

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1081

Subject No: 10811194

Generated By: pfe.levisse

Form: COHORT SELECTION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[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 Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/10/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: DEMOGRAPHY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10811194]
2.	Birth Date:	(b) (6)/1968
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: 1081

Subject No: 10811194

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Done _____
----	---	-------------------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

eCRF Audit Trail History

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Sep/10/2020
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: 1081

Subject No: 10811194

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Chronic obstructive pulmonary disease]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypothyroidism]
	Start Date:	UNK/UNK/1995
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Osteoarthritis of the knees]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Attention deficit disorder]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Postmenopausal]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Allergy to oral NSAIDs]
	Start Date:	UNK/UNK/2007
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Allergy to Sulfa drugs]
	Start Date:	UNK/UNK/2002
	Ongoing:	YES

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/10/2020
2.	Weight:	[210.8]
3.	Unit:	LB
4.	Height:	[66.0]
5.	Unit:	in
6.	Body Mass Index:	[34.0]

Vital Signs Details

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

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/10/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Sep/10/2020
2.	Randomization Number:	[86545]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP1HP2]
5.b	Sample ID	[BP1HP3]
5.c	Sample ID	[BP1HP4]
5.d	Sample ID	[BRTXMH]
5.e	Sample ID	[BRTXMJ]

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP97R3]
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090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[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/10/2020 12:44
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

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[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: 1081

Subject No: 10811194

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Sep/29/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1081

Subject No: 10811194

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/29/2020
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Vital Signs Details

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/29/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/29/2020
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	[BP97WB]
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090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[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/29/2020 13:39
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

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811194

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/27/2020
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: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/27/2020
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	[BS64MF]
5.b	Sample ID	[BS64MG]
5.c	Sample ID	[BRDCPV]
5.d	Sample ID	[BRDCPW]

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811194

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811194

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811194

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811194

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811194

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET
Oct/12/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Date of Visit

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

COVID-19 Illness Visit

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

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
Oct/12/2020**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811194**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 10:11[eCRF Audit Trail History](#)**Signs and Symptoms**

1.	Date of Assessment:	Oct/12/2020
2.	Date of First Symptom Started:	Oct/9/2020
3.	Symptoms Ongoing?	YES

Symptoms

4.a	Symptoms:	FEVER
	Was symptom present?	NO
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	YES
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	NO
4.d	Symptoms:	CHILLS
	Was symptom present?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	NO
4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	YES
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	NO

Symptoms - Other

5.a	Symptoms - Other Text:	[Fatigue]
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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: MICROBIOLOGY SPECIMEN
Oct/12/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

Microbiology Specimen

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

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF
Oct/12/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Oct/12/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[CV34836]
-----	-----------	-----------

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
Oct/12/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

[Form Comments](#)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION
Oct/12/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Health Care Utilization

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

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[]
----	-------------------------------------	-----

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	NO
----	--	----

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT
Oct/12/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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[eCRF Audit Trail History](#)

Respiratory Treatment

1.	What is the treatment Identifier?	Not Applicable _____ []	Comments
2.	Concomitant Non-drug Treatment Pre-specified:	Not Applicable _____	Comments
3.	Treatment:	Not Applicable _____	Comments
4.	Treatment:	Not Applicable _____ []	Comments
5.	Start Date:	Not Applicable _____ //	Comments
6.	Ongoing?	Not Applicable _____	Comments

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS
Oct/12/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Illness Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE

Oct/12/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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[Form Comments](#)

[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	Not Applicable _____	Comments
2.	Subcategory of Clinical Event:	Not Applicable _____	Comments
3.	Was a diagnosis obtained?	Not Applicable _____	Comments
4.	Toxicity Grade:	Not Applicable _____	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Oct/12/2020

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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[eCRF Audit Trail History](#)

Lab Chemistry Details

1.	Lab Panel:	Not Applicable _____	Comments
2.	Laboratory Name and Address	Not Applicable _____ []	Comments
3.	Collection Date:	Not Applicable _____ //	Comments
4.	Specimen Type:	Not Applicable _____	Comments

Lab Result

5.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	C Reactive Protein_PX329	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Oct/12/2020

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.b	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Alanine Aminotransferase_PX30	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.c	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Aspartate Aminotransferase_PX28	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Oct/12/2020

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.d	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Alkaline Phosphatase_PX35	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.e	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Bilirubin_PX21	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Oct/12/2020

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5 f	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Blood Urea Nitrogen_PX47	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.g	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Creatinine_PX48	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Oct/12/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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[eCRF Audit Trail History](#)

Laboratory Data Hematology

1.	Lab Panel:	Not Applicable _____	Comments
2.	Laboratory Name and Address	Not Applicable _____ []	Comments
3.	Collection Date:	Not Applicable _____ //	Comments
4.	Specimen Type:	Not Applicable _____	Comments

Lab Result

5.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Hemoglobin_PX1	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Oct/12/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.b	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Hematocrit_PX2	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.c	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Erythrocytes_PX3	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Oct/12/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.d	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Platelets_PX5	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.e	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Leukocytes_PX7	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING Hematology
Oct/12/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5 f	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Neutrophils_PX608	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.g	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Eosinophils_PX609	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Oct/12/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.h	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Monocytes_PX612	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.i	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Basophils_PX610	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Oct/12/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.j	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Lymphocytes_PX611	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

#	Date:	Vital Signs Details			Form Instance
1.	Not Applicable	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		Not Applicable	Not Applicable	Not Applicable	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: VITAL SIGNS - COVID
Oct/12/2020

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Vital Signs

1.	Date:	Not Applicable _____ //	Comments
----	-------	-------------------------------	--------------------------

Vital Signs Details

2.a	Record Identifier:	Not Applicable _____ 1	
	Systolic:	Not Applicable _____ []	Comments
	Diastolic:	Not Applicable _____ []	Comments
	Respiratory Rate in respirations/minute:	Not Applicable _____ []	Comments
	Heart Rate in beats/minute:	Not Applicable _____ []	Comments

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

#	Date:	Vital Signs Details		Form Instance
1.	Not Applicable	Record Identifier:	Oxygen Saturation	Repeating Pages
		Not Applicable	Not Applicable	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR
Oct/12/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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[Form Comments](#)

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Not Applicable _____ //	Comments
----	-------	-------------------------------	--------------------------

Vital Signs Details

2.a	Record Identifier:	Not Applicable _____ 1	
	SPO2 Pulse Oximetry %	Not Applicable _____ []	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** OXYGENATION PARAMETERS

Oct/12/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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[Form Comments](#)

[eCRF Audit Trail History](#)

Oxygenation Parameters

1.	Date Time of Assessment:	Not Applicable _____ //	Comments
2.	Arterial Blood Gases PaO2 (mmHg):	Not Applicable _____ []	Comments
3.	FiO2 (Fraction of Inhaled Oxygen):	Not Applicable _____ []	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
Oct/12/2020

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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[eCRF Audit Trail History](#)

Concomitant Medications

1.	What is the medication identifier?	Not Applicable _____ []	Comments
2.	Category:	Not Applicable _____	Comments
3.	Concomitant Medications Pre-specified:	Not Applicable _____	Comments
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).	Not Applicable _____ []	Comments
5.	Start Date:	Not Applicable _____ //	Comments
6.	Ongoing?	Not Applicable _____	Comments

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING
Oct/12/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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[Form Comments](#)

[eCRF Audit Trail History](#)

Imaging

1.	Date of Assessment:	Not Applicable _____ //	Comments
2.	Location of Assessment:	Not Applicable _____	Comments
3.	Type of Imaging Exam:	Not Applicable _____	Comments
4.	Assessment:	Not Applicable _____	Comments

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: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Date of Visit

1.	Date of Visit	//
----	---------------	----

2.	Erroneous Visit	
----	-----------------	--

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY Visit

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Oct/27/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1081

Subject No: 10811194

Generated By: pfe.levisse

Form: DISPOSITION - FOLLOW-UP

Form Status: Data Complete, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Disposition - Follow-Up		
1.	Date of Completion/Discontinuation /Death :	Nov/4/2020
2.	Phase of Disposition:	FOLLOW-UP
3.	Status:	DEATH
4.	Specify Status:	[]

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still On going	Form Instance
1.	ADVERSE EVENT	1	Myocardial Infarction	Nov/4/2020 UNK:UNK	NO End Date Time: Nov/4/2020 UNK:UNK	Repeating Pages

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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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)	[Myocardial Infarction]
4.	Start Date Time:	Nov/4/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/4/2020 UNK:UNK
6.	Toxicity Grade:	4
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? YES 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? YES Other medically important serious event 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: [Hypertensive cardiovascular disease]

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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?:	FATAL
14.	Did the adverse event cause the subject to be discontinued from the study?	YES
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020447660]

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisc

Generated Time (GMT): 29-Mar-2021 10:11

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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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	[]

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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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:	//

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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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?	

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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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: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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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: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VITAL SIGNS - TEMP

Form Version: 20-Feb-2021 02:16

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Lab Urinalysis

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

Lab Result

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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?	

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (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: 1081 **Site Name:** (1081) Sterling Research Group - Mt. Auburn
Subject No: 10811194 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:11

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: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

Informed Consent - Asymptomatic Surveillance

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

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

Date of Visit

1.	Date of Visit	//
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: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

Further Vaccination Confirmation

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811194

Generated By: pfe.levisse

Form: TREATMENT UNBLINDED

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Treatment Unblinded

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811194

Generated By: pfe.levisc

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811194

Generated By: pfe.levisse

Form: DEATH DETAILS CODED

Form Status: Data Complete, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Death Details

1.	Date of Collection / Notification of Death:	Nov/11/2020
----	---	-------------

Cause of Death

2.a	Cause of Death Status:	PRIMARY CAUSE OF DEATH
	Cause of Death:	[Myocardial Infarction]

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811194

Generated By: pfe.levisse

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Nov/4/2020

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: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
James Fry	Approved	Jan-23-2021 12:19:24 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, JamesFry, 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: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
Form	Sep-10-2020 12:57:11 (UTC-05:00) Eastern Time (US & Canada)	Tawnyn Ebner (pfe.tebner)	All inclusions and exclusions met <hr/> Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Oct/12/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
Form	Oct-13-2020 11:38:02 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Done
Form	Oct-12-2020 12:59:26 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Oct/12/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

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Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
1	Oct-13-2020 11:38:02 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Done
1	Oct-12-2020 12:59:26 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Oct/12/2020

Form Version: 06-Jul-2020 21:54

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Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
2	Oct-13-2020 11:38:02 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Done
2	Oct-12-2020 12:59:26 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
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Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
3	Oct-13-2020 11:38:02 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Done
3	Oct-12-2020 12:59:26 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
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Item	Date	User	Comment
4	Oct-13-2020 11:38:02 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Done
4	Oct-12-2020 12:59:26 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
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Form Version: 06-Jul-2020 21:54

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Site No: 1081

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Subject No: 10811194

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Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
5	Oct-13-2020 11:38:02 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Done
5	Oct-12-2020 12:59:26 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
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Item	Date	User	Comment
6	Oct-13-2020 11:38:02 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Done
6	Oct-12-2020 12:59:26 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
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Item	Date	User	Comment
7	Oct-13-2020 11:38:02 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Done
7	Oct-12-2020 12:59:26 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Oct/12/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

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Item	Date	User	Comment
8	Oct-13-2020 11:38:02 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Done
8	Oct-12-2020 12:59:26 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
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Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

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Item	Date	User	Comment
9	Oct-13-2020 11:38:02 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Done
9	Oct-12-2020 12:59:26 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments
Oct/12/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
Form	Nov-07-2020 19:26:57 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Telehealth Visit
Form	Oct-15-2020 13:09:30 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Telehealth Visit <hr/> Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
1	Nov-07-2020 19:26:57 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Telehealth Visit
1	Oct-15-2020 13:09:30 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Telehealth Visit <hr/> Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
2	Nov-07-2020 19:26:57 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Telehealth Visit
2	Oct-15-2020 13:09:30 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Telehealth Visit <hr/> Not Done

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Site Name: (1081) Sterling Research Group - Mt. Auburn

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Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
3	Nov-07-2020 19:26:57 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Telehealth Visit
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Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

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Item	Date	User	Comment
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4	Oct-15-2020 13:09:30 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Telehealth Visit <hr/> Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT - Comments
Oct/12/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
Form	Oct-12-2020 13:00:23 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT - Comments
Oct/12/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

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Item	Date	User	Comment
1	Oct-12-2020 13:00:23 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT - Comments
Oct/12/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

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Item	Date	User	Comment
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Item	Date	User	Comment
5	Oct-12-2020 13:00:23 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT - Comments
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Item	Date	User	Comment
6	Oct-12-2020 13:00:23 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE - Comments
Oct/12/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
Form	Oct-12-2020 13:01:10 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE - Comments
Oct/12/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
1	Oct-12-2020 13:01:10 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE - Comments
Oct/12/2020

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Item	Date	User	Comment
2	Oct-12-2020 13:01:10 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE - Comments
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Item	Date	User	Comment
3	Oct-12-2020 13:01:10 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

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Item	Date	User	Comment
4	Oct-12-2020 13:01:10 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
Form	Oct-12-2020 13:01:38 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

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Generated By: pfe.levissc

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Item	Date	User	Comment
1	Oct-12-2020 13:01:38 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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Item	Date	User	Comment
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Header Text: c4591001

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Item	Date	User	Comment
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Item	Date	User	Comment
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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Item	Date	User	Comment
5.a	Oct-12-2020 13:01:38 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

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Item	Date	User	Comment
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Item	Date	User	Comment
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Form Status: Data Complete, Frozen, Verified

Site No: 1081

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Subject No: 10811194

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Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
5.b	Oct-12-2020 13:01:38 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

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5.c	Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

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5.d	Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

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2	Oct-12-2020 13:03:21 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** OXYGENATION PARAMETERS - Comments
Oct/12/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
3	Oct-12-2020 13:03:21 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments
 Oct/12/2020
Form Version: 06-Jul-2020 21:55 **Form Status:** Data Complete, Frozen, Verified
Site No: 1081 **Site Name:** (1081) Sterling Research Group - Mt. Auburn
Subject No: 10811194 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:11

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Item	Date	User	Comment
Form	Oct-12-2020 13:03:41 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments
Form Version: 06-Jul-2020 21:55 **Form Status:** Data Complete, Frozen, Verified
Site No: 1081 **Site Name:** (1081) Sterling Research Group - Mt. Auburn
Subject No: 10811194 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:11

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Item	Date	User	Comment
1	Oct-12-2020 13:03:41 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
2	Oct-12-2020 13:03:41 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
3	Oct-12-2020 13:03:41 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
4	Oct-12-2020 13:03:41 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
5	Oct-12-2020 13:03:41 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
6	Oct-12-2020 13:03:41 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING - Comments
Oct/12/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
Form	Oct-12-2020 13:04:10 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING - Comments
Oct/12/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
1	Oct-12-2020 13:04:10 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING - Comments
Oct/12/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
2	Oct-12-2020 13:04:10 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING - Comments
Oct/12/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
3	Oct-12-2020 13:04:10 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING - Comments
Oct/12/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
4	Oct-12-2020 13:04:10 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	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: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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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
James Fry	Approved	Jan-23-2021 12:19:24 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, JamesFry, 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.

Lora Morris	N/A	Nov-24-2020 08:25:32 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Michael Butcher	Approved	Nov-17-2020 14:15:02 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, MichaelButcher, 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.

Lora Morris	N/A	Nov-11-2020 15:19:14 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Michael Butcher	Approved	Nov-10-2020 13:00:20 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (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: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

Affidavit:

By my dated signature below, I, MichaelButcher, 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.

Lora Morris	N/A	Nov-07-2020 19:26:57 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Michael Butcher	Approved	Nov-03-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, MichaelButcher, 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.

Lora Morris	N/A	Oct-27-2020 12:47:23 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Michael Butcher	Approved	Oct-16-2020 11:22:44 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, MichaelButcher, 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.

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: COHORT SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-10-2020 12:56:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawryn Ebner (pfe.tebner)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 12:56:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawryn Ebner (pfe.tebner)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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I. Consent Was:

Date	Location	User	Value	Reason
Sep-10-2020 12:56:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawbyn Ebner (pfe.tebner)	Data Entry: OBTAINED Date Written Consent Obtained Sep/10/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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1. Subject ID

Date	Location	User	Value	Reason
Sep-10-2020 12:55:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10811194	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-10-2020 12:55:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1968	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-10-2020 12:56:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-10-2020 12:56:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: NOT HISPANIC OR LATINO(A) O R OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 12:56:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: WHITE	Initial Entry

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811194

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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I. Date of Visit

Date	Location	User	Value	Reason
Sep-10-2020 12:57:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sep/10/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-10-2020 12:57:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sep/10/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-10-2020 12:57:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-10-2020 12:57:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: COMPLETED	Initial Entry

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1081**Subject No:** 10811194**Generated By:** pfe.levissc**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)*I.a*

Date	Location	User	Value	Reason
Sep-10-2020 16:41:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Line/MH Nu 1 mber: Medical Hist Chronic obstructive ory Term: pulmonary disease Start Date: UNK/UNK/2015 Ongoing: YES	Changed Information
Sep-10-2020 14:58:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 1 mber: Medical Hist Chronic obstructive ory Term: pulmonary disease Start Date: Jan/1/2015 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 14:58:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 14:58:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Chronic obstructive pulmonary disea se	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 16:41:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: UNK/UNK/2015	Changed Information
Sep-10-2020 14:58:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Jan/1/2015	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

I.a Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 14:58:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

I.b

Date	Location	User	Value	Reason
Sep-10-2020 16:41:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Line/MH Number: 2 Medical History Term: Hypertension Start Date: UNK/UNK/2015 Ongoing: YES	Changed Information
Sep-10-2020 14:59:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term: Hypertension Start Date: Jan/1/2015 Ongoing: YES	Initial Entry

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

I.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 14:59:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 14:59:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Hypertension	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 16:41:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: UNK/UNK/2015	Changed Information
Sep-10-2020 14:59:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Jan/1/2015	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 14:59:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

I.c

Date	Location	User	Value	Reason
Sep-10-2020 16:42:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Line/MH Number: 3 Medical History Te Hypothyroidis rm: m Start Date: UNK/UNK/19 95 Ongoing: YES	Changed Information
Sep-10-2020 15:00:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3	Initial Entry

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

			Medical History Term: Hypothyroidism Start Date: Jan/1/1995 Ongoing: YES	
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I.c Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 15:00:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 15:00:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Hypothyroidism	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 16:42:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: UNK/UNK/1995	Changed Information
Sep-10-2020 15:00:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Jan/1/1995	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 15:00:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Sep-10-2020 16:42:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Line/MH Number: 4 Medical History Term: Osteoarthritis of the knees	Changed Information

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

			Start Date: UNK/UNK/2018 Ongoing: YES	
Sep-10-2020 15:01:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History Term: Start Date: Ongoing:	Initial Entry 4 Osteoarthritis of the knees Jan/1/2018 YES

1.d Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 15:01:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 15:01:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Osteoarthritis of the knees	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 16:42:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: UNK/UNK/2018	Changed Information
Sep-10-2020 15:01:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Jan/1/2018	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 15:01:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

1.e

Date	Location	User	Value	Reason
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090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Sep-10-2020 16:42:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Line/MH Number: 5 Medical History: Attention deficit disorder Term: disorder Start Date: UNK/UNK/2017 Ongoing: YES	Changed Information
Sep-10-2020 15:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History: Attention deficit disorder Term: disorder Start Date: Jan/1/2017 Ongoing: YES	Initial Entry

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

I.e Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 15:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 15:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Attention deficit disorder	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 16:42:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: UNK/UNK/2017	Changed Information
Sep-10-2020 15:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Jan/1/2017	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 15:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Sep-10-2020 16:42:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Line/MH Number: 6 Medical History Te Postmenopaus rm: al Start Date: UNK/UNK/20 18 Ongoing: YES	Changed Information
Sep-10-2020 15:02:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 6	Initial Entry

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811194

Generated By: pfe.levisss

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

			Medical History Term: Start Date: Ongoing:	Postmenopausal Jan/1/2018 YES
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I.f Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 15:02:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

I.f Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-10-2020 15:02:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Postmenopausal	Initial Entry

I.f Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 16:42:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: UNK/UNK/2018	Changed Information
Sep-10-2020 15:02:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Jan/1/2018	Initial Entry

I.f Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 15:02:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

I.g

Date	Location	User	Value	Reason
Sep-11-2020 10:25:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 7 Medical History Term: Allergy to oral NSAIDs	Initial Entry

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

			Start Date: UNK/UNK/2007	
			Ongoing: YES	

I.g Line/MH Number:

Date	Location	User	Value	Reason
Sep-11-2020 10:25:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

I.g Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-11-2020 10:25:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Allergy to oral NSAIDs	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Sep-11-2020 10:25:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: UNK/UNK/2007	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Sep-11-2020 10:25:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

I.h

Date	Location	User	Value	Reason
Sep-11-2020 10:26:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 8 Medical History T Allergy to Sulfam erm: drugs Start Date: UNK/UNK/2002 Ongoing: YES	Initial Entry

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

1.h Line/MH Number:

Date	Location	User	Value	Reason
Sep-11-2020 10:26:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 10:26:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Allergy to Sulfa drugs	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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1.h Start Date:

Date	Location	User	Value	Reason
Sep-11-2020 10:26:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: UNK/UNK/2002	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Sep-11-2020 10:26:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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1. Date:

Date	Location	User	Value	Reason
Sep-10-2020 14:47:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> Sep/10/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-10-2020 14:47:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> 210.8	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-10-2020 14:47:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-10-2020 14:47:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> 66.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-10-2020 14:47:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-10-2020 14:47:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 34.0	Initial Entry

7.a

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Date	Location	User	Value	Reason
Sep-11-2020 09:28:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Record Identifier:: 1 Temperature: 97.1 Temperature Unit: F Temperature Location:: ORAL CAVITY	Transcription Error
Sep-10-2020 14:47:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Record Identifier:: 1 Temperature: 97.1 Temperature Unit: F Temperature Location:: FOREHEAD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-10-2020 14:47:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-10-2020 14:47:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: 97.1	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-10-2020 14:47:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-11-2020 09:28:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: ORAL CAVITY	Transcription Error
Sep-10-2020 14:47:59 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: FOREHEAD	Initial Entry

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

(US & Canada)

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (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: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-10-2020 14:47:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-10-2020 14:47:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-10-2020 14:47:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sep/10/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-10-2020 14:47:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-10-2020 14:47:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-10-2020 14:14:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Define 113 d Identifier:	Initial Entry

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (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: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

			Test:: Choriogonadotropin Beta_PX113 Result:: Not Done:: NOT DONE	
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-10-2020 14:14:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-10-2020 14:14:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-10-2020 14:14:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NOT DONE	Initial Entry

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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1. Randomization Date :

Date	Location	User	Value	Reason
Sep-10-2020 14:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sep/10/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-10-2020 14:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: 86545	Initial Entry

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: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Data Origin

Date	Location	User	Value	Reason
Sep-10-2020 13:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-10-2020 13:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-10-2020 13:02:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-10-2020 13:00:36 (UTC-05:00) Eastern 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-10-2020 13:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Sep/10/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-10-2020 13:02:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BP1HP2	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (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: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Sep-10-2020 13:02:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawryn Ebner (pfe.tebner)	Data Entry: BP1HP2	Initial Entry
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5.b

Date	Location	User	Value	Reason
Sep-10-2020 13:02:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawryn Ebner (pfe.tebner)	Data Entry: Sample ID: BP1HP3	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-10-2020 13:02:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawryn Ebner (pfe.tebner)	Data Entry: BP1HP3	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-10-2020 13:03:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawryn Ebner (pfe.tebner)	Data Entry: Sample ID: BP1HP4	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-10-2020 13:03:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawryn Ebner (pfe.tebner)	Data Entry: BP1HP4	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-10-2020 13:03:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawryn Ebner (pfe.tebner)	Data Entry: Sample ID: BRTXMH	Initial Entry

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (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: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.d Sample ID

Date	Location	User	Value	Reason
Sep-10-2020 13:03:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawyn Ebner (pfe.tebner)	<u>Data Entry:</u> BRTXMH	Initial Entry

5.e

Date	Location	User	Value	Reason
Sep-10-2020 13:03:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawyn Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BRTXMJ	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Sep-10-2020 13:03:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawyn Ebner (pfe.tebner)	<u>Data Entry:</u> BRTXMJ	Initial Entry

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (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: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Data Origin

Date	Location	User	Value	Reason
Sep-10-2020 12:59:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-10-2020 12:59:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-10-2020 13:00:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-10-2020 12:59:08 (UTC-05:00) Eastern 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-10-2020 12:59:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Sep/10/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-10-2020 13:00:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BP97R3	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (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: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

Sep-10-2020 13:00:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawyn Ebner (pfe.tebner)	Data Entry: BP97R3	Initial Entry
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811194

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-10-2020 14:13:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-10-2020 14:13:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-10-2020 14:13:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-10-2020 14:13:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sep/10/2020 12:44	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-10-2020 14:13:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-10-2020 14:13:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: LEFT	Initial Entry

7. Route:

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Date	Location	User	Value	Reason
Sep-10-2020 14:13:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-10-2020 14:13:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBS ERVATION 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-10-2020 14:13:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-10-2020 14:12:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811194

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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I. Date of Visit

Date	Location	User	Value	Reason
Sep-29-2020 13:47:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sep/29/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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I. Date:

Date	Location	User	Value	Reason
Sep-29-2020 14:24:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> Sep/29/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-29-2020 14:24:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> Record Identifier:: 1 Temperature: 98.4 Temperature Unit: F Temperature Location:: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-29-2020 14:24:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-29-2020 14:24:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> 98.4	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-29-2020 14:24:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
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090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Sep-29-2020 14:24:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: ORAL CAVITY	Initial Entry
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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: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-29-2020 14:24:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-29-2020 14:24:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-29-2020 14:24:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sep/29/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-29-2020 14:24:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-29-2020 14:24:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-29-2020 14:24:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Define 113 d Identifier:	Initial Entry

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (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: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

			Test:: Choriogonadotropin Beta_PX113 Result:: Not Done:: NOT DONE	
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 14:24:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-29-2020 14:24:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-29-2020 14:24:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NOT DONE	Initial Entry

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (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: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Data Origin

Date	Location	User	Value	Reason
Sep-29-2020 13:47:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-29-2020 13:47:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-29-2020 13:48:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-29-2020 13:47:57 (UTC-05:00) Eastern 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-29-2020 13:47:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Sep/29/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-29-2020 13:48:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BP97WB	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (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: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Sep-29-2020 13:48:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawyn Ebner (pfe.tebner)	Data Entry: BP97WB	Initial Entry
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811194

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-29-2020 14:24:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-29-2020 14:24:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-29-2020 14:24:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-29-2020 14:24:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sep/29/2020 13:39	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-29-2020 14:24:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-29-2020 14:24:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: LEFT	Initial Entry

7. Route:

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Date	Location	User	Value	Reason
Sep-29-2020 14:24:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-29-2020 14:24:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBS ERVATION 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-29-2020 14:24:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811194

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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I. Date of Visit

Date	Location	User	Value	Reason
Oct-27-2020 12:47:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Oct/27/2020	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: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Data Origin

Date	Location	User	Value	Reason
Oct-27-2020 12:47:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-27-2020 12:47:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-27-2020 12:47:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-27-2020 12:47:32 (UTC-05:00) Eastern 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-27-2020 12:47:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES Date of Collection: Oct/27/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-27-2020 12:47:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sample ID: BS64MF	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (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: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Oct-27-2020 12:47:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: BS64MF	Initial Entry
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5.b

Date	Location	User	Value	Reason
Oct-27-2020 12:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sample ID: BS64MG	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-27-2020 12:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: BS64MG	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-27-2020 12:48:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sample ID: BRDCPV	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-27-2020 12:48:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: BRDCPV	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-27-2020 12:48:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sample ID: BRDCPW	Initial Entry

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (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: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.d Sample ID

Date	Location	User	Value	Reason
Oct-27-2020 12:48:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> BRDCPW	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020 **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: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

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I. Date of Visit

Date	Location	User	Value	Reason
Mar-09-2021 04:59:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Caoimhe Fagan (pfe.faganc02)	Query 3: Closed	Response satisfies query
Mar-02-2021 08:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 3: Answered	subject passed away, no convalescent visit able to be completed
Mar-01-2021 10:28:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Caoimhe Fagan (pfe.faganc02)	Query 3: Opened	Convalescent visit is expected 28-35 days after illness visit, but no convalescent visit is entered. Please conduct a convalescent visit and complete data entry or respond with reason visit is not expected. If scheduled, please provide date expected
Oct-12-2020 14:32:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-12-2020 12:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Oct-12-2020 12:39:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Oct-12-2020 12:39:24 (UTC-05:00) Eastern 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

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History
Oct/12/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

				missing. Please review and update as appropriate.
Oct-12-2020 12:39:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Oct/12/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Oct-12-2020 12:39:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020 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: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Date of Assessment:

Date	Location	User	Value	Reason
Oct-12-2020 12:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Oct/12/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Oct-12-2020 12:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Oct/9/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Feb-26-2021 04:55:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ananta Gogoi (pfe.gogoia)	Query 1: Closed	Response satisfies query
Feb-24-2021 07:39:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Amol Deshmukh (pfe.deshma24)	Query 1: Reissued:Candidate	To be highlighted to Triad to confirm on this.
Feb-23-2021 11:56:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	subject is deceased. symptoms were ongoing at time of death
Feb-15-2021 06:15:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ashwini Devi Subhash (pfe.subhaa)	Query 1: Opened	Please confirm the symptoms are still ongoing for this COVID Illness. If all symptoms for this illness are resolved; please update the Last Symptoms Resolved Date else clarify.
Oct-12-2020 12:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES	Initial Entry

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020 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: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

4.a

Date	Location	User	Value	Reason
Oct-12-2020 12:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Oct-12-2020 12:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Oct-12-2020 12:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Oct-12-2020 12:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptoms: NEW OR INCREASE D COUGH Symptom Present: YES	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Oct-12-2020 12:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Oct-12-2020 12:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES	Initial Entry

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020

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: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

4.c

Date	Location	User	Value	Reason
Oct-12-2020 12:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptom NEW OR INCREASED S s: HORTNESS OF BREAT H Symptom NO Present:	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Oct-12-2020 12:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NEW OR INCREASED SHORTNES S OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Oct-12-2020 12:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Oct-12-2020 12:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Oct-12-2020 12:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Oct-12-2020 12:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020

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: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

4.e

Date	Location	User	Value	Reason
Oct-12-2020 12:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptoms: NEW OR INCREASED MUSCLE PAIN Symptom Present: NO	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Oct-12-2020 12:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NEW OR INCREASED MUSCLE P AIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Oct-12-2020 12:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Oct-12-2020 12:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptoms: NEW LOSS OF TAST E OR SMELL Symptom Present: NO	Initial Entry

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020 **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:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811194**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11**4.f Symptoms:**

Date	Location	User	Value	Reason
Oct-12-2020 12:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Oct-12-2020 12:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Oct-12-2020 12:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptoms: NEW OR INCREASED SORE THROAT Symptom Present: YES	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Oct-12-2020 12:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Oct-12-2020 12:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES	Initial Entry

4.h

Date	Location	User	Value	Reason
Oct-12-2020 12:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptoms: DIARRHEA Symptom Present: NO	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020 **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:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811194**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11**4.h Symptoms:**

Date	Location	User	Value	Reason
Oct-12-2020 12:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Oct-12-2020 12:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Oct-12-2020 12:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptoms: VOMITING Symptom Present: NO	Initial Entry

4.i Symptoms:

Date	Location	User	Value	Reason
Oct-12-2020 12:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Oct-12-2020 12:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-12-2020 12:59:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptoms - Other: Fatigue	Initial Entry

5.a Symptoms - Other Text:

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020 **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: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

Date	Location	User	Value	Reason
Oct-12-2020 12:59:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Fatigue	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020 **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:54**Form Status:** Data Complete, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811194**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Oct-13-2020 12:55:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Stephen Paolini (pfe.paolis01)	Query 1: Closed	Response satisfies query
Oct-13-2020 11:39:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	Changed data per query
Oct-13-2020 11:38:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Done	Initial Entry
Oct-13-2020 11:17:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Stephen Paolini (pfe.paolis01)	Query 1: Opened	CLIQUEY: Per CCG's 'Not Done' needs to be applied to the CRF if local test was not completed. Please update.
Oct-12-2020 12:59:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Oct-13-2020 11:38:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Done	Initial Entry
Oct-12-2020 12:59:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Oct-13-2020 11:38:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Done	Initial Entry
Oct-12-2020 12:59:26	ACV0PFEINFP6000	James Fry	Data Entry:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
Oct/12/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

(UTC-05:00) Eastern Time (US & Canada)		(pfe.jfry)	Not Applicable	
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4. Assay Code and Description:

Date	Location	User	Value	Reason
Oct-13-2020 11:38:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> Not Done	Initial Entry
Oct-12-2020 12:59:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> Not Applicable	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Oct-13-2020 11:38:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> Not Done	Initial Entry
Oct-12-2020 12:59:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> Not Applicable	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Oct-13-2020 11:38:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> Not Done	Initial Entry
Oct-12-2020 12:59:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> Not Applicable	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Oct-13-2020 11:38:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> Not Done	Initial Entry
Oct-12-2020 12:59:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> Not Applicable	Initial Entry

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
Oct/12/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Oct-13-2020 11:38:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> Not Done	Initial Entry
Oct-12-2020 12:59:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> Not Applicable	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Oct-13-2020 11:38:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> Not Done	Initial Entry
Oct-12-2020 12:59:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> Not Applicable	Initial Entry

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811194**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-12-2020 14:32:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-12-2020 14:32:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-12-2020 14:33:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-12-2020 14:32:46 (UTC-05:00) Eastern 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-12-2020 14:32:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Oct/12/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-12-2020 14:33:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: CV34836	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

Oct-12-2020 14:33:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: CV34836	Initial Entry
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090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020 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: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Data Origin

Date	Location	User	Value	Reason
Nov-07-2020 19:27:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry
Nov-07-2020 19:26:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry
Oct-15-2020 13:09:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Done	Initial Entry
Oct-15-2020 13:08:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Changed Information
Oct-15-2020 07:57:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Telehealth Visit

2. Sample Type

Date	Location	User	Value	Reason
Nov-07-2020 19:27:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry
Nov-07-2020 19:26:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry
Oct-15-2020 13:09:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Done	Initial Entry
Oct-15-2020 13:08:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Changed Information
Oct-15-2020 07:57:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Telehealth Visit

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020

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: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-08-2020 03:30:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 3: Closed	Auto closed by Validation Check: VC_BEETRK001_07
Nov-07-2020 19:27:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Closed	Close Auto Query
Nov-07-2020 19:27:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: 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.
Nov-07-2020 19:27:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Initial Entry
Nov-07-2020 19:27:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry
Nov-07-2020 19:26:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020 **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:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811194**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11

Nov-07-2020 15:44:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gladys Noi (pfe.noig)	Query 3: Reissued: Opened	DM: Page unlocked. Please update
Nov-07-2020 14:09:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 3: Answered	page is locked,munable to change data
Nov-07-2020 02:25:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Teena Patra (pfe.patrat02)	Query 3: Opened	DM: If only self-swab type is taken, nasal swab form that is not used should have "Sample Collected" as NO and the reason documented.' Kindly review and update.
Nov-06-2020 06:37:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 3: Candidate	DMW5244306;Sample Collected is not expected to be Not Done. Please review and update appropriately or clarify
Oct-15-2020 13:09:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Done	Initial Entry
Oct-15-2020 13:08:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Changed Information
Oct-15-2020 08:55:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Stephen Paolini (pfe.paolis01)	Query 1: Closed	Response satisfies query

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020 **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:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811194**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 10:11

Oct-15-2020 07:58:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Oct-15-2020 07:57:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: 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-15-2020 07:57:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Telehealth Visit
Oct-15-2020 07:57:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Telehealth Visit
Oct-15-2020 04:15:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Swetha Thangellapally (pfe.thangs22)	Query 1: Opened	CLIQUEY: Per CCG, this is a required CRF and should be completed with NO if sample not taken. Please review and update as appropriate.
Oct-13-2020 15:28:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Stephen Paolini (pfe.paolis01)	Query 1: Candidate	CLIQUEY: Per CCG, this is a required CRF and should be completed with NO if sample not taken. Please review and update as appropriate.

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020 **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: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Date	Location	User	Value	Reason
Nov-07-2020 19:27:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Self Swab collected	Initial Entry
Nov-07-2020 19:26:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry
Oct-15-2020 13:09:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Done	Initial Entry
Oct-15-2020 13:09:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Changed Information
Oct-15-2020 07:58:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Telehealth Visit	Initial Entry

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020 Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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I.a

Date	Location	User	Value	Reason
Oct-12-2020 12:59:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Type of Practitioner: SPECIAL IST Occurrence of Visits or Contacts: NO	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-12-2020 12:59:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-12-2020 12:59:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Oct-12-2020 12:59:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Type of Practitioner EMERGENC : Y ROOM Occurrence of Visits NO or Contacts:	Initial Entry

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Oct/12/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811194**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11***I.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Oct-12-2020 12:59:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: EMERGENCY ROOM	Initial Entry

I.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-12-2020 12:59:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

I.c

Date	Location	User	Value	Reason
Oct-12-2020 12:59:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry

I.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-12-2020 12:59:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

I.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-12-2020 12:59:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

I.d

Date	Location	User	Value	Reason
Oct-12-2020 12:59:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Type of Practitioner: URGENT CARE	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Oct/12/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811194**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11

			Occurrence of Visits or Contacts:	NO
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I.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-12-2020 12:59:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: URGENT CARE	Initial Entry

I.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-12-2020 12:59:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

I.e

Date	Location	User	Value	Reason
Oct-12-2020 12:59:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO	Initial Entry

I.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-12-2020 12:59:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-12-2020 12:59:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

I.f

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020 Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Oct-12-2020 12:59:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Type of Practitioner: OTHE R Occurrence of Visits or Con NO tacts:	Initial Entry
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1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-12-2020 12:59:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-12-2020 12:59:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

3. Has the subject been hospitalized due to potential COVID-19 illness?

Date	Location	User	Value	Reason
Oct-12-2020 12:59:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020 Form: RESPIRATORY TREATMENT - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. What is the treatment Identifier?

Date	Location	User	Value	Reason
Oct-12-2020 13:00:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Oct-12-2020 13:00:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Oct-12-2020 13:00:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Oct-12-2020 13:00:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Oct-12-2020 13:00:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Oct-12-2020 13:00:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - eCRF Audit Trail History
Oct/12/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Oct-12-2020 13:00:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNESS	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Oct-12-2020 13:00:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-12-2020 13:00:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: 2	Initial Entry

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020 Form: ILLNESS DETAILS - SEVERE - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Oct-12-2020 13:01:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

2. Subcategory of Clinical Event:

Date	Location	User	Value	Reason
Oct-12-2020 13:01:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

3. Was a diagnosis obtained?

Date	Location	User	Value	Reason
Oct-12-2020 13:01:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

4. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-12-2020 13:01:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Lab Panel:

Date	Location	User	Value	Reason
Oct-12-2020 13:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Oct-12-2020 13:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-12-2020 13:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Oct-12-2020 13:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-12-2020 13:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable	Initial Entry

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

			Lab Normal Range: Not Applicable	
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5.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-12-2020 13:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Oct-12-2020 13:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Oct-12-2020 13:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Oct-12-2020 13:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Oct-12-2020 13:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-12-2020 13:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sponsor-Defined Identifier: Not Applicable	Initial Entry

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

			Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	
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5.b Sponsor ID:

Date	Location	User	Value	Reason
Oct-12-2020 13:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Oct-12-2020 13:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Oct-12-2020 13:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Oct-12-2020 13:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Oct-12-2020 13:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.c

Date	Location	User	Value	Reason
Oct-12-2020 13:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:49**Form Status:** Data Complete, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811194**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11**5.c Sponsor ID:**

Date	Location	User	Value	Reason
Oct-12-2020 13:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
Oct-12-2020 13:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
Oct-12-2020 13:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Oct-12-2020 13:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Oct-12-2020 13:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-12-2020 13:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable	Initial Entry

Header Text: c4591001

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			Result::	Not Applicable
			Not Done::	Not Applicable
			Lab Normal Range:	Not Applicable

5.d Sponsor ID:

Date	Location	User	Value	Reason
Oct-12-2020 13:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
Oct-12-2020 13:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.e

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

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Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

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Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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Header Text: c4591001

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Subject No: 10811194

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Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

			Result::	Not Applicable
			Not Done::	Not Applicable
			Lab Normal Range:	Not Applicable

5.f Sponsor ID:

Date	Location	User	Value	Reason
Oct-12-2020 13:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> Not Applicable	Initial Entry

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5.f LNMT

Date	Location	User	Value	Reason
Oct-12-2020 13:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.g

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

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Form Version: 21-Aug-2020 02:49

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Site No: 1081

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Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

Date	Location	User	Value	Reason
Oct-12-2020 13:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

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5.g Sponsor ID:

Date	Location	User	Value	Reason
Oct-12-2020 13:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
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Oct-12-2020 13:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Oct-12-2020 13:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable	Initial Entry

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

			Lab Normal Range: Not Applicable	
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5.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sponsor-Defined Identifier: Not Applicable	Initial Entry

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Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

			Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	
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5.b Sponsor ID:

Date	Location	User	Value	Reason
Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
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			Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	
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5.f Test:

Date	Location	User	Value	Reason
Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.g

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

Date	Location	User	Value	Reason
Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:51**Form Status:** Data Complete, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811194**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11**5.g Sponsor ID:**

Date	Location	User	Value	Reason
Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.h

Date	Location	User	Value	Reason
Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

			Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	
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5.h Sponsor ID:

Date	Location	User	Value	Reason
Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.i

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

Date	Location	User	Value	Reason
Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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5.i Sponsor ID:

Date	Location	User	Value	Reason
Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.i Not Done:

Date	Location	User	Value	Reason
Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.j

Date	Location	User	Value	Reason
Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sponsor-Defined Identifier: Not Applicable	Initial Entry

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

			Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	
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5.j Sponsor ID:

Date	Location	User	Value	Reason
Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.j Not Done:

Date	Location	User	Value	Reason
Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History
Oct/12/2020**Form Version:** 21-Aug-2020 02:50**Form Status:** Data Complete, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811194**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Oct-12-2020 13:02:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-12-2020 13:02:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Record Identifier:: Not Appl icable Systolic:: Not Appl icable Diastolic:: Not Appl icable Respiratory Rate in respi rations/minute: Not Appl icable Heart Rate in beats/min ute: Not Appl icable	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-12-2020 13:02:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Oct-12-2020 13:02:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Oct-12-2020 13:02:38 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History
Oct/12/2020

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

(US & Canada)

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Oct-12-2020 13:02:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Oct-12-2020 13:02:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020 Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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I. Date:

Date	Location	User	Value	Reason
Oct-12-2020 13:03:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-12-2020 13:03:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Record Identifier:: Not Applicable Oxygen Saturation: Not Applicable	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-12-2020 13:03:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Oct-12-2020 13:03:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020 **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Date Time of Assessment:

Date	Location	User	Value	Reason
Oct-12-2020 13:03:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

2. Arterial Blood Gases PaO2 (mmHg):

Date	Location	User	Value	Reason
Oct-12-2020 13:03:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

3. FiO2 (Fraction of Inhaled Oxygen):

Date	Location	User	Value	Reason
Oct-12-2020 13:03:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020 Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Oct-12-2020 13:03:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Oct-12-2020 13:03:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Oct-12-2020 13:03:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

4. Medication:

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

Date	Location	User	Value	Reason
Oct-12-2020 13:03:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Oct-12-2020 13:03:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
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090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

Oct-12-2020 13:03:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING - eCRF Audit Trail History
Oct/12/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Date of Assessment:

Date	Location	User	Value	Reason
Oct-12-2020 13:04:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Oct-12-2020 13:04:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Oct-12-2020 13:04:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Oct-12-2020 13:04:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1081

Subject No: 10811194

Generated By: pfe.levisse

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-27-2020 12:48:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Oct/27/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-27-2020 12:48:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-27-2020 12:48:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: COMPLETED	Initial Entry

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1081

Subject No: 10811194

Generated By: pfe.levisse

Form: DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Nov-30-2020 08:57:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Nov/4/2020	Changed from presumed date of death to the date on death certificate
Nov-12-2020 07:46:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Nov/1/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Nov-12-2020 07:46:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-12-2020 07:46:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: DEATH	Initial Entry

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811194

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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Date	Location	User	Value	Reason
Nov-11-2020 15:19:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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1. Category:

Date	Location	User	Value	Reason
Nov-11-2020 15:19:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-11-2020 15:19:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-08-2021 16:43:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Clo sed	Response satisfies query
Feb-23-2021 11:55:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 3: Ans wered	SAE follow-up report has been updated and faxed
Feb-11-2021 01:37:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sathenapalli Suguna Srujan (pfe.srujas)	Query 3: Ope ned	Clinical - Subject has several Past med Hx conditions ongoing at time of death; please submit Concomitant Medications to the SAE medication section
Feb-10-2021 20:44:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Can didate	Clinical - Subject has several Past med Hx conditions ongoing at time of death; please submit Concomitant Medications to the SAE medication section

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

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Nov-24-2020 15:39:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Clo sed	Auto closed by Validation Check: VC_AE001_05
Nov-24-2020 08:25:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ans wered	New Information
Nov-24-2020 08:25:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry : Myoca rdial I nfarcti on	New Information
Nov-24-2020 07:56:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Minal Pathak (pfe.patham13)	Query 1: Rei ssued: Opene d	Thank you for response. Please consider to enter data when available and route this query to DM only once data is entered.
Nov-23-2020 07:42:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Ans wered	No report has been received as of 23Nov2020
Nov-23-2020 05:08:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ananta Gogoi (pfe.gogoia)	Query 1: Rei ssued: Opene d	DM: Please confirm if death certificate has been received now, If yes, then update information as per previous query.
Nov-16-2020 11:52:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pamela Benne prod (pfe.bennep07)	Query 1: Rei ssued: Candi date	Waiting on Death Certificate to update details. Not sure when they will receive
Nov-16-2020	ACV0PFEINFP6000	Ricell Ann Piojo	Query	Per PSSR confirmation

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10:22:05 (UTC-05:00) Eastern Time (US & Canada)		(pfe.quitor)	2: Clo sed	during the call, DOB was reported as (b) (6) 1968. Issue resolved
Nov-16-2020 08:04:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Rei ssued: Candi date	Pending PSSR confirmation/SDB update
Nov-16-2020 07:58:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 2: Ans wered	DOB was on SAE, but needed corrected (year of birth), which was completed 12Nov2020
Nov-16-2020 07:57:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Ans wered	Death Cert has not been received and we do not know a time frame when it will be, they are waiting on toxicology results. Data will be updated immediately upon receipt of the death cert
Nov-16-2020 04:49:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Ope ned	SAE RECON:AER#2020447660 ,the date of birth was missing in Safety database but was recorded as (b) (6) 1968 in AE CRF. Please confirm if date of birth was reported. If safety update is required, please submit a follow-up form.
Nov-15-2020 09:00:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Josee Robillard (pfe.robilj01)	Query 1: Rei ssued: Ope ned	Please confirm if death certificate was received. If not, please provide an estimate date as to when data is expected.
Nov-12-2020 10:21:30 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Behnaz Yousefzadeh- Khiabani (pfe.youseb01)	Query 1: Rei ssued: Candi	Data will be updated soon. Please review in a few days.

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(US & Canada)			date	
Nov-12-2020 07:35:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	This information is not currently available. Upon receipt of the death certificate, this data will be updated.
Nov-11-2020 18:35:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW5359579;This 'Adverse Event' contains the term DEATH. If known, please provide the cause of death as the AE term with an outcome of FATAL or clarify.
Nov-11-2020 15:19:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry : Death	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-30-2020 15:24:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Closed	Auto closed by Validation Check: VC_AE001_09_AN
Nov-30-2020 08:59:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	Disposition date has been corrected to 04Nov2020
Nov-29-2020 23:26:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 1: Reissued: Opened	DM : The form is unfrozen now. Start Date' is after 'Date of Completion/Discontinuation /Death' on the Disposition - Follow-up eCRF. Please clarify or correct.

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Nov-25-2020 08:23:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Ans wered	Could you please unlock the Disposition FUP page so that the date can be corrected.
Nov-24-2020 15:40:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Op ened	DMW6233817;Start Date' is after 'Date of Completion/Discontinuation '/Death' on the Disposition - Follow-up eCRF. Please clarify or correct.
Nov-24-2020 09:17:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry : Nov/4 /2020 UNK: UNK	changed date to reflex actual date subject found deceased
Nov-11-2020 15:19:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry : Nov/1 /2020 UNK: UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-30-2020 15:29:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Clo sed	Auto closed by Validation Check: VC_AE001_10_AN
Nov-30-2020 09:00:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Ans wered	Date has been corrected
Nov-26-2020 02:03:17 (UTC-05:00)	ACV0PFEINFP6000	Vikas Joshi (pfe.joshiv22)	Query 1: Rei ssued:	DM: 'Disposition - Follow up' is unfrozen. Please consider to update and

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Eastern Time (US & Canada)			Opened	confirm. Thanks
Nov-25-2020 08:23:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	Please unlock the disposition page. The date entered was the presumed date of death however the death certificate has 04Nov2020 so we changed all dates to match with death certificate
Nov-24-2020 15:40:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW6234253;'End Date' is after 'Date of Completion/Discontinuation /Death' on the Disposition - Follow-up eCRF. Please clarify or correct.
Nov-24-2020 08:26:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry : NO End Date Time: Nov/4/2020 UNKN UNK	changed date to reflect the date subject was found deceased
Nov-12-2020 07:35:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry : NO End Date Time: No	Transcription Error

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			v/1 /20 20 U N K: U N K	
Nov-11-2020 15:19:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry : YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-11-2020 15:19:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: 4	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Nov-12-2020 13:18:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gladys Noi (pfe.noig)	Query 1: Closed	Response satisfies query
Nov-12-2020 08:17:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	We have not received the SAE number
Nov-12-2020 08:10:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ananta Gogoi (pfe.gogoa)	Query 1: Opened	For AE Death: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.

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Nov-11-2020 15:19:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Death: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-11-2020 15:19:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<p>Data Entry: YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>YES</p> <p>Did this serious event require or prolong hospitalization?</p> <p>NO</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>YES</p> <p>Other medically important serious event</p> <p>NO</p>	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
Nov-11-2020 15:19:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<p>Data Entry: NO</p>	Initial Entry

Header Text: c4591001

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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-24-2020 09:17:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NOT RELATED If Not Related to study treatment(s) , this event is due to: OTHER <i>If Other, specify:</i> Hypertensive cardiovascular disease	Changed Information
Nov-24-2020 08:27:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NOT RELATED If Not Related to study treatment(s) , this event is due to: OTHER <i>If Other, specify:</i> Hypertension	New Information
Nov-11-2020 15:19:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NOT RELATED If Not Related to study treatment(s) , this event is due to: OTHER <i>If Other, specify:</i> Unknown cause of death at this time	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-11-2020 15:19:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
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Nov-11-2020 15:19:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-11-2020 15:19:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-12-2020 07:35:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-11-2020 15:19:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Nov-11-2020 15:19:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Response to "What was the outcome of this adverse event?" is 'Fatal' but Date of Collection / Notification of Death on the Death Details form is not completed. Please review and update as appropriate.
Nov-11-2020 15:19:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Death: Response to "What was the outcome of this adverse event?" is 'Fatal' but "Is the adverse event still ongoing?" is marked 'Yes'.
Nov-11-2020 15:19:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: FATAL	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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Nov-12-2020 10:22:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Closed	Response satisfies query
Nov-12-2020 07:47:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	This has been completed
Nov-12-2020 07:41:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	CLINQUERY: Please complete the FUP tab to indicate end of study due to death
Nov-11-2020 15:19:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Nov-12-2020 13:17:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gladys Noi (pfe.noig)	Data Entry: 2020447660	Initial Entry

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Form: DEATH DETAILS CODED - eCRF Audit Trail History

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I. Date of Collection / Notification of Death:

Date	Location	User	Value	Reason
Dec-02-2020 00:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Astrud van der Merwe (pfe.vandea62)	Query 2: Closed	Response satisfies query
Dec-01-2020 12:46:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 2: Answered	No other updates needed, date we were notified was 11Nov2020
Dec-01-2020 02:08:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Usha Ogirala (pfe.ogirau)	Query 2: Reissued:Opened	DM: This form has been unlocked and available for update. Please review and amend the data as appropriate else clarify.
Nov-30-2020 09:02:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 2: Answered	Please unlock this page so that we can update the death details.
Nov-30-2020 08:57:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Date of Collection / Notification of Death is greater than the Date of Completion/Discontinuation /Death on the Disposition form 04/Nov/2020. Please review and update as appropriate
Nov-13-2020 09:32:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 1: Closed	Response satisfies query
Nov-12-2020 07:51:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	The date that we were notified of death was 11Nov202 however the suspected date of death was 01Nov2020. The 2 dates are not the same, data entered is correct
Nov-12-2020 07:46:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of Collection / Notification of Death is greater than the Date of Completion/Discontinuation /Death on the Disposition form 01/Nov/2020. Please

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				review and update as appropriate
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2.a

Date	Location	User	Value	Reason
Nov-30-2020 15:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Cause of Death Status: PRIMARY CAUSE OF DEATH Cause of Death: Myocardial Infarction	New Information
Nov-11-2020 15:20:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Cause of Death Status: PRIMARY CAUSE OF DEATH Cause of Death: Cause is currently unknown. Detail will be updated once the death certificate has been received	Initial Entry

2.a Cause of Death Status:

Date	Location	User	Value	Reason
Nov-11-2020 15:20:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: PRIMARY CAUSE OF DEATH	Initial Entry

2.a Cause of Death:

Date	Location	User	Value	Reason
Nov-30-2020 15:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Myocardial Infarction	New Information
Nov-11-2020 15:20:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Cause is currently unknown. Detail will be updated once the death certificate has been received	Initial Entry

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Date	Location	User	Value	Reason
Nov-12-2020 07:46:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Initial Entry
Oct-27-2020 12:48:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-10-2020 14:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-10-2020 12:57:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Nov-30-2020 08:57:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/4/2020	Changed from presumed date of death to the date on death certificate
Nov-12-2020 07:46:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/1/2020	Initial Entry
Oct-27-2020 12:48:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/27/2020	Initial Entry
Sep-10-2020 14:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/10/2020	Initial Entry
Sep-10-2020 12:57:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/10/2020	Initial Entry

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

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I. Casebook Signature

Date	Location	User	Value	Reason
Oct-16-2020 10:56:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: Click Here to Enable	Initial Entry