //	<a href="#">Comments</a>
3.	Symptoms Ongoing?	Not Applicable _____	<a href="#">Comments</a>

**Symptoms**

4.a	Symptoms:	FEVER	
	Was symptom present?	Not Applicable _____	<a href="#">Comments</a>
4.b	Symptoms:	NEW OR INCREASED COUGH	
	Was symptom present?	Not Applicable _____	<a href="#">Comments</a>
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH	
	Was symptom present?	Not Applicable _____	<a href="#">Comments</a>
4.d	Symptoms:	CHILLS	
	Was symptom present?	Not Applicable _____	<a href="#">Comments</a>
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN	
	Was symptom present?	Not Applicable _____	<a href="#">Comments</a>

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

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

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

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

4 f	Symptoms:	NEW LOSS OF TASTE OR SMELL	
	Was symptom present?	Not Applicable _____	<a href="#">Comments</a>
4.g	Symptoms:	NEW OR INCREASED SORE THROAT	
	Was symptom present?	Not Applicable _____	<a href="#">Comments</a>
4 h	Symptoms:	DIARRHEA	
	Was symptom present?	Not Applicable _____	<a href="#">Comments</a>
4.i	Symptoms:	VOMITING	
	Was symptom present?	Not Applicable _____	<a href="#">Comments</a>
<b>Symptoms - Other</b>			
5.	Symptoms - Other Text:	Not Applicable _____ [ ]	

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**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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020

**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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**Microbiology Specimen**

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

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levisse

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB  
SELF

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

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

**Subject Initials:** ---

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

[Form Comments](#)

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	Not Applicable _____	<a href="#">Comments</a>
2.	Sample Type	Not Applicable _____	<a href="#">Comments</a>
3.	Sample Collected?	Not Applicable _____	<a href="#">Comments</a>
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	Not Applicable _____ [ ]	<a href="#">Comments</a>

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	Not Applicable _____ [ ]
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090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020

**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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Form Comments](#)

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	Not Applicable _____	<a href="#">Comments</a>
2.	Sample Type	Not Applicable _____	<a href="#">Comments</a>
3.	Sample Collected?	Not Applicable _____	<a href="#">Comments</a>
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	Not Applicable _____ [ ]	<a href="#">Comments</a>

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	Not Applicable _____ [ ]
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090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020**Form:** HEALTH CARE UTILIZATION**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic  
South**Subject No:** 10091135**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12[Form Comments](#)[eCRF Audit Trail History](#)**Health Care Utilization**

1.a	Physician or Healthcare Professional:	SPECIALIST	
	Occurrence of Visits or Contacts:	Not Applicable _____	<a href="#">Comments</a>
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM	
	Occurrence of Visits or Contacts:	Not Applicable _____	<a href="#">Comments</a>
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN	
	Occurrence of Visits or Contacts:	Not Applicable _____	<a href="#">Comments</a>
1.d	Physician or Healthcare Professional:	URGENT CARE	
	Occurrence of Visits or Contacts:	Not Applicable _____	<a href="#">Comments</a>
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION	
	Occurrence of Visits or Contacts:	Not Applicable _____	<a href="#">Comments</a>
1.f	Physician or Healthcare Professional:	OTHER	
	Occurrence of Visits or Contacts:	Not Applicable _____	<a href="#">Comments</a>

**Health Care Utilization Other**

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020

**Form:** HEALTH CARE UTILIZATION

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

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

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

2.	Other Type of Practitioner Specify:	Not Applicable _____ [ ]	<a href="#">Comments</a>
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**Health Care Utilization**

3.	Has the subject been hospitalized due to potential COVID-19 illness?	Not Applicable _____	<a href="#">Comments</a>
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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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020

**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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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**Respiratory Treatment**

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



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020

**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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Form Comments](#)

[eCRF Audit Trail History](#)

**Illness Details**

1.	Category of Clinical Event:	Not Applicable _____	<a href="#">Comments</a>
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	Not Applicable _____	<a href="#">Comments</a>
3.	Toxicity Grade:	Not Applicable _____	<a href="#">Comments</a>

**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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020

**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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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**Illness Details**

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

**Header Text:** c4591001

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

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

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020

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

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Not Started

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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**Lab Chemistry Details**

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

**Lab Result**

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

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

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

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

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020

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

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Not Started

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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**Laboratory Data Hematology**

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

**Lab Result**

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

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

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

**Form:** VITAL SIGNS - COVID

**Form Version:** 21-Aug-2020 02:50

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020

**Form:** VITAL SIGNS - COVID

**Form Version:** 21-Aug-2020 02:50

**Form Status:** Not Started

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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**Vital Signs**

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

**Vital Signs Details**

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

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**Header Text:** c4591001

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

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

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020

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

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Not Started

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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**Vital Signs**

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

**Vital Signs Details**

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[ ]

**Header Text:** c4591001

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

**Form:** OXYGENATION PARAMETERS

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

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

#	Date Time of Assessment	Arterial Blood Gases PaO <sub>2</sub>	FiO <sub>2</sub> (Fraction of Inhaled Oxygen)	Form Instance
1.				<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020

**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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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**Oxygenation Parameters**

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

**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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020

**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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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**Concomitant Medications**

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

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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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020

**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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

**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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

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

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levisse

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**Unplanned Assessments**

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

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT

**Form Version:** 15-Sep-2020 21:55

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

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation /Death :	Oct/21/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Disposition - Follow-Up**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New **Form:** DATE OF VISIT - REPEAT SWAB  
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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

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



**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB  
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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

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

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	right breast lump	Sep/2/2020 UNK:UNK	YES	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	Right Breast Ductal Carcinoma In Situ	Sep/2/2020 UNK:UNK	YES	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

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[Form Audit Trail](#)

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[right breast lump]
4.	Start Date Time:	Sep/2/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	1
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [cancer]

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT 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	[ ]

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

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

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[eCRF Audit Trail History](#)  
[Form Audit Trail](#)

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Right Breast Ductal Carcinoma In Situ]
4.	Start Date Time:	Sep/2/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	1
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES  Is this serious event associated with congenital anomaly or birth defect? NO  Did this serious event result in death? NO  Did this serious event require or prolong hospitalization? NO  Did this serious event result in persistent or significant disability/incapacity? NO  Is this serious event life threatening? NO  Other medically important serious event YES
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

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

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

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: [spontaneous onset]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT 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	[2020411592]

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**Form:** MEDICATION ERROR

**Form Status:** Not Started

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

**Subject Initials:** ---

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

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**Medication Error**

1.	Category:	
2.	Medication Error (Type of Medication Error):	[ ]
3.	Start Date:	//
4.	Is the medication error still ongoing?	
5.	Latest Action Taken with Study Treatment:	
6.	Was a Concomitant Medication given?	
7.	Was a Non-Drug Treatment given?	
8.	Did the Medication Error cause the subject to be discontinued from the study?	
9.	Was this medication error associated with any adverse events?	
10.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** 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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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**Concomitant Medications**

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

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

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

**Subject Initials:** ---

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

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**Concomitant Medications**

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

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

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**Radiation Treatment**

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levisse

**Form:** TRANSFUSIONS

**Form Status:** Not Started

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

**Subject Initials:** ---

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

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



**Header Text:** c4591001

**Visit:** Unplanned 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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled      **Form:** VITAL SIGNS - TEMP

**Form Version:** 20-Feb-2021 02:16      **Form Status:** Not Started

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

**Subject No:** 10091135      **Subject Initials:** ---

**Generated By:** pfe.levisse      **Generated Time (GMT):** 29-Mar-2021 04:12

**Vital Signs**

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

**Vital Signs Details**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** 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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**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:	

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**Vaccination**

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

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 1

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

**Form Status:** Not Started

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** 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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**Contact Outcome**

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

**Header Text:** c4591001

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

**Form:** 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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levisse

**Form:** INFORMED CONSENT - ASYMPTOMATIC  
SURVEILLANCE

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Informed Consent - Asymptomatic Surveillance**

1.	Consent Was:	
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**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levisse

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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

**Form Status:** Not Started

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

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

**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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisc

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

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** c4591001

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

**Form:** FURTHER VACCINATION CONFIRMATION

**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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**Form:** TREATMENT UNBLINDED

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Feb/25/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** WITHDRAWAL OF CONSENT

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

**Form Status:** Not Started

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**Withdrawal Of Consent**

1.	Withdrawal of Consent Date :	//
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**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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**Death Details**

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

**Cause of Death**

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

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:31

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levisse

**Form:** INFORMED CONSENT - FURTHER VACCINATION

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Informed Consent - Further Vaccination**

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

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

**Form Version:** 10-Dec-2020 02:30

**Form Status:** Not Started

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**Inclusion Criteria Not Met**

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

**Exclusion Criteria Met**

2.	Description of Exclusion Criterion Met	
----	--	--

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION

**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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**Disposition - Screening for Further Vaccination**

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

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.lewissc

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/21/2020

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Casebook Signature Form**

1.	Casebook Signature	Click Here to Enable
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**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

[Audit Trail](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Shane Christensen	Approved	Mar-08-2021 20:54:16 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed

**Affidavit:**

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

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

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

**Header Text:** c4591001

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

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

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

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Aug-31-2020 14:35:10 (UTC-07:00) Mountain Time (US & Canada)	Annjanette Kemp (pfe.akemp)	Not Applicable

**Header Text:** c4591001

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

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Aug-31-2020 14:54:24 (UTC-07:00) Mountain Time (US & Canada)	Annjanette Kemp (pfe.akemp)	Not Applicable



**Header Text:** c4591001

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

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
1	Aug-31-2020 14:54:24 (UTC-07:00) Mountain Time (US & Canada)	Annjanette Kemp (pfe.akemp)	Not Applicable

**Header Text:** c4591001

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

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
2	Aug-31-2020 14:54:24 (UTC-07:00) Mountain Time (US & Canada)	Annjanette Kemp (pfe.akemp)	Not Applicable

**Header Text:** c4591001

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

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
3	Aug-31-2020 14:54:24 (UTC-07:00) Mountain Time (US & Canada)	Annjanette Kemp (pfe.akemp)	Not Applicable

**Header Text:** c4591001

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

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
4	Aug-31-2020 14:54:24 (UTC-07:00) Mountain Time (US & Canada)	Annjanette Kemp (pfe.akemp)	Not Applicable

**Header Text:** c4591001

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

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
5	Aug-31-2020 14:54:24 (UTC-07:00) Mountain Time (US & Canada)	Annjanette Kemp (pfe.akemp)	Not Applicable

**Header Text:** c4591001

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

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
6.a	Aug-31-2020 14:54:24 (UTC-07:00) Mountain Time (US & Canada)	Annjanette Kemp (pfe.akemp)	Not Applicable

**Header Text:** c4591001

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

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
6.a	Aug-31-2020 14:54:24 (UTC-07:00) Mountain Time (US & Canada)	Annjanette Kemp (pfe.akemp)	Not Applicable

**Header Text:** c4591001

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

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
6.a	Aug-31-2020 14:54:24 (UTC-07:00) Mountain Time (US & Canada)	Annjanette Kemp (pfe.akemp)	Not Applicable



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Sep-22-2020 16:21:46 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	Not Applicable

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
1	Sep-22-2020 16:21:46 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
2	Sep-22-2020 16:21:46 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	Not Applicable

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
3	Sep-22-2020 16:21:46 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.down)	Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
4	Sep-22-2020 16:21:46 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	Not Applicable

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
5	Sep-22-2020 16:21:46 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.downen)	Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
6.a	Sep-22-2020 16:21:46 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	Not Applicable

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
6.a	Sep-22-2020 16:21:46 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	Not Applicable



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
6.a	Sep-22-2020 16:21:46 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	Not Applicable

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levisse

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Oct-29-2020 08:43:25 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	Not Applicable

**Header Text:** c4591001

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

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
Comments

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

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

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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Item	Date	User	Comment
1	Oct-29-2020 08:43:25 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	Not Applicable

**Header Text:** c4591001

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

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
Comments

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

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

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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Item	Date	User	Comment
2	Oct-29-2020 08:43:25 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	Not Applicable

**Header Text:** c4591001

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

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
Comments

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

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

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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Item	Date	User	Comment
3	Oct-29-2020 08:43:25 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	Not Applicable

**Header Text:** c4591001

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

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
Comments

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

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

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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Item	Date	User	Comment
4.a	Oct-29-2020 08:43:25 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	Not Applicable

**Header Text:** c4591001

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

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
Comments

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

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

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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Item	Date	User	Comment
4.b	Oct-29-2020 08:43:25 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	Not Applicable

**Header Text:** c4591001

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

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
Comments

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

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

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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Item	Date	User	Comment
4.c	Oct-29-2020 08:43:25 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	Not Applicable



**Header Text:** c4591001

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

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
Comments

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

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

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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Item	Date	User	Comment
4.d	Oct-29-2020 08:43:25 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	Not Applicable

**Header Text:** c4591001

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

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
Comments

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

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

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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Item	Date	User	Comment
4.e	Oct-29-2020 08:43:25 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	Not Applicable

**Header Text:** c4591001

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

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
Comments

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

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

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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Item	Date	User	Comment
4.f	Oct-29-2020 08:43:25 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	Not Applicable

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

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Item	Date	User	Comment
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**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020

**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  
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**Subject No:** 10091135

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Item	Date	User	Comment
Form	Oct-29-2020 08:43:49 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	Not Applicable
Form	Oct-29-2020 08:36:51 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	
Form	Oct-28-2020 10:52:42 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	Not Done

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Item	Date	User	Comment
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2	Oct-29-2020 08:43:49 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	Not Applicable
2	Oct-29-2020 08:36:51 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	
2	Oct-28-2020 10:52:42 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	Not Done

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4	Oct-29-2020 08:36:51 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	
4	Oct-28-2020 10:52:42 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	Not Done

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5	Oct-29-2020 08:43:49 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	Not Applicable
5	Oct-29-2020 08:36:51 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	
5	Oct-28-2020 10:52:42 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	Not Done

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6	Oct-29-2020 08:43:49 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	Not Applicable
6	Oct-29-2020 08:36:51 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	
6	Oct-28-2020 10:52:42 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	Not Done

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7	Oct-29-2020 08:43:49 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	Not Applicable
7	Oct-29-2020 08:36:51 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	
7	Oct-28-2020 10:52:42 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	Not Done

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Item	Date	User	Comment
8	Oct-29-2020 08:43:49 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	Not Applicable
8	Oct-29-2020 08:36:51 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	
8	Oct-28-2020 10:52:42 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	Not Done

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Item	Date	User	Comment
9	Oct-29-2020 08:43:49 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	Not Applicable
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9	Oct-28-2020 10:52:42 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	Not Done



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levisse

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB  
SELF - Comments

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

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

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

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Item	Date	User	Comment
Form	Oct-29-2020 08:44:01 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	Not Applicable

**Header Text:** c4591001

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

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**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB  
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Item	Date	User	Comment
1	Oct-29-2020 08:44:01 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	Not Applicable

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Item	Date	User	Comment
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Item	Date	User	Comment
Form	Oct-29-2020 08:44:15 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	Not Applicable

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**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020

**Form:** HEALTH CARE UTILIZATION - Comments

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

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

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Item	Date	User	Comment
Form	Oct-29-2020 08:44:28 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	Not Applicable

**Header Text:** c4591001

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Item	Date	User	Comment
3	Oct-29-2020 08:44:28 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	Not Applicable

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020

**Form:** ILLNESS DETAILS - Comments

**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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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Item	Date	User	Comment
Form	Oct-29-2020 08:44:43 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	Not Applicable

**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1  
**Form Version:** 06-Jul-2020 21:52  
**Site No:** 1009  
**Subject No:** 10091135  
**Generated By:** pfe.levissc

**Form:** ILLNESS DETAILS - Comments  
**Form Status:** Data Complete, Frozen, Verified  
**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 04:12

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Item	Date	User	Comment
1	Oct-29-2020 08:44:43 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	Not Applicable

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**Form:** ILLNESS DETAILS - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
2	Oct-29-2020 08:44:43 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	Not Applicable

**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1  
**Form Version:** 06-Jul-2020 21:52  
**Site No:** 1009  
**Subject No:** 10091135  
**Generated By:** pfe.levissc

**Form:** ILLNESS DETAILS - Comments  
**Form Status:** Data Complete, Frozen, Verified  
**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 04:12

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Item	Date	User	Comment
3	Oct-29-2020 08:44:43 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	Not Applicable

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

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

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

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Shane Christensen	Approved	Mar-08-2021 20:54:16 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed

**Affidavit:**

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

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

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

Jenessa Folsom	N/A	Mar-08-2021 14:50:28 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Shane Christensen	Approved	Mar-06-2021 17:03:27 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
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**Affidavit:**

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

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

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

Allyson Christensen	N/A	Mar-01-2021 10:08:19 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)



**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

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

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

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**Affidavit:**

N/A

Shane Christensen	Approved	Oct-29-2020 17:46:59 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
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**Affidavit:**

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

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

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

Dylan Owen	N/A	Oct-28-2020 10:51:34 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Shane Christensen	Approved	Oct-23-2020 15:31:02 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
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**Affidavit:**

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

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

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

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Form Version:** 30-Jul-2020 21:29

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

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Aug-31-2020 14:33:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 14:33:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levisse

**Form:** MAIN INFORMED CONSENT - 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):** 29-Mar-2021 04:12

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***I. Consent Was:***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Aug-31-2020 14:34:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b><u>Data Entry:</u></b> OBTAINED Date Written Consent Obtained  Aug/31/2020	Initial Entry

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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**1. Subject ID**

Date	Location	User	Value	Reason
Aug-31-2020 14:33:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10091135	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Aug-31-2020 14:33:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6) /1957	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Aug-31-2020 14:34:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Aug-31-2020 14:34:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 14:34:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**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):** 29-Mar-2021 04:12

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*1. Date of Visit*

Date	Location	User	Value	Reason
Aug-31-2020 14:35:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> Aug/31/2020	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levisse

**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):** 29-Mar-2021 04:12

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

Date	Location	User	Value	Reason
Aug-31-2020 14:35:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> Aug/31/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Aug-31-2020 14:35:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Aug-31-2020 14:35:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091135

Generated By: pfe.lewissc

Form: GENERAL MEDICAL HISTORY - 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): 29-Mar-2021 04:12

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*1.a*

Date	Location	User	Value	Reason
Aug-31-2020 14:36:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 1 Medical History Term: HYSTERECTOMY Start Date: UNK/UNK/1986 Ongoing: NO End Date: UNK/UNK/1986	Initial Entry

*1.a Line/MH Number:*

Date	Location	User	Value	Reason
Aug-31-2020 14:36:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 14:36:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> HYSTERECTOMY	Initial Entry

*1.a Start Date:*

Date	Location	User	Value	Reason
Aug-31-2020 14:36:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> UNK/UNK/1986	Initial Entry

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001  
**Visit:** V1\_DAY1\_VAX1\_L  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1009  
**Subject No:** 10091135  
**Generated By:** pfe.levissc

**Form:** GENERAL MEDICAL HISTORY - 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):** 29-Mar-2021 04:12

***I.a Ongoing:***

Date	Location	User	Value	Reason
Aug-31-2020 14:36:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> NO End Date:  UNK/UNK/1986	Initial Entry

***I.b***

Date	Location	User	Value	Reason
Aug-31-2020 14:37:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH N umber:</b> 2 <b>Medical History Term:</b> ENVIRONMENTAL ALLERGIES <b>Start Date:</b> UNK/UNK/1958 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091135

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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): 29-Mar-2021 04:12

***1.b Line/MH Number:***

Date	Location	User	Value	Reason
Aug-31-2020 14:37:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 14:37:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> ENVIRONMENTAL ALLERG IES	Initial Entry

***1.b Start Date:***

Date	Location	User	Value	Reason
Aug-31-2020 14:37:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> UNK/UNK/1958	Initial Entry

***1.b Ongoing:***

Date	Location	User	Value	Reason
Aug-31-2020 14:37:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> YES	Initial Entry

***1.c***

Date	Location	User	Value	Reason
Aug-31-2020 14:37:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 3 <b>Medical History Term:</b> MILD AST HMA <b>Start Date:</b> UNK/UNK/2018 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001  
**Visit:** V1\_DAY1\_VAX1\_L  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1009  
**Subject No:** 10091135  
**Generated By:** pfe.levisse

**Form:** GENERAL MEDICAL HISTORY - 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):** 29-Mar-2021 04:12

**I.c Line/MH Number:**

Date	Location	User	Value	Reason
Aug-31-2020 14:37:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

**I.c Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Aug-31-2020 14:37:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> MILD ASTHMA	Initial Entry

**I.c Start Date:**

Date	Location	User	Value	Reason
Aug-31-2020 14:37:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> UNK/UNK/2018	Initial Entry

**I.c Ongoing:**

Date	Location	User	Value	Reason
Aug-31-2020 14:37:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> YES	Initial Entry

**I.d**

Date	Location	User	Value	Reason
Aug-31-2020 14:44:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> <b>Line/MH</b> 4 <b>Number:</b> <b>Medical H</b> OSTEOARTHRI <b>istory Ter</b> TIS (GENERALI <b>m:</b> ZED) <b>Start Date</b> Jun/UNK/2019 :	Transcription Error

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001  
**Visit:** V1\_DAY1\_VAX1\_L  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1009  
**Subject No:** 10091135  
**Generated By:** pfe.levisse

**Form:** GENERAL MEDICAL HISTORY - 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):** 29-Mar-2021 04:12

			<b>Ongoing:</b> YES	
Aug-31-2020 14:38:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> 4 <b>Number:</b> <b>Medical History Term:</b> OSTEOARTHRI TIS (GENERALIZED) <b>Start Date:</b> UNK/UNK/2019 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1009**Subject No:** 10091135**Generated By:** pfe.levisse**Form:** GENERAL MEDICAL HISTORY - 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):** 29-Mar-2021 04:12***I.d Line/MH Number:***

Date	Location	User	Value	Reason
Aug-31-2020 14:38:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

***I.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Aug-31-2020 14:38:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> OSTEOARTHRITIS (GENERALIZED)	Initial Entry

***I.d Start Date:***

Date	Location	User	Value	Reason
Aug-31-2020 14:44:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> Jun/UNK/2019	Transcription Error
Aug-31-2020 14:38:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> UNK/UNK/2019	Initial Entry

***I.d Ongoing:***

Date	Location	User	Value	Reason
Aug-31-2020 14:38:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> YES	Initial Entry

***I.e***

Date	Location	User	Value	Reason
Aug-31-2020 14:44:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> <b>Line/MH Number:</b> 5 <b>Medical History Term:</b> HYPOTHYROIDISM	Transcription Error

**Header Text:** c4591001  
**Visit:** V1\_DAY1\_VAX1\_L  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1009  
**Subject No:** 10091135  
**Generated By:** pfe.levissc

**Form:** GENERAL MEDICAL HISTORY - 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):** 29-Mar-2021 04:12

			<b>Start Date:</b> Jun/UNK/2011 <b>Ongoing:</b> YES	
Aug-31-2020 14:42:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 5 <b>Medical History Term:</b> HYPOTHYROIDISM <b>Start Date:</b> UNK/UNK/2011 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1009**Subject No:** 10091135**Generated By:** pfe.levisse**Form:** GENERAL MEDICAL HISTORY - 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):** 29-Mar-2021 04:12***I.e Line/MH Number:***

Date	Location	User	Value	Reason
Aug-31-2020 14:42:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

***I.e Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Aug-31-2020 14:42:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> HYPOTHYROIDISM	Initial Entry

***I.e Start Date:***

Date	Location	User	Value	Reason
Aug-31-2020 14:44:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> Jun/UNK/2011	Transcription Error
Aug-31-2020 14:42:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> UNK/UNK/2011	Initial Entry

***I.e Ongoing:***

Date	Location	User	Value	Reason
Aug-31-2020 14:42:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> YES	Initial Entry

***I.f***

Date	Location	User	Value	Reason
Aug-31-2020 14:43:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> <b>Line/MH Number:</b> <b>Medical History Term:</b> DEPRESSION	Transcription Error

**Header Text:** c4591001  
**Visit:** V1\_DAY1\_VAX1\_L  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1009  
**Subject No:** 10091135  
**Generated By:** pfe.levisse

**Form:** GENERAL MEDICAL HISTORY - 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):** 29-Mar-2021 04:12

			<b>Start Date:</b> Jun/UNK/2011 <b>Ongoing:</b> YES	
Aug-31-2020 14:42:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 6 <b>Medical History Term:</b> DEPRESSI ON <b>Start Date:</b> UNK/UNK/2011 <b>Ongoing:</b> YES	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091135

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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): 29-Mar-2021 04:12

**If Line/MH Number:**

Date	Location	User	Value	Reason
Aug-31-2020 14:42:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 6	Initial Entry

**If Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Aug-31-2020 14:42:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> DEPRESSION	Initial Entry

**If Start Date:**

Date	Location	User	Value	Reason
Aug-31-2020 14:43:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> Jun/UNK/2011	Transcription Error
Aug-31-2020 14:42:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> UNK/UNK/2011	Initial Entry

**If Ongoing:**

Date	Location	User	Value	Reason
Aug-31-2020 14:42:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> YES	Initial Entry

**I.g**

Date	Location	User	Value	Reason
Aug-31-2020 14:43:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number 7 : Medical History T ANXIETY erm:	Initial Entry

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)



**Header Text:** c4591001  
**Visit:** V1\_DAY1\_VAX1\_L  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1009  
**Subject No:** 10091135  
**Generated By:** pfe.levisse

**Form:** GENERAL MEDICAL HISTORY - 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):** 29-Mar-2021 04:12

			<b>Start Date:</b> Jun/UNK/2011 <b>Ongoing:</b> YES
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***I.g Line/MH Number:***

Date	Location	User	Value	Reason
Aug-31-2020 14:43:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

***I.g Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Aug-31-2020 14:43:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> ANXIETY	Initial Entry

***I.g Start Date:***

Date	Location	User	Value	Reason
Aug-31-2020 14:43:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> Jun/UNK/2011	Initial Entry

***I.g Ongoing:***

Date	Location	User	Value	Reason
Aug-31-2020 14:43:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> YES	Initial Entry

***I.h***

Date	Location	User	Value	Reason
Aug-31-2020 14:45:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 8	Initial Entry

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001  
**Visit:** V1\_DAY1\_VAX1\_L  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1009  
**Subject No:** 10091135  
**Generated By:** pfe.levisse

**Form:** GENERAL MEDICAL HISTORY - 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):** 29-Mar-2021 04:12

			<b>Medical History Term:</b> MTHFR GENE MUTATION <b>Start Date:</b> (b) (6) /1957 <b>Ongoing:</b> YES
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**1.h Line/MH Number:**

Date	Location	User	Value	Reason
Aug-31-2020 14:45:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 8	Initial Entry

**1.h Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Aug-31-2020 14:45:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> MTHFR GENE MUTATION	Initial Entry

**1.h Start Date:**

Date	Location	User	Value	Reason
Aug-31-2020 14:45:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> (b) (6) /1957	Initial Entry

**1.h Ongoing:**

Date	Location	User	Value	Reason
Aug-31-2020 14:45:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> YES	Initial Entry

**1.i**

Date	Location	User	Value	Reason
Sep-02-2020 13:40:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Line/MH Number: 9	Transcription Error

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001  
**Visit:** V1\_DAY1\_VAX1\_L  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1009  
**Subject No:** 10091135  
**Generated By:** pfe.levisse

**Form:** GENERAL MEDICAL HISTORY - 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):** 29-Mar-2021 04:12

			<b>Medical History Term:</b> ASPIRIN INTOLERANCE <b>Start Date:</b> UNK/UNK/1986 <b>Ongoing:</b> YES	
Aug-31-2020 14:46:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 9 <b>Medical History Term:</b> ASPIRIN INTOLERANCE <b>Start Date:</b> UNK/UNK/1986 <b>Ongoing:</b> YES	Initial Entry

**1.i Line/MH Number:**

Date	Location	User	Value	Reason
Aug-31-2020 14:46:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 9	Initial Entry

**1.i Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Sep-03-2020 04:08:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 1: Closed	Response satisfies query

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091135

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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): 29-Mar-2021 04:12

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***1.i Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Sep-02-2020 13:40:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-02-2020 13:40:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> ASPIRIN INTOLERANCE	Transcription Error
Sep-01-2020 13:36:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Swaranjali Subhash Pawar (pfe.pawars01)	Query 1: Opened	DM: A trailing space is identified. To avoid processing errors, please remove the identified character by deleting the entry and re-entering the data (without using copy and paste).
Aug-31-2020 14:46:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> ASPIRIN INTOLERANCE	Initial Entry

***1.i Start Date:***

Date	Location	User	Value	Reason
Aug-31-2020 14:46:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> UNK/UNK/1986	Initial Entry

***1.i Ongoing:***

Date	Location	User	Value	Reason
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090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levisse

**Form:** GENERAL MEDICAL HISTORY - 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):** 29-Mar-2021 04:12

Aug-31-2020 14:46:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> YES	Initial Entry
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*Lj*

Date	Location	User	Value	Reason
Aug-31-2020 14:47:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Nu</b> 10 <b>mber:</b> <b>Medical Histo</b> GLUTEN INTO <b>ry Term:</b> LERANCE <b>Start Date:</b> UNK/UNK/200 3 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1009**Subject No:** 10091135**Generated By:** pfe.levisse**Form:** GENERAL MEDICAL HISTORY - 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):** 29-Mar-2021 04:12***I.j Line/MH Number:***

Date	Location	User	Value	Reason
Aug-31-2020 14:47:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10	Initial Entry

***I.j Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Aug-31-2020 14:47:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> GLUTEN INTOLERANCE	Initial Entry

***I.j Start Date:***

Date	Location	User	Value	Reason
Aug-31-2020 14:47:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> UNK/UNK/2003	Initial Entry

***I.j Ongoing:***

Date	Location	User	Value	Reason
Aug-31-2020 14:47:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> YES	Initial Entry

***I.k***

Date	Location	User	Value	Reason
Aug-31-2020 14:48:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 11 <b>Medical History Term:</b> LACTOSE INTOLERANCE <b>Start Date:</b> UNK/UNK/1970 <b>Ongoing:</b> YES	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levisse

**Form:** GENERAL MEDICAL HISTORY - 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):** 29-Mar-2021 04:12

***I.k Line/MH Number:***

Date	Location	User	Value	Reason
Aug-31-2020 14:48:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 11	Initial Entry

***I.k Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Aug-31-2020 14:48:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> LACTOSE INTOLERANCE	Initial Entry

***I.k Start Date:***

Date	Location	User	Value	Reason
Aug-31-2020 14:48:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> UNK/UNK/1970	Initial Entry

***I.k Ongoing:***

Date	Location	User	Value	Reason
Aug-31-2020 14:48:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> YES	Initial Entry

***I.l***

Date	Location	User	Value	Reason
Aug-31-2020 14:48:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 12 <b>Medical History Term:</b> MORPHINE INTOLERANCE <b>Start Date:</b> UNK/UNK/1986 <b>Ongoing:</b> YES	Initial Entry

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**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**Form:** GENERAL MEDICAL HISTORY - 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):** 29-Mar-2021 04:12

**1.1 Line/MH Number:**

Date	Location	User	Value	Reason
Aug-31-2020 14:48:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 12	Initial Entry

**1.1 Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Aug-31-2020 14:48:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> MORPHINE INTOLERANCE	Initial Entry

**1.1 Start Date:**

Date	Location	User	Value	Reason
Aug-31-2020 14:48:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> UNK/UNK/1986	Initial Entry

**1.1 Ongoing:**

Date	Location	User	Value	Reason
Aug-31-2020 14:48:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)



**Header Text:** c4591001

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

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**Form:** VITAL SIGNS - BASELINE - 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):** 29-Mar-2021 04:12

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**1. Date:**

Date	Location	User	Value	Reason
Aug-31-2020 14:50:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> Aug/31/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Aug-31-2020 14:50:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> 243.2	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Aug-31-2020 14:50:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> LB	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Aug-31-2020 14:50:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> 64.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Aug-31-2020 14:50:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> in	Initial Entry

**6. Body Mass Index:**

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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1009

Subject No: 10091135

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - 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): 29-Mar-2021 04:12

Date	Location	User	Value	Reason
Aug-31-2020 14:50:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 41.7	Initial Entry

**7.a**

Date	Location	User	Value	Reason
Aug-31-2020 14:50:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> <b>Record Identifier 1</b> :: <b>Temperature:</b> 97.9 <b>Temperature Unit:</b> <b>Temperature Location:</b> ORAL CAVITY	Initial Entry

**7.a Record Identifier:**

Date	Location	User	Value	Reason
Aug-31-2020 14:50:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> 1	Initial Entry

**7.a Temperature:**

Date	Location	User	Value	Reason
Aug-31-2020 14:50:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> 97.9	Initial Entry

**7.a Unit:**

Date	Location	User	Value	Reason
Aug-31-2020 14:50:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> F	Initial Entry

**7.a Temperature Location:**

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

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

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levisse

**Form:** VITAL SIGNS - BASELINE - 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):** 29-Mar-2021 04:12

Date	Location	User	Value	Reason
Aug-31-2020 14:50:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

**Header Text:** c4591001

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

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

**Form Version:** 21-Aug-2020 02:49

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

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Aug-31-2020 14:54:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Aug-31-2020 14:54:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Aug-31-2020 14:54:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Aug-31-2020 14:54:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Aug-31-2020 14:54:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a**

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091135

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Aug-31-2020 14:54:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-31-2020 14:54:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-31-2020 14:54:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Aug-31-2020 14:54:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Aug-31-2020 14:54:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**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):** 29-Mar-2021 04:12

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Aug-31-2020 14:54:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> Aug/31/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Aug-31-2020 14:54:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> 244646	Initial Entry

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1009**Subject No:** 10091135**Generated By:** pfe.levisse**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):** 29-Mar-2021 04:12[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-31-2020 14:55:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-31-2020 14:55:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-31-2020 15:19:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-31-2020 14:55:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-31-2020 14:55:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> YES Date of Collection:  Aug/31/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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**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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Aug-31-2020 15:19:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> <b>Sample ID:</b> BP9GKG	Initial Entry
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**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-31-2020 15:19:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> BP9GKG	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Aug-31-2020 15:19:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> <b>Sample ID:</b> BP9GKH	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Aug-31-2020 15:19:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> BP9GKH	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Aug-31-2020 15:19:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> <b>Sample ID:</b> BP9GKJ	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Aug-31-2020 15:19:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> BP9GKJ	Initial Entry

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**5.d**

Date	Location	User	Value	Reason
Aug-31-2020 15:22:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> <b>Sample ID:</b> BPR980	Initial Entry

**5.d Sample ID**

Date	Location	User	Value	Reason
Aug-31-2020 15:22:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> BPR980	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Aug-31-2020 15:22:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> <b>Sample ID:</b> BPR981	Initial Entry

**5.e Sample ID**

Date	Location	User	Value	Reason
Aug-31-2020 15:22:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> BPR981	Initial Entry

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (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:** 10091135**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-31-2020 15:18:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-31-2020 15:18:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-31-2020 15:18:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-31-2020 15:18:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-31-2020 15:18:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> YES Date of Collection:  Aug/31/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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**Header Text:** c4591001  
**Visit:** V1\_DAY1\_VAX1\_L  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1009  
**Subject No:** 10091135  
**Generated By:** pfe.levisse

**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):** 29-Mar-2021 04:12

Aug-31-2020 15:18:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> <b>Sample ID:</b> BP9G29	Initial Entry
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**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-31-2020 15:18:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> BP9G29	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1009

Subject No: 10091135

Generated By: pfe.levisse

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): 29-Mar-2021 04:12

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

Date	Location	User	Value	Reason
Aug-31-2020 14:56:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Aug-31-2020 14:56:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Aug-31-2020 14:56:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Aug-31-2020 14:56:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> Aug/31/2020 13:44	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-31-2020 14:56:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levisse

**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):** 29-Mar-2021 04:12

Date	Location	User	Value	Reason
Aug-31-2020 14:56:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Aug-31-2020 14:56:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Aug-31-2020 14:56:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 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
Aug-31-2020 14:56:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**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):** 29-Mar-2021 04:12

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Aug-31-2020 14:56:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<b>Data Entry:</b> NO - REACTOGENICITY E-D IARY NOT COLLECTED FO R THIS SUBJECT	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**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):** 29-Mar-2021 04:12

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*1. Date of Visit*

Date	Location	User	Value	Reason
Sep-22-2020 16:20:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Sep/22/2020	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 15-Sep-2020 21:54

Site No: 1009

Subject No: 10091135

Generated By: pfe.levisse

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): 29-Mar-2021 04:12

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**1. Date:**

Date	Location	User	Value	Reason
Sep-22-2020 16:21:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Sep/22/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-22-2020 16:21:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> <b>Record Identifier 1</b> :: <b>Temperature:</b> 98.1 <b>Temperature Unit:</b> <b>Temperature Location:</b> ORAL CAVITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-22-2020 16:21:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Sep-22-2020 16:21:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> 98.1	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
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090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levisse

**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):** 29-Mar-2021 04:12

Sep-22-2020 16:21:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.downen)	<b>Data Entry:</b> F	Initial Entry
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**2.a Temperature Location:**

Date	Location	User	Value	Reason
Sep-22-2020 16:21:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.downen)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 21-Aug-2020 02:49

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

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-22-2020 16:21:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Sep-22-2020 16:21:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Sep-22-2020 16:21:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Sep-22-2020 16:21:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Sep-22-2020 16:21:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a**

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091135

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Sep-22-2020 16:21:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-22-2020 16:21:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-22-2020 16:21:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-22-2020 16:21:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-22-2020 16:21:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (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:** 10091135**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-22-2020 16:22:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-22-2020 16:22:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-22-2020 16:22:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-22-2020 16:22:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-22-2020 16:22:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> YES Date of Collection:  Sep/22/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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**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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Sep-22-2020 16:22:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.downen)	<b>Data Entry:</b> <b>Sample ID:</b> BP9G84	Initial Entry
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**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-22-2020 16:22:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.downen)	<b>Data Entry:</b> BP9G84	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1009

Subject No: 10091135

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Sep-22-2020 16:23:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-22-2020 16:23:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-22-2020 16:23:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Sep-22-2020 16:23:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Sep/22/2020 16:22	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-22-2020 16:23:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levisse

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

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

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

**Subject Initials:** ---

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

Date	Location	User	Value	Reason
Sep-22-2020 16:23:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Sep-22-2020 16:23:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Sep-22-2020 16:23:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 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
Sep-22-2020 16:23:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**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):** 29-Mar-2021 04:12

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*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-22-2020 17:18:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Oct/21/2020	Transcription Error
Oct-22-2020 17:13:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Oct/22/2020	Initial Entry



**Header Text:** c4591001

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

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

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

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

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-22-2020 17:14:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-22-2020 17:14:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-22-2020 17:18:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.downen)	<b>Data Entry:</b> YES Date of Collection:  Oct/21/2020	Transcription Error
Oct-22-2020 17:14:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-22-2020 17:14:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-22-2020 17:14:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.downen)	<b>Data Entry:</b> YES Date of Collection:	Initial Entry

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (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: 10091135

Subject Initials: ---

Generated By: pfe.levisse

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

			Oct/22/2020	
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5.a

Date	Location	User	Value	Reason
Oct-22-2020 17:14:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> <b>Sample ID: BR9FNH</b>	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-22-2020 17:14:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> BR9FNH	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-22-2020 17:16:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> <b>Sample ID: BKYCYM</b>	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-22-2020 17:16:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> BKYCYM	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-22-2020 17:17:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> <b>Sample ID: BKYCV C</b>	Initial Entry

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**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levisse

**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):** 29-Mar-2021 04:12

**5.c Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Oct-22-2020 17:17:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> BKYCV C	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020

**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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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***1. Date of Visit***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Oct-29-2020 23:02:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi (pfe.suryas18)	Query 5: Closed	Visit is marked as ERRONEOUS VISIT hence query closed.
Oct-29-2020 13:13:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.downen)	Query 5: Answered	Original value is correct
Oct-29-2020 12:08:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jennifer Riddle (pfe.riddlj)	Query 4: Closed	Erroneous visit
Oct-29-2020 10:51:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 3: Deleted	Site entered not applicable.
Oct-29-2020 10:50:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 5: Opened	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Oct-29-2020 10:49:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 4: Opened	Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1009**Subject No:** 10091135**Generated By:** pfe.levisse**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):** 29-Mar-2021 04:12

				visit.
Oct-29-2020 08:43:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Oct-29-2020 08:39:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Candidate	Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this visit.
Oct-29-2020 08:36:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: 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.
Oct-28-2020 10:52:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-28-2020 10:52:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Oct-28-2020 10:51:32 (UTC-07:00) Mountain Time (US	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1009**Subject No:** 10091135**Generated By:** pfe.levisse**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):** 29-Mar-2021 04:12

& Canada)				Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Oct-28-2020 10:51:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Oct-28-2020 10:51:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.downen)	<b>Data Entry:</b> Oct/28/2020	Initial Entry

**2. Erroneous Visit**

Date	Location	User	Value	Reason
Oct-29-2020 08:39:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.downen)	<b>Data Entry:</b> ERRONEOUS VISIT	Initial Entry

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

Date	Location	User	Value	Reason
Oct-28-2020 10:51:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> COVID_A	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1009**Subject No:** 10091135**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic  
South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Oct-29-2020 08:43:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-29-2020 08:43:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b>	Transcription Error
Oct-28-2020 10:52:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Oct/28/2020	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Oct-29-2020 08:43:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-29-2020 08:37:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b>	Transcription Error
Oct-28-2020 10:52:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Oct/28/2020	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Oct-29-2020 08:43:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-29-2020 08:39:42 (UTC-07:00) Mountain	ACV0PFEINFP6000	Dylan Owen	<b>Data Entry:</b>	Transcription Error

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1009**Subject No:** 10091135**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic  
South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12

Time (US & Canada)		(pfe.dowen)		
Oct-28-2020 10:52:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> YES	Initial Entry

**4.a**

Date	Location	User	Value	Reason
Oct-29-2020 08:43:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> <b>Symptoms:</b> FEVER <b>Symptom Present:</b> Not Applicable	Initial Entry
Oct-29-2020 08:37:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> <b>Symptoms:</b> FEVER <b>Symptom Present:</b>	Transcription Error
Oct-28-2020 10:52:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> <b>Symptoms:</b> FEVER <b>Symptom Present:</b> NO	Initial Entry

**4.a Symptoms:**

Date	Location	User	Value	Reason
Oct-28-2020 10:52:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> FEVER	Initial Entry

**4.a Was symptom present?**

Date	Location	User	Value	Reason
Oct-29-2020 08:43:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-29-2020 08:37:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b>	Transcription Error



**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/28/2020  
**Form Version:** 10-Oct-2020 16:02  
**Site No:** 1009  
**Subject No:** 10091135  
**Generated By:** pfe.levisse

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History  
**Form Status:** Data Complete, Frozen, Verified  
**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 04:12

Oct-28-2020 10:52:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> NO	Initial Entry
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**4.b**

Date	Location	User	Value	Reason
Oct-29-2020 08:43:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> <b>Symptom s:</b> NEW OR INCREASED COUGH <b>Symptom Present:</b> Not Applicable	Initial Entry
Oct-29-2020 08:38:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> <b>Symptom s:</b> NEW OR INCREASED COUGH <b>Symptom Present:</b>	Transcription Error
Oct-28-2020 10:52:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> <b>Symptom s:</b> NEW OR INCREASED COUGH <b>Symptom Present:</b> NO	Initial Entry

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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1009**Subject No:** 10091135**Generated By:** pfe.levissc**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic  
South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12**4.b Symptoms:**

Date	Location	User	Value	Reason
Oct-28-2020 10:52:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> NEW OR INCREASED COUG H	Initial Entry

**4.b Was symptom present?**

Date	Location	User	Value	Reason
Oct-29-2020 08:43:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-29-2020 08:38:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b>	Transcription Error
Oct-28-2020 10:52:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> NO	Initial Entry

**4.c**

Date	Location	User	Value	Reason
Oct-29-2020 08:43:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> <b>Symptom:</b> NEW OR INCREAS ED SHORTNESS O F BREATH <b>Symptom Present:</b> Not Applicable	Initial Entry
Oct-29-2020 08:38:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> <b>Symptom:</b> NEW OR INCREAS ED SHORTNESS O F BREATH <b>Symptom Present:</b>	Transcription Error

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1009**Subject No:** 10091135**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic  
South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12

Oct-28-2020 10:52:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> <b>Symptom</b> NEW OR INCREASED SHORTNESS OF BREATH <b>Symptom Present:</b> NO	Initial Entry
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**4.c Symptoms:**

Date	Location	User	Value	Reason
Oct-28-2020 10:52:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

**4.c Was symptom present?**

Date	Location	User	Value	Reason
Oct-29-2020 08:43:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-29-2020 08:38:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b>	Transcription Error
Oct-28-2020 10:52:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> NO	Initial Entry

**4.d**

Date	Location	User	Value	Reason
Oct-29-2020 08:43:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> <b>Symptoms:</b> CHILLS <b>Symptom Present:</b> Not Applicable	Initial Entry
Oct-29-2020 08:38:38 (UTC-07:00) Mountain	ACV0PFEINFP6000	Dylan Owen	<b>Data Entry:</b> <b>Symptoms:</b> CHILLS	Transcription Error

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1009**Subject No:** 10091135**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic  
South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12

Time (US & Canada)		(pfe.down)	<b>Symptom Present:</b>	
Oct-28-2020 10:52:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.down)	<b>Data Entry:</b> <b>Symptoms:</b> CHILLS <b>Symptom Present:</b> NO	Initial Entry

**4.d Symptoms:**

Date	Location	User	Value	Reason
Oct-28-2020 10:52:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.down)	<b>Data Entry:</b> CHILLS	Initial Entry

**4.d Was symptom present?**

Date	Location	User	Value	Reason
Oct-29-2020 08:43:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.down)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-29-2020 08:38:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.down)	<b>Data Entry:</b>	Transcription Error
Oct-28-2020 10:52:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.down)	<b>Data Entry:</b> NO	Initial Entry

**4.e**

Date	Location	User	Value	Reason
Oct-29-2020 08:43:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.down)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED MUSCLE PAIN <b>Symptom Present:</b> Not Applicable	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1009**Subject No:** 10091135**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic  
South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12

Oct-29-2020 08:38:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> <b>Symptom Present:</b> NEW OR INCREASED MUSCLE PAIN	Transcription Error
Oct-28-2020 10:52:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> <b>Symptom Present:</b> NEW OR INCREASED MUSCLE PAIN <b>Symptom Present:</b> NO	Initial Entry

**4.e Symptoms:**

Date	Location	User	Value	Reason
Oct-28-2020 10:52:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> NEW OR INCREASED MUSCLE PAIN	Initial Entry

**4.e Was symptom present?**

Date	Location	User	Value	Reason
Oct-29-2020 08:43:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-29-2020 08:38:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b>	Transcription Error
Oct-28-2020 10:52:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> NO	Initial Entry

**4.f**

Date	Location	User	Value	Reason
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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1009**Subject No:** 10091135**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic  
South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12

Oct-29-2020 08:43:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> <b>Symptom</b> NEW LOSS OF T <b>s:</b> ASTE OR SMELL <b>Symptom</b> Not Applicable <b>Present:</b>	Initial Entry
Oct-29-2020 08:39:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> <b>Symptom</b> NEW LOSS OF T <b>s:</b> ASTE OR SMELL <b>Symptom</b> <b>Present:</b>	Transcription Error
Oct-28-2020 10:52:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> <b>Symptom</b> NEW LOSS OF T <b>s:</b> ASTE OR SMELL <b>Symptom</b> NO <b>Present:</b>	Initial Entry

**4.f Symptoms:**

Date	Location	User	Value	Reason
Oct-28-2020 10:52:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> NEW LOSS OF TASTE OR S MELL	Initial Entry

**4.f Was symptom present?**

Date	Location	User	Value	Reason
Oct-29-2020 08:43:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-29-2020 08:39:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b>	Transcription Error
Oct-28-2020 10:52:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levisse

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

**4.g**

Date	Location	User	Value	Reason
Oct-29-2020 08:43:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> <b>Symptom Present:</b> NEW OR INCREASED SORE THROAT <b>Symptom Present:</b> Not Applicable	Initial Entry
Oct-29-2020 08:39:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> <b>Symptom Present:</b> NEW OR INCREASED SORE THROAT <b>Symptom Present:</b>	Transcription Error
Oct-28-2020 10:52:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> <b>Symptom Present:</b> NEW OR INCREASED SORE THROAT <b>Symptom Present:</b> NO	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

**4.g Symptoms:**

Date	Location	User	Value	Reason
Oct-28-2020 10:52:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> NEW OR INCREASED SORE THROAT	Initial Entry

**4.g Was symptom present?**

Date	Location	User	Value	Reason
Oct-29-2020 08:43:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-29-2020 08:39:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b>	Transcription Error
Oct-28-2020 10:52:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> NO	Initial Entry

**4.h**

Date	Location	User	Value	Reason
Oct-29-2020 08:43:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> <b>Symptoms:</b> DIARRHEA <b>Symptom Present:</b> Not Applicable	Initial Entry

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levisse

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

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**4.h**

Date	Location	User	Value	Reason
Oct-29-2020 08:39:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> <b>Symptoms:</b> DIARRHE A <b>Symptom Present:</b>	Transcription Error
Oct-28-2020 10:52:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> <b>Symptoms:</b> DIARRHE A <b>Symptom Present:</b> YES	Initial Entry

**4.h Symptoms:**

Date	Location	User	Value	Reason
Oct-28-2020 10:52:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> DIARRHEA	Initial Entry

**4.h Was symptom present?**

Date	Location	User	Value	Reason
Oct-29-2020 08:43:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-29-2020 08:39:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b>	Transcription Error
Oct-28-2020 10:52:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> YES	Initial Entry

**4.i**

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History

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

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

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Date	Location	User	Value	Reason
Oct-29-2020 08:43:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> <b>Symptoms:</b> VOMITING <b>Symptom Present:</b> Not Applicable	Initial Entry
Oct-29-2020 08:39:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> <b>Symptoms:</b> VOMITING <b>Symptom Present:</b>	Transcription Error
Oct-28-2020 10:52:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> <b>Symptoms:</b> VOMITING <b>Symptom Present:</b> NO	Initial Entry

**4.i Symptoms:**

Date	Location	User	Value	Reason
Oct-28-2020 10:52:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> VOMITING	Initial Entry

**4.i Was symptom present?**

Date	Location	User	Value	Reason
Oct-29-2020 08:43:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-29-2020 08:39:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b>	Transcription Error
Oct-28-2020 10:52:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020**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:** 10091135**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Oct-29-2020 08:43:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-29-2020 08:36:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b>	Initial Entry
Oct-28-2020 10:52:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Oct-29-2020 08:43:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-29-2020 08:36:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b>	Initial Entry
Oct-28-2020 10:52:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Oct-29-2020 08:43:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-29-2020 08:36:51 (UTC-07:00) Mountain	ACV0PFEINFP6000	Dylan Owen	<b>Data Entry:</b>	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020**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:** 10091135**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12

Time (US & Canada)		(pfe.dowen)		
Oct-28-2020 10:52:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Done	Initial Entry

**4. Assay Code and Description:**

Date	Location	User	Value	Reason
Oct-29-2020 08:43:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-29-2020 08:36:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b>	Initial Entry
Oct-28-2020 10:52:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Done	Initial Entry

**5. Device Type:**

Date	Location	User	Value	Reason
Oct-29-2020 08:43:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-29-2020 08:36:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b>	Initial Entry
Oct-28-2020 10:52:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Done	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
Oct-29-2020 08:43:49 (UTC-07:00) Mountain	ACV0PFEINFP6000	Dylan Owen	<b>Data Entry:</b> Not Applicable	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020**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:** 10091135**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12

Time (US & Canada)		(pfe.dowen)		
Oct-29-2020 08:36:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b>	Initial Entry
Oct-28-2020 10:52:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Done	Initial Entry

**7. Test Result:**

Date	Location	User	Value	Reason
Oct-29-2020 08:43:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-29-2020 08:36:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b>	Initial Entry
Oct-28-2020 10:52:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Done	Initial Entry

**8. Comments/Findings/Details:**

Date	Location	User	Value	Reason
Oct-29-2020 08:43:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-29-2020 08:36:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b>	Initial Entry
Oct-28-2020 10:52:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Done	Initial Entry

**9. Trade Name Other, Specify:**

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020

**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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Date	Location	User	Value	Reason
Oct-29-2020 08:43:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-29-2020 08:36:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b>	Initial Entry
Oct-28-2020 10:52:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Done	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1009**Subject No:** 10091135**Generated By:** pfe.levisse**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):** 29-Mar-2021 04:12[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-29-2020 08:44:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-29-2020 08:36:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Oct-28-2020 10:52:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-29-2020 08:44:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-29-2020 08:36:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Oct-28-2020 10:52:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-29-2020 08:44:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-29-2020 08:36:35 (UTC-07:00) Mountain	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1009**Subject No:** 10091135**Generated By:** pfe.levisse**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):** 29-Mar-2021 04:12

Time (US & Canada)				
Oct-29-2020 08:36:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b>	Transcription Error
Oct-29-2020 05:35:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Roshni Nair (pfe.nairr29)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-28-2020 10:52:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-28-2020 10:52:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> YES Date of Collection:  Oct/28/2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-29-2020 08:44:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Applicable	Initial Entry



**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020**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:** 10091135**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-29-2020 08:44:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-29-2020 08:36:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Oct-28-2020 10:53:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-29-2020 08:44:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-29-2020 08:36:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Oct-28-2020 10:53:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-29-2020 08:44:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-29-2020 08:36:21 (UTC-07:00) Mountain	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020**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:** 10091135**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12

Time (US & Canada)				
Oct-29-2020 08:36:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b>	Transcription Error
Oct-29-2020 08:36:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Oct-28-2020 10:53:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> 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
Oct-29-2020 08:44:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-29-2020 08:36:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b>	Transcription Error
Oct-28-2020 10:53:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> self swab collected	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic  
South**Subject No:** 10091135**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)*I.a*

Date	Location	User	Value	Reason
Oct-29-2020 08:44:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> <b>Type of Practitioner:</b> SPECIALIST <b>Occurrence of Visits or Contacts:</b> Not Applicable	Initial Entry
Oct-29-2020 08:34:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> <b>Type of Practitioner:</b> SPECIALIST <b>Occurrence of Visits or Contacts:</b>	Transcription Error
Oct-28-2020 10:53:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> <b>Type of Practitioner:</b> SPECIALIST <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

*I.a Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Oct-28-2020 10:53:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> SPECIALIST	Initial Entry

*I.a Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Oct-29-2020 08:44:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-29-2020 08:34:22 (UTC-07:00) Mountain	ACV0PFEINFP6000	Dylan Owen	<b>Data Entry:</b>	Transcription Error

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

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

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

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Time (US & Canada)		(pfe.down)		
Oct-28-2020 10:53:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.down)	<b>Data Entry:</b> NO	Initial Entry

***1.b***

Date	Location	User	Value	Reason
Oct-29-2020 08:44:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.down)	<b>Data Entry:</b> <b>Type of Practitioner:</b> EMERGENCY ROOM <b>Occurrence of Visits or Contacts:</b> Not Applicable	Initial Entry
Oct-29-2020 08:34:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.down)	<b>Data Entry:</b> <b>Type of Practitioner:</b> EMERGENCY ROOM <b>Occurrence of Visits or Contacts:</b>	Transcription Error
Oct-28-2020 10:53:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.down)	<b>Data Entry:</b> <b>Type of Practitioner:</b> EMERGENCY ROOM <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic  
South**Subject No:** 10091135**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12***I.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Oct-28-2020 10:53:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> EMERGENCY ROOM	Initial Entry

***I.b Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Oct-29-2020 08:44:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-29-2020 08:34:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b>	Transcription Error
Oct-28-2020 10:53:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> NO	Initial Entry

***I.c***

Date	Location	User	Value	Reason
Oct-29-2020 08:44:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> <b>Type of Practitioner:</b> PRIMARY CARE PHYSICIAN <b>Occurrence of Visits or Contacts:</b> Not Applicable	Initial Entry
Oct-29-2020 08:35:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> <b>Type of Practitioner:</b> PRIMARY CARE PHYSICIAN <b>Occurrence of Visits or Contacts:</b>	Transcription Error

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic  
South**Subject No:** 10091135**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12

Oct-28-2020 10:53:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> <b>Type of Practitioner:</b> PRIMARY CARE PHYSICIAN <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry
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***I.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Oct-28-2020 10:53:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> PRIMARY CARE PHYSICIAN	Initial Entry

***I.c Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Oct-29-2020 08:44:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-29-2020 08:35:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b>	Transcription Error
Oct-28-2020 10:53:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> NO	Initial Entry

***I.d***

Date	Location	User	Value	Reason
Oct-29-2020 08:44:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> <b>Type of Practitioner:</b> URGENT CARE <b>Occurrence of Visits or Contacts:</b> Not Applicable	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic  
South**Subject No:** 10091135**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12

Oct-29-2020 08:35:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> <b>Type of Practitioner:</b> URGENT CARE <b>Occurrence of Visits or Contacts:</b>	Transcription Error
Oct-28-2020 10:53:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> <b>Type of Practitioner:</b> URGENT CARE <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

***I.d Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Oct-28-2020 10:53:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> URGENT CARE	Initial Entry

***I.d Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Oct-29-2020 08:44:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-29-2020 08:35:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b>	Transcription Error
Oct-28-2020 10:53:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> NO	Initial Entry

***I.e***

Date	Location	User	Value	Reason
Oct-29-2020 08:44:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> <b>Type of Practitioner:</b> TELEPHONE CONSULTATION	Initial Entry

**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/28/2020  
**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History  
**Form Version:** 10-Oct-2020 15:59  
**Form Status:** Data Complete, Frozen, Verified  
**Site No:** 1009  
**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South  
**Subject No:** 10091135  
**Subject Initials:** ---  
**Generated By:** pfe.levisse  
**Generated Time (GMT):** 29-Mar-2021 04:12

			ION Occurrence of Not Applicabl Visits or Cont e acts:	
Oct-29-2020 08:35:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> <b>Type of Practi TELEPHONE tioner:</b> CONSULTAT ION <b>Occurrence of Visits or Cont acts:</b>	Transcription Error
Oct-28-2020 10:53:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> <b>Type of Practi TELEPHONE tioner:</b> CONSULTAT ION <b>Occurrence of NO Visits or Cont acts:</b>	Initial Entry

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

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

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

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

***I.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Oct-28-2020 10:53:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> TELEPHONE CONSULTATIO N	Initial Entry

***I.e Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Oct-29-2020 08:44:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-29-2020 08:35:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b>	Transcription Error
Oct-28-2020 10:53:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> NO	Initial Entry

***I.f***

Date	Location	User	Value	Reason
Oct-29-2020 08:44:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> <b>Type of Practitioner:</b> OTHER <b>Occurrence of Visits or Contacts:</b> Not Applicable	Initial Entry
Oct-29-2020 08:35:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> <b>Type of Practitioner:</b> OTHER <b>Occurrence of Visits or Contacts:</b>	Transcription Error
Oct-28-2020 10:53:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> <b>Type of Practitioner:</b> OTHER	Initial Entry

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic  
South**Subject No:** 10091135**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12Occurrence of Visits or  
Contacts:**1.f Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Oct-28-2020 10:53:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> OTHER	Initial Entry

**1.f Occurrence of Visits or Contacts:**

Date	Location	User	Value	Reason
Oct-29-2020 08:44:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-29-2020 08:35:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b>	Transcription Error
Oct-28-2020 10:53:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> NO	Initial Entry

**2. Other Type of Practitioner Specify:**

Date	Location	User	Value	Reason
Oct-29-2020 08:44:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Oct-29-2020 08:44:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Applicable	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

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

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

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Oct-29-2020 08:35:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b>	Transcription Error
Oct-28-2020 10:53:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020**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:** 10091135**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Oct-29-2020 08:44:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-29-2020 08:34:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Oct-28-2020 10:53:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> POTENTIAL COVID-19 ILLN ESS	Initial Entry

**2. Was a diagnosis obtained for Potential COVID-19 Illness?**

Date	Location	User	Value	Reason
Oct-29-2020 08:44:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-29-2020 08:34:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b>	Transcription Error
Oct-28-2020 10:53:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> NO	Initial Entry

**3. Toxicity Grade:**

Date	Location	User	Value	Reason
Oct-29-2020 08:44:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-29-2020 08:34:00 (UTC-07:00) Mountain	ACV0PFEINFP6000	Dylan Owen	<b>Data Entry:</b>	Transcription Error

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/28/2020

**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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Time (US & Canada)		(pfe.dowen)		
Oct-28-2020 10:53:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> 2	Initial Entry

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

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

**Form Version:** 15-Sep-2020 21:55

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

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.leviscc

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

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

Date	Location	User	Value	Reason
Oct-22-2020 17:17:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Oct/21/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-22-2020 17:17:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-22-2020 17:17:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

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

**Subject Initials:** ---

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

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Date	Location	User	Value	Reason
Oct-22-2020 17:24:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.downen)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

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

**Subject Initials:** ---

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

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Date	Location	User	Value	Reason
Oct-22-2020 17:29:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	Form Created	



Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091135

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

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**1. Category:**

Date	Location	User	Value	Reason
Oct-22-2020 17:24:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Oct-22-2020 17:24:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Oct-22-2020 17:24:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> right breast lump	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Oct-22-2020 17:24:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Sep/2/2020 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Oct-22-2020 17:24:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> YES	Initial Entry

**6. Toxicity Grade:**

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091135

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Oct-22-2020 17:24:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> 1	Initial Entry

**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

Date	Location	User	Value	Reason
Oct-22-2020 17:24:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> 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
Oct-22-2020 17:24:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Oct-27-2020 13:42:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 1: Closed	Response satisfies query
Oct-27-2020 10:35:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	Query 1: Answered	cancer is captured as AE R (DCIS)

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

Canada)				
Oct-26-2020 14:44:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (pfe.PFESDQ_PROD)	Query 1: Opened	Please review "If not related to study treatment other" field, the following text was indicated in the comment field [cancer]. Any symptoms, AEs or other key data should be collected on the appropriate page. Please review and update as necessary. "[nazairl SDQ=20884]"
Oct-22-2020 17:24:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> NOT RELATED  If Not Related to study treatment(s), this event is due to:  OT	Initial Entry

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

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**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Oct-22-2020 17:24:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Oct-22-2020 17:24:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Oct-22-2020 17:24:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> NO	Initial Entry

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

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

Date	Location	User	Value	Reason
Oct-22-2020 17:24:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> NOT RECOVERED/NOT RES OLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-22-2020 17:24:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

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

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**1. Category:**

Date	Location	User	Value	Reason
Oct-22-2020 17:29:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Oct-22-2020 17:29:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Oct-22-2020 17:29:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Right Breast Ductal Carcinoma In Situ	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Oct-28-2020 22:31:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Oct-28-2020 15:18:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Oct-28-2020 15:18:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Sep/2/2020 UNK:UNK	New Information
Oct-27-2020 11:49:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell	Query 1: Opened	Clinical Rt. breast lump discovered

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1009**Subject No:** 10091135**Generated By:** pfe.levissc**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12

Time (US & Canada)		(pfe.sewelk02)		on 02Sep2020. In Vaccine study, SAE start date is day an event starts; not day it meets serious criteria (item 11 in vaccine SAE instruct). Please review start date; consider 1 event only.
Oct-22-2020 17:29:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Sep/24/2020 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Oct-22-2020 17:29:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> YES	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Oct-22-2020 17:29:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> 1	Initial Entry

**7. Is the adverse event serious?****If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

Date	Location	User	Value	Reason
Oct-23-2020 05:06:33	ACV0PFEINFP6000	auto query	Query 1: Deleted	Close Auto Query

**Header Text:** c4591001  
**Visit:** Logs - Unscheduled  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1009  
**Subject No:** 10091135  
**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History  
**Form Status:** Data Complete, Verified  
**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 04:12

(UTC-07:00) Mountain Time (US & Canada)		(autoquery)		
Oct-22-2020 17:29:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Right Breast Ductal Carcinoma In Situ: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Oct-22-2020 17:29:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.downen)	<b>Data Entry:</b> YES Is this serious event associated with congenital anomaly or birth defect?  NO  Did this serious event result in death?  NO  Did this serious event require or prolong hospitalization?  NO  Did this serious event result in persistent or significant disability/incapacity?  NO  Is this serious event life threatening?  NO  Other medically important serious event	Initial Entry

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Header Text: c4591001

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Site No: 1009

Subject No: 10091135

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

			YES	
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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
Oct-22-2020 17:29:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.downen)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Oct-22-2020 17:29:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.downen)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  spontaneous onset	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Oct-22-2020 17:29:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.downen)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Oct-22-2020 17:29:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.downen)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1009**Subject No:** 10091135**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12

Date	Location	User	Value	Reason
Mar-09-2021 03:11:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 1: Closed	Response satisfies query
Mar-08-2021 14:50:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Mar-08-2021 14:50:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jenessa Folsom (pfe.jfolsom)	<b>Data Entry:</b> YES	Changed Information
Mar-07-2021 14:27:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 1: Opened	GPDCLIN; non-drug treatment is listed as NO. Please clarify if resection was performed and whether additional therapy was given. If yes, please specify, update CRF (therapy and outcome)and submit a FU SAE report. Else, please clarify.
Oct-22-2020 17:29:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-22-2020 17:29:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> NOT RECOVERED/NOT 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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**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, Verified

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

Oct-22-2020 17:29:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.downen)	<b>Data Entry:</b> NO	Initial Entry
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**15. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
Oct-23-2020 05:06:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	<b>Data Entry:</b> 2020411592	Initial Entry

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**Header Text:** c4591001

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

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

**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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Mar-01-2021 10:08:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Allyson Christensen (pfe.achristensen)	<b>Data Entry:</b> Feb/19/2021	Initial Entry

**Header Text:** c4591001

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

**Form:** FURTHER VACCINATION CONFIRMATION - 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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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

Date	Location	User	Value	Reason
Mar-01-2021 10:09:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-01-2021 10:08:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	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.
Mar-01-2021 10:08:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Allyson Christensen (pfe.achristensen)	<b>Data Entry:</b> 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

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED - 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:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Mar-01-2021 10:11:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-01-2021 10:11:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Allyson Christensen (pfe.achristensen)	<b>Data Entry:</b> Feb/25/2021	Transcription Error
Mar-01-2021 10:09:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Date Treatment Unblinded" 25/Mar/2021 is a future date relative to when it was entered on 01/Mar/2021. Please correct.
Mar-01-2021 10:09:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Allyson Christensen (pfe.achristensen)	<b>Data Entry:</b> Mar/25/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Mar-01-2021 10:09:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Allyson Christensen (pfe.achristensen)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

090177e196ae3fa2\Final\Final On: 01-Apr-2021 05:20 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1009

**Subject No:** 10091135

**Generated By:** pfe.levissc

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

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

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

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**1. Subject Status**

Date	Location	User	Value	Reason
Oct-22-2020 17:17:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Aug-31-2020 14:54:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Aug-31-2020 14:35:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Oct-22-2020 17:17:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/21/2020	Initial Entry
Oct-22-2020 17:17:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/31/2020	Initial Entry
Aug-31-2020 14:54:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/31/2020	Initial Entry
Aug-31-2020 14:35:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/31/2020	Initial Entry

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**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

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

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

**Site No:** 1009

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

**Subject No:** 10091135

**Subject Initials:** ---

**Generated By:** pfe.levissc

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Date	Location	User	Value	Reason
Oct-22-2020 11:21:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	<b>Data Entry:</b> Click Here to Enable	Initial Entry