

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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: 10811026

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 Aug/12/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1081

Subject No: 10811026

Generated By: pfe.levisse

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	[10811026]
2.	Birth Date:	(b) (6)/1952
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:	

090177e196ae3f01\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: 10811026

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	Aug/12/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1081

Subject No: 10811026

Generated By: pfe.levisse

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 _____
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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: 10811026

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	Aug/12/2020
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: 10811026

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

eCRF Audit Trail History

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	UNK/UNK/1987
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Dyslipidemia]
	Start Date:	UNK/UNK/2002
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Diabetes Mellitus Type 2]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Obesity]
	Start Date:	UNK/UNK/1962
	Ongoing:	YES

090177e196ae3f01\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: 10811026

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

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypothyroidism]
	Start Date:	UNK/UNK/1984
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Adrenal Hyperplasia]
	Start Date:	UNK/UNK/1997
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Gallstones]
	Start Date:	Feb/UNK/2002
	Ongoing:	NO End Date: Feb/UNK/2003
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Colon Polyps- Benign]
	Start Date:	UNK/UNK/2011
	Ongoing:	NO End Date: UNK/UNK/2011

090177e196ae3f01\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: 10811026

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

1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Osteoarthritis-Bilateral Knees]
	Start Date:	UNK/UNK/2003
	Ongoing:	YES
1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Osteoarthritis of Right Thumb]
	Start Date:	UNK/UNK/2003
	Ongoing:	YES
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Fracture-Bilateral Wrists]
	Start Date:	UNK/UNK/2007
	Ongoing:	NO End Date: UNK/UNK/2007
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Seasonal Allergies]
	Start Date:	UNK/UNK/1972
	Ongoing:	YES
1.m	Line/MH Number:	[13]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Carpal Tunnel Syndrome- Bilateral]
	Start Date:	UNK/UNK/2002
	Ongoing:	YES

090177e196ae3f01\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: 10811026

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

1.n	Line/MH Number:	[14]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Anemia]
	Start Date:	UNK/UNK/2011
	Ongoing:	NO End Date: UNK/UNK/2015
1.o	Line/MH Number:	[15]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Skin Cancer-Squamous Cell on Nose]
	Start Date:	UNK/UNK/2010
	Ongoing:	NO End Date: UNK/UNK/2010
1.p	Line/MH Number:	[16]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Squamous Cell Skin Cancer removed from Nose]
	Start Date:	UNK/UNK/2010
	Ongoing:	NO End Date: UNK/UNK/2010
1.q	Line/MH Number:	[17]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Bilateral Carpal Tunnel Surgery]
	Start Date:	UNK/UNK/2002
	Ongoing:	NO End Date: UNK/UNK/2002

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811026

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

1.r	Line/MH Number:	[18]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Cholecystectomy]
	Start Date:	UNK/UNK/2003
	Ongoing:	NO End Date: UNK/UNK/2003
1.s	Line/MH Number:	[19]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Total Knee Replacement Right Knee]
	Start Date:	UNK/UNK/2003
	Ongoing:	NO End Date: UNK/UNK/2009
1.t	Line/MH Number:	[20]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Colonoscopy/Removal of Benign Colon Polyps]
	Start Date:	Dec/1/2011
	Ongoing:	NO End Date: Dec/1/2011

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1081

Subject No: 10811026

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:	Aug/12/2020
2.	Weight:	[259.4]
3.	Unit:	LB
4.	Height:	[66.0]
5.	Unit:	in
6.	Body Mass Index:	[41.9]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[98.0]
	Unit:	F
	Temperature Location:	FOREHEAD

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1081

Subject No: 10811026

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:	Aug/12/2020
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

090177e196ae3f01\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: 10811026

Generated By: pfe.levisse

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 :	Aug/12/2020
2.	Randomization Number:	[226458]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811026

Generated By: pfe.levisse

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: Aug/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	[BPHZFH]
5.b	Sample ID	[BPHZFG]
5.c	Sample ID	[BP1J58]
5.d	Sample ID	[BP1J59]
5.e	Sample ID	[BP1J5B]

090177e196ae3f01\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: 10811026

Generated By: pfe.levisse

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: Aug/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	[BP1J57]
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090177e196ae3f01\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: 10811026

Generated By: pfe.levisse

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:	Aug/12/2020 11:49
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

090177e196ae3f01\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: 10811026

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	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811026

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/2/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

eCRF Audit Trail History

Vaccination Symptoms Diary - Symptom Resolved Dates

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

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	YES Ongoing? NO Stop Date: Aug/18/2020
2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1081

Subject No: 10811026

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/2/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[96.6]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1081

Subject No: 10811026

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/2/2020
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

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811026

Generated By: pfe.levisse

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/2/2020
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	[BP97M5]
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090177e196ae3f01\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: 10811026

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/2/2020 11:06
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

090177e196ae3f01\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: 10811026

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/30/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

eCRF Audit Trail History

Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	YES Ongoing? NO Stop Date: Sep/8/2020
2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	YES Ongoing? YES
2.g	Symptom:	NEW OR WORSENERD MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERD JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811026

Generated By: pfe.levisse

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/30/2020
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	[BP1HSS]
5.b	Sample ID	[BRTXR7]
5.c	Sample ID	[BRTXR8]

090177e196ae3f01\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: 10811026

Generated By: pfe.levisse

Form: DATE OF VISIT

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

Date of Visit

1.	Date of Visit	Mar/3/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811026

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRM4MH]
5.b	Sample ID	[BRM4MJ]
5.c	Sample ID	[BKZ4HV]
5.d	Sample ID	[BKZ4HW]

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811026

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: 10811026

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: 10811026

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: 10811026

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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090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET
on Oct/01/2020

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: 10811026

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/1/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Oct/01/2020

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

eCRF Audit Trail History

Signs and Symptoms

1.	Date of Assessment:	Oct/1/2020
2.	Date of First Symptom Started:	Sep/2/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Oct/5/2020

Symptoms

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

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Oct/01/2020

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

4.i	Symptoms:	VOMITING
	Was symptom present?	NO

Symptoms - Other

5.	Symptoms - Other Text:	[]
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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: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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 **Form:** MICROBIOLOGY SPECIMEN
on Oct/01/2020

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: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

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[eCRF Audit Trail History](#)

Microbiology Specimen

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

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Oct/01/2020

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: 10811026

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	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Oct/5/2020
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	[RW79396]
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090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
on Oct/01/2020

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: 10811026

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	NASAL_SWAB
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Telehealth visit]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[]
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090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION
on Oct/01/2020**Form Version:** 15-Sep-2020 21:53**Form Status:** Data Complete, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811026**Subject Initials:** ---**Generated By:** pfe.levisse**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:	YES Number of Visits or Contacts: [1]
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	NO
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	NO
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
----	--	----

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: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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 **Form:** RESPIRATORY TREATMENT
on Oct/01/2020

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: 10811026

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

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS
on Oct/01/2020

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: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE
on Oct/01/2020

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: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

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[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: 30-Jul-2020 21:27

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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	

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Oct/01/2020

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

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

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Oct/01/2020

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

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

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Oct/01/2020

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

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

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Oct/01/2020

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

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

090177e196ae3f01\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: 30-Jul-2020 21:28

Site No: 1081

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

Subject No: 10811026

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	
					Not Applicable	Not Applicable	Not Applicable	

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Oct/01/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

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[Form Comments](#)

[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

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING Hematology on Oct/01/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

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

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING Hematology on Oct/01/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

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

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING Hematology on Oct/01/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

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

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING Hematology on Oct/01/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

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

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Oct/01/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

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

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 30-Jul-2020 21:27

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Oct/01/2020

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

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Vital Signs

1.	Date:	Unknown _____ //	Comments
----	-------	------------------------	--------------------------

Vital Signs Details

2.a	Record Identifier:	Unknown _____ 1	
	Systolic:	Unknown _____ []	Comments
	Diastolic:	Unknown _____ []	Comments
	Respiratory Rate in respirations/minute:	Unknown _____ []	Comments
	Heart Rate in beats/minute:	Unknown _____ []	Comments

090177e196ae3f01\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: 30-Jul-2020 21:28

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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	

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Oct/01/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

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	
	SPO2 Pulse Oximetry %	Not Applicable _____ []	Comments

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

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: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS
on Oct/01/2020

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: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

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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: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
on Oct/01/2020

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: 10811026

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?	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

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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: 10811026

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 **Form:** IMAGING
on Oct/01/2020

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: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

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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 1 - Unscheduled **Form:** DATE OF VISIT - ILLNESS CONVALESCENT
Visit on Oct/29/2020

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

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/29/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A1
----	-------------------------	----------

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Visit on Oct/29/2020

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: 10811026

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/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	[BS64MV]
5.b	Sample ID	[BS64MW]
5.c	Sample ID	[BRDCR7]
5.d	Sample ID	[BRDCR8]

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

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: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

Unplanned Assessments

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1081

Subject No: 10811026

Generated By: pfe.levisse

Form: DISPOSITION - TREATMENT

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 - Treatment

1.	Date of Completion/Discontinuation/Death :	Sep/30/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

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Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1081

Subject No: 10811026

Generated By: pfe.levisse

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

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

Subject Initials: ---

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

Disposition - Follow-Up

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
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: 10811026

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 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: 10811026

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	[]
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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: 10811026

Subject Initials: ---

Generated By: pfe.levissc

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Diarrhea	Aug/13/2020 UNK:UNK	NO End Date Time: Aug/17/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	Urinary Tract Infection	Oct/5/2020 UNK:UNK	NO End Date Time: Oct/16/2020 UNK:UNK	Repeating Pages
3.	ADVERSE EVENT	3	Serous borderline tumor of left ovary	Oct/11/2020 UNK:UNK	NO End Date Time: Oct/16/2020 UNK:UNK	Repeating Pages
4.	ADVERSE EVENT	4	lower abdominal pain	Oct/11/2020 UNK:UNK	NO End Date Time: Oct/16/2020 UNK:UNK	Repeating Pages
5. DELETED	ADVERSE EVENT	5	Diarrhea	Sep/2/2020 16:00	NO End Date Time: Oct/5/2020 UNK:UNK	Repeating Pages
6.	ADVERSE EVENT	6	Worsening of Anemia	Oct/11/2020 UNK:UNK	NO End Date Time: Oct/29/2020 UNK:UNK	Repeating Pages

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811026

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Queries, Verified

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

Subject Initials: ---

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Diarrhea]
4.	Start Date Time:	Aug/13/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/17/2020 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [idiopathic]

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811026

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Queries, 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?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1081**Subject No:** 10811026**Generated By:** pfe.levisse**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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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Urinary Tract Infection]
4.	Start Date Time:	Oct/5/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/16/2020 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Idiopathic]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811026

Generated By: pfe.levisse

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

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1081**Subject No:** 10811026**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Queries, Frozen, Verified**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)[eCRF Audit Trail History](#)[Form Audit Trail](#)**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Serous borderline tumor of left ovary]
4.	Start Date Time:	Oct/11/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/16/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO 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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811026

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Queries, Frozen, Verified

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

Subject Initials: ---

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

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: [Cancerous]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020405804]

090177e196ae3f01\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:** 10811026**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Frozen**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)[eCRF Audit Trail History](#)[Form Audit Trail](#)**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[lower abdominal pain]
4.	Start Date Time:	Oct/11/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/16/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Neoplasm of uncertain behavior of left ovary]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811026

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

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

090177e196ae3f01\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:** 10811026**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Deleted, Frozen, Verified**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:11

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

[Back to Form](#)[eCRF Audit Trail History](#)[Form Audit Trail](#)**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Diarrhea]
4.	Start Date Time:	Sep/2/2020 16:00
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/5/2020 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).	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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811026

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted, Frozen, Verified

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

Subject Initials: ---

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

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

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

090177e196ae3f01\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:** 10811026**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Frozen**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)[eCRF Audit Trail History](#)[Form Audit Trail](#)**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[6]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Worsening of Anemia]
4.	Start Date Time:	Oct/11/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/29/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Tumor of left ovary]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811026

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

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

090177e196ae3f01\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: 10811026

Subject Initials: ---

Generated By: pfe.levissc

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1081

Subject No: 10811026

Generated By: pfe.levisse

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	[]

090177e196ae3f01\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: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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: 10811026

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:	//

090177e196ae3f01\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: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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: 10811026

Generated By: pfe.levisse

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?	

090177e196ae3f01\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: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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: 10811026

Generated By: pfe.levisse

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: 10811026

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: 10811026

Generated By: pfe.levisse

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:	//

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1081

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

Subject No: 10811026

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: 10811026

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: 10811026

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:	

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

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: 10811026

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?	

090177e196ae3f01\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: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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: 10811026

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 Version: 14-Jan-2021 02:29

Site No: 1081

Subject No: 10811026

Generated By: pfe.levisse

Form: INFORMED CONSENT - ASYMPTOMATIC
SURVEILLANCE

Form Status: Not Started

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

Subject Initials: ---

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

Informed Consent - Asymptomatic Surveillance

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1081

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

Subject No: 10811026

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: 10811026

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	[]
----	-----------	-----

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

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	Dec/16/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2
----	---	--

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811026

Generated By: pfe.levisse

Form: TREATMENT UNBLINDED

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](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Dec/16/2020
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811026

Generated By: pfe.levisse

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 :	//
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090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811026

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	FOLLOW-UP
2.	Subject Status Date	Sep/30/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1081

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

Subject No: 10811026

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, Verified

Site No: 1081

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

Subject No: 10811026

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
- CRF_Sign_1

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1081

Subject No: 10811026

Generated By: pfe.levisse

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	Aug-12-2020 12:16:30 (UTC-05:00) Eastern Time (US & Canada)	Tawnyn Ebner (pfe.tebner)	all inclusion and exclusion met <hr/> Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Oct/01/2020

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: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
Form	Oct-05-2020 13:44:19 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	She saw her PCP but no COVID testing was done. <hr/> Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Oct/01/2020

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: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
1	Oct-05-2020 13:44:19 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	She saw her PCP but no COVID testing was done. <hr/> Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments on Oct/01/2020

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: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
2	Oct-05-2020 13:44:19 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	She saw her PCP but no COVID testing was done. <hr/> Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
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Item	Date	User	Comment
3	Oct-05-2020 13:44:19 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	She saw her PCP but no COVID testing was done. <hr/> Not Done

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

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Item	Date	User	Comment
4	Oct-05-2020 13:44:19 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	She saw her PCP but no COVID testing was done. <hr/> Not Done

Header Text: c4591001

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

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Item	Date	User	Comment
5	Oct-05-2020 13:44:19 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	She saw her PCP but no COVID testing was done. <hr/> Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments on Oct/01/2020

Form Version: 06-Jul-2020 21:54

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Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
6	Oct-05-2020 13:44:19 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	She saw her PCP but no COVID testing was done. <hr/> Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments on Oct/01/2020

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: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
7	Oct-05-2020 13:44:19 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	She saw her PCP but no COVID testing was done. <hr/> Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments on Oct/01/2020

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: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
8	Oct-05-2020 13:44:19 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	She saw her PCP but no COVID testing was done. <hr/> Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Oct/01/2020

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: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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Item	Date	User	Comment
9	Oct-05-2020 13:44:19 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	She saw her PCP but no COVID testing was done. <hr/> Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments on Oct/01/2020

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: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
Form	Oct-05-2020 13:45:51 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Oct/01/2020

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: 10811026

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Generated By: pfe.levisc

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

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Item	Date	User	Comment
1	Oct-05-2020 13:45:51 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments on Oct/01/2020

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Item	Date	User	Comment
2	Oct-05-2020 13:45:51 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments on Oct/01/2020

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Item	Date	User	Comment
3	Oct-05-2020 13:45:51 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
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Item	Date	User	Comment
4	Oct-05-2020 13:45:51 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
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Item	Date	User	Comment
6	Oct-05-2020 13:45:51 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
on Oct/01/2020

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: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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Item	Date	User	Comment
Form	Oct-05-2020 13:46:25 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments on Oct/01/2020

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: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
1	Oct-05-2020 13:46:25 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments on Oct/01/2020

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Subject No: 10811026

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Item	Date	User	Comment
2	Oct-05-2020 13:46:25 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments on Oct/01/2020

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Item	Date	User	Comment
4	Oct-05-2020 13:46:25 (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/01/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

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Generated By: pfe.levisse

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

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Item	Date	User	Comment
Form	Oct-05-2020 13:46:57 (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/01/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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Item	Date	User	Comment
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Item	Date	User	Comment
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090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/01/2020

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Item	Date	User	Comment
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Item	Date	User	Comment
5.a	Oct-05-2020 13:46:57 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

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Item	Date	User	Comment
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Item	Date	User	Comment
5.a	Oct-05-2020 13:46:57 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

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Item	Date	User	Comment
5.a	Oct-05-2020 13:46:57 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

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Site No: 1081

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Generated By: pfe.levisse

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Item	Date	User	Comment
5.b	Oct-05-2020 13:46:57 (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/01/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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Generated By: pfe.levisse

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

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Item	Date	User	Comment
5.b	Oct-05-2020 13:46:57 (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/01/2020

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Item	Date	User	Comment
5.b	Oct-05-2020 13:46:57 (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 Oct/01/2020

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Item	Date	User	Comment
5.b	Oct-05-2020 13:46:57 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

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Item	Date	User	Comment
5.c	Oct-05-2020 13:46:57 (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/01/2020

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Item	Date	User	Comment
5.c	Oct-05-2020 13:46:57 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

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Item	Date	User	Comment
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/01/2020

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Site No: 1081

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Subject No: 10811026

Subject Initials: ---

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

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Item	Date	User	Comment
5.d	Oct-05-2020 13:46:57 (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/01/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

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
5.d	Oct-05-2020 13:46:57 (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 Oct/01/2020

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2	Oct-05-2020 13:47:18 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

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3	Oct-05-2020 13:47:18 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

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4	Oct-05-2020 13:47:18 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

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5 f	Oct-05-2020 13:47:18 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/01/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
5 f	Oct-05-2020 13:47:18 (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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Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
Form	Oct-05-2020 13:48:01 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	No records from PCP visit yet <hr/> Unknown

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Comments
on Oct/01/2020

Form Version: 30-Jul-2020 21:27

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Item	Date	User	Comment
1	Oct-05-2020 13:48:01 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	No records from PCP visit yet <hr/> Unknown

Header Text: c4591001

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Item	Date	User	Comment
2.a	Oct-05-2020 13:48:01 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	No records from PCP visit yet <hr/> Unknown

Header Text: c4591001

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments on Oct/01/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

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Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments on Oct/01/2020

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: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
Form	Oct-05-2020 13:48:51 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments on Oct/01/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/01/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

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Form	Oct-05-2020 13:49:07 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

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Header Text: c4591001

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6	Oct-05-2020 13:49:07 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Oct/01/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

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Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
Form	Oct-05-2020 13:49:31 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Oct/01/2020

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: 10811026

Subject Initials: ---

Generated By: pfe.levisc

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

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Item	Date	User	Comment
1	Oct-05-2020 13:49:31 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Oct/01/2020

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: 10811026

Subject Initials: ---

Generated By: pfe.levisc

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

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Item	Date	User	Comment
2	Oct-05-2020 13:49:31 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Oct/01/2020

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: 10811026

Subject Initials: ---

Generated By: pfe.levisc

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

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Item	Date	User	Comment
3	Oct-05-2020 13:49:31 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Oct/01/2020

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: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
4	Oct-05-2020 13:49:31 (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, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
Lora Morris	N/A	Mar-03-2021 16:03:33 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

James Fry	Approved	Jan-23-2021 11:52:04 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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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	Jan-07-2021 15:20:38 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:
N/A

Michael Butcher	Approved	Nov-10-2020 12:58:44 (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.

090177e196ae3f01\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, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

James Fry	N/A	Oct-19-2020 15:53:12 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Michael Butcher	Approved	Oct-13-2020 11:53:04 (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.

Tawyn Ebner	N/A	Sep-30-2020 10:21:30 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

James Fry	Approved	Sep-14-2020 16:02:12 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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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.

090177e196ae3f01\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: 10811026

Generated By: pfe.levisse

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
Aug-12-2020 12:15:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын 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
Aug-12-2020 12:15:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын 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: 10811026

Generated By: pfe.levisse

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
Aug-12-2020 12:15:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawyn Ebner (pfe.tebner)	Data Entry: OBTAINED Date Written Consent Obtained Aug/12/2020	Initial Entry

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1081

Subject No: 10811026

Generated By: pfe.levisse

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
Aug-12-2020 12:15:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10811026	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-12-2020 12:15:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1952	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-12-2020 12:15:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawyn Ebner (pfe.tebner)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-12-2020 12:15:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawyn Ebner (pfe.tebner)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 12:15:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawyn Ebner (pfe.tebner)	Data Entry: WHITE	Initial Entry

090177e196ae3f01\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: 10811026

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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1. Date of Visit

Date	Location	User	Value	Reason
Aug-12-2020 12:16:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Aug/12/2020	Initial Entry

090177e196ae3f01\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: 10811026

Generated By: pfe.levisse

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
Aug-12-2020 12:16:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Aug/12/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-12-2020 12:16:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-12-2020 12:16:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: COMPLETED	Initial Entry

090177e196ae3f01\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: 10811026

Generated By: pfe.levisse

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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I.a

Date	Location	User	Value	Reason
Aug-12-2020 13:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 1 : Medical History T Hypertension erm: Start Date: UNK/UNK/1 987 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-12-2020 13:42:17 (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
Aug-12-2020 13:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Hypertension	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Aug-12-2020 13:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/1987	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Aug-12-2020 13:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

090177e196ae3f01\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: 10811026

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Aug-12-2020 13:42:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 2 : Medical History T Dyslipidemia erm: Start Date: UNK/UNK/2 002 Ongoing: YES	Initial Entry

I.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-12-2020 13:42:37 (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
Aug-12-2020 13:42:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Dyslipidemia	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Aug-12-2020 13:42:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2002	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Aug-12-2020 13:42:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

I.c

090177e196ae3f01\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: 10811026

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Aug-12-2020 13:43:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 3 ber: Medical Histor Diabetes Mellitu y Term: s Type 2 Start Date: UNK/UNK/201 6 Ongoing: YES	Initial Entry

I.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-12-2020 13:43:00 (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
Aug-12-2020 13:43:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Diabetes Mellitus Type 2	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Aug-12-2020 13:43:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2016	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Aug-12-2020 13:43:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
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090177e196ae3f01\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: 10811026

Generated By: pfe.levisse

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

Aug-12-2020 13:43:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 4 : Medical History T Obesity erm: Start Date: UNK/UNK/1 962 Ongoing: YES	Initial Entry
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1.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-12-2020 13:43:24 (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
Aug-12-2020 13:43:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Obesity	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Aug-12-2020 13:43:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/1962	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Aug-12-2020 13:43:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

1.e

Date	Location	User	Value	Reason
Aug-12-2020 13:43:48	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae3f01\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: 10811026

Generated By: pfe.levisse

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

(UTC-05:00) Eastern Time (US & Canada)		(autocalc)	Line/MH Number 5 : Medical History T Hypothyroidism: Start Date: UNK/UNK/1984 Ongoing: YES	
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I.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-12-2020 13:43:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 5	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 13:43:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> Hypothyroidism	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Aug-12-2020 13:43:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> UNK/UNK/1984	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Aug-12-2020 13:43:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Aug-12-2020 13:45:33 (UTC-05:00) Eastern	ACV0PFEINFP6000	Phillip Ross	<u>Data Entry:</u> Line/MH Numb 6	Initial Entry

090177e196ae3f01\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: 10811026

Generated By: pfe.levisse

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

Time (US & Canada)		(pfe.pross)	er: Medical History Adrenal Hyperplasia Term: plasia Start Date: UNK/UNK/1997 Ongoing: YES	
Aug-12-2020 13:44:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numb 6 er: Medical History Adrenal Hyperplasia Term: plasia Start Date: UNK/UNK/1997 Ongoing:	Initial Entry

090177e196ae3f01\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: 10811026

Generated By: pfe.levisse

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.f Line/MH Number:

Date	Location	User	Value	Reason
Aug-12-2020 13:44:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 13:44:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Adrenal Hyperplasia	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Aug-12-2020 13:44:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/1997	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Aug-12-2020 13:45:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

1.g

Date	Location	User	Value	Reason
Aug-12-2020 13:44:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 7 Medical History Term: Gallstones Start Date: Feb/UNK/2002	Initial Entry

090177e196ae3f01\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: 10811026

Generated By: pfe.levisse

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

			Ongoing:	NO End Date: Feb/UNK/2003
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I.g Line/MH Number:

Date	Location	User	Value	Reason
Aug-12-2020 13:44:44 (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
Aug-12-2020 13:44:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Gallstones	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Aug-12-2020 13:44:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Feb/UNK/2002	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Aug-12-2020 13:44:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO End Date: Feb/UNK/2003	Initial Entry

I.h

Date	Location	User	Value	Reason
Aug-12-2020 13:46:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 8 ber:	Initial Entry

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Subject No: 10811026

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			Medical History Term: Colon Polyps- Benign Start Date: UNK/UNK/2011 Ongoing: NO End Date: UNK/UNK/2011	
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1.h Line/MH Number:

Date	Location	User	Value	Reason
Aug-12-2020 13:46:37 (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
Aug-12-2020 13:46:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Colon Polyps- Benign	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Aug-12-2020 13:46:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2011	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Aug-12-2020 13:46:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO End Date: UNK/UNK/2011	Initial Entry

1.i

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Header Text: c4591001

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Site No: 1081

Subject No: 10811026

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Date	Location	User	Value	Reason
Aug-12-2020 13:47:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 9 mber: Medical History Term: Osteoarthritis-Bilateral Knees Start Date: UNK/UNK/2003 Ongoing: YES	Initial Entry

1.i Line/MH Number:

Date	Location	User	Value	Reason
Aug-12-2020 13:47:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 13:47:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Osteoarthritis-Bilateral Knees	Initial Entry

1.i Start Date:

Date	Location	User	Value	Reason
Aug-12-2020 13:47:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2003	Initial Entry

1.i Ongoing:

Date	Location	User	Value	Reason
Aug-12-2020 13:47:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

1.j

Date	Location	User	Value	Reason
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Aug-12-2020 13:47:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 10 Medical History Term: Osteoarthritis of Right Thumb Start Date: UNK/UNK/2003 Ongoing: YES	Initial Entry
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1.j Line/MH Number:

Date	Location	User	Value	Reason
Aug-12-2020 13:47:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 13:47:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Osteoarthritis of Right Thumb	Initial Entry

1.j Start Date:

Date	Location	User	Value	Reason
Aug-12-2020 13:47:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2003	Initial Entry

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Subject No: 10811026

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l.j Ongoing:

Date	Location	User	Value	Reason
Aug-12-2020 13:47:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

l.k

Date	Location	User	Value	Reason
Aug-14-2020 13:12:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Line/MH Num 11 ber: Medical Histo Fracture-Bilater ry Term: al Wrists Start Date: UNK/UNK/200 7 Ongoing: NO End Date: UNK/UNK/2 007	Due to trauma of same date
Aug-14-2020 10:38:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Line/MH 11 Number: Medical Fracture-Bilateral Wri History T sts-Due to trauma of s erm: ame date Start Dat UNK/UNK/2007 e: Ongoing: NO End Date: UNK/UNK/2007	New Information
Aug-12-2020 13:48:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 11 ber: Medical Histo Fracture-Bilater ry Term: al Wrists	Initial Entry

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

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			Start Date: UNK/UNK/2007	
			Ongoing: NO	
			End Date:	
			UNK/UNK/2007	

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Header Text: c4591001

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1.k Line/MH Number:

Date	Location	User	Value	Reason
Aug-12-2020 13:48:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11	Initial Entry

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

Date	Location	User	Value	Reason
Aug-14-2020 13:14:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Closed	Response satisfies query
Aug-14-2020 13:12:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Due to trauma of same date
Aug-14-2020 13:12:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Fracture-Bilateral Wrists	Due to trauma of same date
Aug-14-2020 13:06:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Reissued:Opened	GPD Clin: Thank you for the response - please add the extra information into the query response only. Event term can remain as was for coding.
Aug-14-2020 10:38:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Aug-14-2020 10:38:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Fracture-Bilateral Wrists-Due to trauma of same date	New Information
Aug-14-2020 10:36:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	GPD Clin: Please clarify if there was any underlying medical condition to these fractures, or if due to trauma. If

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				there is a corresponding medical condition please add to the MH listing as a separate entry.
Aug-12-2020 13:48:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Fracture-Bilateral Wrists	Initial Entry

1.k Start Date:

Date	Location	User	Value	Reason
Aug-12-2020 13:48:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2007	Initial Entry

1.k Ongoing:

Date	Location	User	Value	Reason
Aug-12-2020 13:48:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO End Date: UNK/UNK/2007	Initial Entry

1.l

Date	Location	User	Value	Reason
Aug-12-2020 13:48:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: r: Medical History Term: Seasonal Allergies Start Date: UNK/UNK/1972 Ongoing: YES	Initial Entry

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1.1 Line/MH Number:

Date	Location	User	Value	Reason
Aug-12-2020 13:48:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12	Initial Entry

1.1 Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-12-2020 13:48:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Seasonal Allergies	Initial Entry

1.1 Start Date:

Date	Location	User	Value	Reason
Aug-12-2020 13:48:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/1972	Initial Entry

1.1 Ongoing:

Date	Location	User	Value	Reason
Aug-12-2020 13:48:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

1.m

Date	Location	User	Value	Reason
Aug-12-2020 13:49:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 13 mber: Medical Hist Carpal Tunnel Syn ory Term: drome- Bilateral Start Date: UNK/UNK/2002 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Subject No: 10811026

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Subject Initials: ---

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I.m Line/MH Number:

Date	Location	User	Value	Reason
Aug-12-2020 13:49:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 13	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 13:49:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Carpal Tunnel Syndrome- Bilatera 1	Initial Entry

I.m Start Date:

Date	Location	User	Value	Reason
Aug-12-2020 13:49:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2002	Initial Entry

I.m Ongoing:

Date	Location	User	Value	Reason
Aug-12-2020 13:49:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

I.n

Date	Location	User	Value	Reason
Aug-12-2020 13:50:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 14 Medical History Term: Anemia Start Date: UNK/UNK/2011	Initial Entry

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			Ongoing:	NO	
				End Date:	
				UNK/UNK/ 2015	

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Date	Location	User	Value	Reason
Aug-12-2020 13:50:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 14	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 11:46:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Closed	Query N/A - End date
Aug-13-2020 11:36:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	GPD Clin: Anemia: Please can you confirm if subject has received any blood products in the past 60 days for this medhx?
Aug-12-2020 13:50:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Anemia	Initial Entry

I.n Start Date:

Date	Location	User	Value	Reason
Aug-12-2020 13:50:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2011	Initial Entry

I.n Ongoing:

Date	Location	User	Value	Reason
Aug-12-2020 13:50:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO End Date: UNK/UNK/2015	Initial Entry

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I.o

Date	Location	User	Value	Reason
Aug-12-2020 13:53:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: N 15 Medical History Term: Skin Cancer-Squamous Cell on Nose Start Date: UNK/UNK/2010 Ongoing: NO End Date: UNK/UNK/2010	Initial Entry

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I.o Line/MH Number:

Date	Location	User	Value	Reason
Aug-12-2020 13:53:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 15	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 13:53:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Skin Cancer-Squamous Cell on N ose	Initial Entry

I.o Start Date:

Date	Location	User	Value	Reason
Aug-12-2020 13:53:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2010	Initial Entry

I.o Ongoing:

Date	Location	User	Value	Reason
Aug-12-2020 13:53:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO End Date: UNK/UNK/2010	Initial Entry

I.p

Date	Location	User	Value	Reason
Aug-12-2020 13:54:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 16 Number: Medical H Squamous Cell Skin istory Ter Cancer removed from m: Nose Start Date UNK/UNK/2010 :	Initial Entry

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			Ongoing: NO End Date: UNK/UNK/2010	
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I.p Line/MH Number:

Date	Location	User	Value	Reason
Aug-12-2020 13:54:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 16	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 13:54:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Squamous Cell Skin Cancer remo ved from Nose	Initial Entry

I.p Start Date:

Date	Location	User	Value	Reason
Aug-12-2020 13:54:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2010	Initial Entry

I.p Ongoing:

Date	Location	User	Value	Reason
Aug-12-2020 13:54:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO End Date: UNK/UNK/2010	Initial Entry

I.q

Date	Location	User	Value	Reason
Aug-12-2020 13:55:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 17 mber:	Initial Entry

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			Medical History Term: Bilateral Carpal Tunnel Surgery Start Date: UNK/UNK/2002 Ongoing: NO End Date: UNK/UNK/2002	
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I.q Line/MH Number:

Date	Location	User	Value	Reason
Aug-12-2020 13:55:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 17	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 13:55:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Bilateral Carpal Tunnel Surgery	Initial Entry

I.q Start Date:

Date	Location	User	Value	Reason
Aug-12-2020 13:55:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2002	Initial Entry

I.q Ongoing:

Date	Location	User	Value	Reason
Aug-12-2020 13:55:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO End Date: UNK/UNK/2002	Initial Entry

I.r

Date	Location	User	Value	Reason
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090177e196ae3f01\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: 10811026

Generated By: pfe.levisse

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

Aug-12-2020 13:55:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 18 Medical History Term: Cholecystectomy Start Date: UNK/UNK/2003 Ongoing: NO End Date: UNK/UNK/ 2003	Initial Entry
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1.r Line/MH Number:

Date	Location	User	Value	Reason
Aug-12-2020 13:55:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 18	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 13:55:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Cholecystectomy	Initial Entry

090177e196ae3f01\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: 10811026

Generated By: pfe.levisse

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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I.r Start Date:

Date	Location	User	Value	Reason
Aug-12-2020 13:55:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2003	Initial Entry

I.r Ongoing:

Date	Location	User	Value	Reason
Aug-12-2020 13:55:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO End Date: UNK/UNK/2003	Initial Entry

I.s

Date	Location	User	Value	Reason
Aug-12-2020 13:57:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 19 umber: Medical His Total Knee Replace tory Term: ment Right Knee Start Date: UNK/UNK/2003 Ongoing: NO End Date: UNK/UNK/2009	Initial Entry

090177e196ae3f01\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:** 10811026**Generated By:** pfe.levisse**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.s Line/MH Number:***

Date	Location	User	Value	Reason
Aug-12-2020 13:57:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 19	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 13:57:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Total Knee Replacement Right Knee	Initial Entry

I.s Start Date:

Date	Location	User	Value	Reason
Aug-12-2020 13:57:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2003	Initial Entry

I.s Ongoing:

Date	Location	User	Value	Reason
Aug-12-2020 13:57:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO End Date: UNK/UNK/2009	Initial Entry

I.t

Date	Location	User	Value	Reason
Aug-12-2020 13:58:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 20 Medical History Term: Colonoscopy/Removal of Benign Colon Polyps Start Date: Dec/1/2011 :	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811026

Generated By: pfe.levisse

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

			Ongoing: NO End Date: Dec/1/2011	
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1.t Line/MH Number:

Date	Location	User	Value	Reason
Aug-12-2020 13:58:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 20	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 13:58:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Colonoscopy/Removal of Benign Colon Polyps	Initial Entry

1.t Start Date:

Date	Location	User	Value	Reason
Aug-12-2020 13:58:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Dec/1/2011	Initial Entry

1.t Ongoing:

Date	Location	User	Value	Reason
Aug-12-2020 13:58:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO End Date: Dec/1/2011	Initial Entry

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1081

Subject No: 10811026

Generated By: pfe.levisse

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
Aug-12-2020 13:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> Aug/12/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-12-2020 13:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> 259.4	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-12-2020 13:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-12-2020 13:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> 66.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-12-2020 13:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-12-2020 13:58:49	ACV0PFEINFP6000	auto calc	<u>Data Entry:</u>	Initial Entry

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form Version: 30-Jul-2020 21:28
Site No: 1081
Subject No: 10811026
Generated By: pfe.levisse
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

(UTC-05:00) Eastern Time (US & Canada)		(autocalc)	41.9	
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7.a

Date	Location	User	Value	Reason
Aug-12-2020 13:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Record Identifier:: 1 Temperature: 98.0 Temperature Unit: F Temperature Location:: FOREHEAD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-12-2020 13:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-12-2020 13:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: 98.0	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-12-2020 13:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-12-2020 13:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: FOREHEAD	Initial Entry

090177e196ae3f01\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:** 30-Jul-2020 21:27**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811026**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Aug-12-2020 13:59:22 (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
Aug-12-2020 13:59:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-12-2020 13:59:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Aug/12/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Aug-12-2020 13:59:22 (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
Aug-12-2020 13:59:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

Aug-12-2020 13:59:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Choriogonadotropin Beta_PX113 Result:: Not Done:: NOT DONE	Initial Entry
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-12-2020 13:59:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-12-2020 13:59:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Aug-12-2020 13:59:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NOT DONE	Initial Entry

090177e196ae3f01\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: 10811026

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
Aug-12-2020 13:59:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Aug/12/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-12-2020 13:59:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: 226458	Initial Entry

090177e196ae3f01\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:** 10811026**Generated By:** pfe.levisse**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-12-2020 13:20:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-12-2020 13:20:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-12-2020 13:20:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-12-2020 13:20:49 (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.
Aug-12-2020 13:20:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Aug/12/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-12-2020 13:20:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BPHZFH	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: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Aug-12-2020 13:20:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	<u>Data Entry:</u> BPHZFH	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-12-2020 13:21:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BPHZFG	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-12-2020 13:21:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	<u>Data Entry:</u> BPHZFG	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-12-2020 13:21:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BP1J58	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-12-2020 13:21:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	<u>Data Entry:</u> BP1J58	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-12-2020 13:21:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BP1J59	Initial Entry

090177e196ae3f01\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: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

5.d Sample ID

Date	Location	User	Value	Reason
Aug-12-2020 13:21:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> BP1J59	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-12-2020 13:21:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BP1J5B	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-12-2020 13:21:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> BP1J5B	Initial Entry

090177e196ae3f01\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:** 10811026**Generated By:** pfe.levisse**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-12-2020 13:14:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-12-2020 13:14:43 (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
Aug-12-2020 13:14:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-12-2020 13:14:43 (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.
Aug-12-2020 13:14:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Aug/12/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-12-2020 13:14:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BP1J57	Initial Entry

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: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Aug-12-2020 13:14:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BP1J57	Initial Entry

090177e196ae3f01\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: 10811026

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
Aug-12-2020 14:00:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-12-2020 14:00:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-12-2020 14:00:47 (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
Aug-12-2020 14:00:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Aug/12/2020 11:49	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-12-2020 14:00:47 (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
Aug-12-2020 14:00:47	ACV0PFEINFP6000	Phillip	Data Entry:	Initial Entry

090177e196ae3f01\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: 10811026

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

(UTC-05:00) Eastern Time (US & Canada)		Ross (pfe.pross)	LEFT	
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7. Route:

Date	Location	User	Value	Reason
Aug-12-2020 14:00:47 (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
Aug-12-2020 14:00:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 14:00:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

090177e196ae3f01\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: 10811026

Generated By: pfe.levisse

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

[Back to Form](#)

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-12-2020 14:00:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES - REACTOGENICITY E-DI ARY COLLECTED FOR THIS S UBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811026

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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1. Date of Visit

Date	Location	User	Value	Reason
Sep-02-2020 11:00:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawynn Ebner (pfe.tebner)	Data Entry: Sep/2/2020	Initial Entry

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 30-Jul-2020 21:30**Site No:** 1081**Subject No:** 10811026**Generated By:** pfe.levisse**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - 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](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Sep-02-2020 12:13:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-02-2020 12:13:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Symptom:: FE VE R Were fever or systemic sym N ptoms present on the last d O ay the Subject Diary was co mpleted?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Sep-02-2020 12:13:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 12:13:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-02-2020 12:13:44 (UTC-05:00) Eastern	ACV0PFEINFP6000	Phillip Ross	Data Entry: Symptom:: FA	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

Time (US & Canada)		(pfe.pross)	TI GU E Were fever or systemic sy mptoms present on the last day the Subject Diary was completed?:	NO
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2.b Symptom:

Date	Location	User	Value	Reason
Sep-02-2020 12:13:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 12:13:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-02-2020 12:13:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> Symptom:: HE AD AC HE Were fever or systemic sy mptoms present on the las t day the Subject Diary w as completed?:	Initial Entry

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

2.c Symptom:

Date	Location	User	Value	Reason
Sep-02-2020 12:13:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 12:13:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-02-2020 12:13:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> Symptom:: CH IL LS Were fever or systemic sym ptoms present on the last d ay the Subject Diary was c ompleted?: NO	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Sep-02-2020 12:13:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 12:13:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> NO	Initial Entry

2.e

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Sep-02-2020 12:13:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Symptom:: VO MIT ING Were fever or systemic sy NO mptoms present on the las t day the Subject Diary w as completed?:	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Sep-02-2020 12:13:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 12:13:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Sep-03-2020 13:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Symptom:: DIARRH EA	Changed Information

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

			<p>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</p> <p>YES Ongoing ?</p> <p>NO</p> <p>Stop Date:</p> <p>Au g/1 8/2 020</p>	
Sep-02-2020 12:13:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<p>Data Entry:</p> <p>Symptom::</p> <p>DIA</p> <p>RR</p> <p>HE</p> <p>A</p> <p>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</p> <p>NO</p>	Initial Entry

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

2.f Symptom:

Date	Location	User	Value	Reason
Sep-02-2020 12:13:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Sep-04-2020 01:28:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pramod Margaj (pfe.margap03)	Query 1: Closed	Closed by DM: PM.
Sep-03-2020 13:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Sep-03-2020 13:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES Ongoing? NO Stop Date: Aug/18/2020	Changed Information
Sep-03-2020 12:10:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Isaac Arasavalli (pfe.arasai)	Query 1: Opened	e-Diary: Per eDiary records, DIARRHEA is reported on Last day (Day 7) however the last day in inform is entered as 'No' for the same. Please verify and update. Else, clarify. Thanks.
Sep-02-2020 12:13:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO	Initial Entry

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

2.g

Date	Location	User	Value	Reason
Sep-02-2020 12:13:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Symptom:: NEW OR WORSE NED MUS CLE PAI N Were fever or system NO ic symptoms present on the last day the S ubject Diary was co mpleted?:	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Sep-02-2020 12:13:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NEW OR WORSE NED MUSCL E PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 12:13:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Sep-02-2020 12:13:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Symptom:: NEW OR WORSE NED JOI NT PAIN	Initial Entry

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

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

Date	Location	User	Value	Reason
Sep-02-2020 12:13:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> NEW OR WORSENEED JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 12:13:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-02-2020 12:13:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-02-2020 12:13:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-02-2020 12:13:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> Injection Site Reaction:: RE DN ESS	Initial Entry

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

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

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-02-2020 12:13:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 12:13:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-02-2020 12:13:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> Injection Site Reaction:: SWE LLI NG Were injection site reactions present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-02-2020 12:13:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 12:13:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-02-2020 12:13:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> Injection Site Reaction PAIN A :: T INJE CTION SITE Were injection site rea NO ctions present on the la st day the Subject Diar y was completed?:	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-02-2020 12:13:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 12:13:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1081

Subject No: 10811026

Generated By: pfe.levisse

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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1. Date:

Date	Location	User	Value	Reason
Sep-02-2020 12:14:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> Sep/2/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-02-2020 12:14:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> Record Identifier: 1 : Temperature: 96.6 Temperature Unit F : Temperature Loca ORAL CAV tion:: ITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-02-2020 12:14:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-03-2020 00:02:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pramod Margaj (pfe margap03)	Query 1: Closed	Closed by DM: PM.
Sep-02-2020 12:14:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Query 1: Answered	Correct. Not clinically significant.
Sep-02-2020 12:14:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Temperature 96.6 F is outside of Normal Range 97 -

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1081

Subject No: 10811026

Generated By: pfe.levisse

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

				99.5 F.
Sep-02-2020 12:14:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: 96.6	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-02-2020 12:14:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-02-2020 12:14:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3f01\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: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-02-2020 12:14:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-02-2020 12:14:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-02-2020 12:14:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> Sep/2/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-02-2020 12:14:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-02-2020 12:14:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
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090177e196ae3f01\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: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

Sep-02-2020 12:14:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Choriogonadotropin Beta_PX113 Result:: Not Done:: NOT DONE	Initial Entry
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-02-2020 12:14:22 (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-02-2020 12:14:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-02-2020 12:14:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NOT DONE	Initial Entry

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1081**Subject No:** 10811026**Generated By:** pfe.levisse**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-02-2020 11:00:40 (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-02-2020 11:00:40 (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-02-2020 11:00:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-02-2020 11:00:40 (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-02-2020 11:00:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Sep/2/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-02-2020 11:00:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BP97M5	Initial Entry

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: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Sep-02-2020 11:00:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawynn Ebner (pfe.tebner)	<u>Data Entry:</u> BP97M5	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811026

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-02-2020 12:15:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-02-2020 12:15:44 (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-02-2020 12:15:44 (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-02-2020 12:15:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Sep/2/2020 11:06	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-02-2020 12:15:44 (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-02-2020 12:15:44	ACV0PFEINFP6000	Phillip	Data Entry:	Initial Entry

090177e196ae3f01\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: 10811026

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

(UTC-05:00) Eastern Time (US & Canada)		Ross (pfe.pross)	LEFT	
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7. Route:

Date	Location	User	Value	Reason
Sep-02-2020 12:15:44 (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-02-2020 12:15:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 12:15:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

090177e196ae3f01\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: 10811026

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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1. Date of Visit

Date	Location	User	Value	Reason
Sep-30-2020 10:21:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: Sep/30/2020	Initial Entry

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form Version:** 30-Jul-2020 21:30**Site No:** 1081**Subject No:** 10811026**Generated By:** pfe.levisse**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - 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](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Sep-30-2020 10:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-30-2020 10:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom:: FE VE R Were fever or systemic sy mptoms present on the las t day the Subject Diary wa s completed?: N O	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Sep-30-2020 10:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Sep-30-2020 10:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-30-2020 10:58:23 (UTC-05:00) Eastern	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom:: FA	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

Time (US & Canada)			TI GU E NO	
Were fever or systemic symptoms present on the last day the Subject Diary was completed?:				

2.b Symptom:

Date	Location	User	Value	Reason
Sep-30-2020 10:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-30-2020 10:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Oct-01-2020 14:56:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> <u>Symptom::</u> HEADACHE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: YES Ongoing? NO Stop Date: September 8 / 2020	New Information

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

Sep-30-2020 10:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<p>Data Entry:</p> <p>Symptom::</p> <p>HE AD AC HE</p> <p>Were fever or systemic sy NO mptoms present on the la st day the Subject Diary was completed?:</p>	Initial Entry
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090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

2.c Symptom:

Date	Location	User	Value	Reason
Sep-30-2020 10:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-02-2020 02:31:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pramod Margaj (pfe margap03)	Query 1: Closed	Closed by DM: PM.
Oct-01-2020 14:56:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Oct-01-2020 14:56:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES Ongoing? NO Stop Date: Sep/8/2020	New Information
Oct-01-2020 08:23:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pramod Margaj (pfe margap03)	Query 1: Opened	eDiary: Per diary records, HEADACHE present on Last day however inform entered with 'No' for the same. Please verify and update. If diary entered in error, please enter stop date as last date of diary. Thanks.
Sep-30-2020 10:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

2.d

Date	Location	User	Value	Reason
Sep-30-2020 10:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom:: CH IL LS Were fever or systemic sy NO mptoms present on the las t day the Subject Diary w as completed?:	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Sep-30-2020 10:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-30-2020 10:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Sep-30-2020 10:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom:: VO MIT ING Were fever or systemic s NO ymptoms present on the l ast day the Subject Diary was completed?:	Initial Entry

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

2.e Symptom:

Date	Location	User	Value	Reason
Sep-30-2020 10:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-30-2020 10:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Oct-01-2020 12:09:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> Symptom:: DIAR RHEA Were fever or systemic YES symptoms present on t Ong he last day the Subject oing Diary was completed?: ? YE S	Transcription Error
Sep-30-2020 10:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> Symptom:: DIA RR HE A Were fever or systemic s NO ymptoms present on the l ast day the Subject Diary was completed?:	Initial Entry

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

2.f Symptom:

Date	Location	User	Value	Reason
Sep-30-2020 10:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Oct-02-2020 01:36:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pramod Margaj (pfe margap03)	Query 1: Closed	Closed by DM: PM.
Oct-01-2020 12:09:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-01-2020 12:09:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES Ongoing? YES	Transcription Error
Oct-01-2020 08:24:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pramod Margaj (pfe margap03)	Query 1: Opened	eDiary: Per diary records, DIARRHEA present on Last day however inform entered with 'No' for the same. Please verify and update. If diary entered in error, please enter stop date as last date of diary. Thanks.
Sep-30-2020 10:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
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090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001
Visit: V3_MONTH1_POSTVAX2_L
Form Version: 30-Jul-2020 21:30
Site No: 1081
Subject No: 10811026
Generated By: pfe.levisse

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - 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-30-2020 10:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom:: NEW OR WORSE NED MU SCLE PA IN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry
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2.g Symptom:

Date	Location	User	Value	Reason
Sep-30-2020 10:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NEW OR WORSE NED MUSCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-30-2020 10:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Sep-30-2020 10:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom:: NEW OR WORSE NED JOINT PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811026**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11**2.h Symptom:**

Date	Location	User	Value	Reason
Sep-30-2020 10:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NEW OR WORSENERD JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-30-2020 10:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-30-2020 10:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-30-2020 10:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-30-2020 10:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reacti NO ons present on the last da y the Subject Diary was c ompleted?:	Initial Entry

5.a Injection Site Reaction:

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Sep-30-2020 10:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-30-2020 10:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-30-2020 10:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Injection Site Reaction:: SW ELL ING Were injection site reacti NO ons present on the last d ay the Subject Diary was completed?:	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-30-2020 10:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-30-2020 10:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
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090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

Sep-30-2020 10:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Injection Site Reaction: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry
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5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-30-2020 10:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-30-2020 10:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

090177e196ae3f01\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:** 10811026**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-30-2020 10:21:48 (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-30-2020 10:21:48 (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-30-2020 10:22:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-30-2020 10:21:48 (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-30-2020 10:21:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Sep/30/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-30-2020 10:22:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BPIHSS	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: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Sep-30-2020 10:22:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> BPIHSS	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-30-2020 10:22:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BRTXR7	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-30-2020 10:22:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> BRTXR7	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-30-2020 10:22:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BRTXR8	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-30-2020 10:22:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> BRTXR8	Initial Entry

090177e196ae3f01\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: 10811026

Generated By: pfe.levisse

Form: DATE OF VISIT - 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 Visit

Date	Location	User	Value	Reason
Mar-03-2021 16:03:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Mar/3/2021	Initial Entry

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Data Origin

Date	Location	User	Value	Reason
Mar-03-2021 16:24:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-03-2021 16:24:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-04-2021 15:08:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jennifer Riddle (pfe.riddlj)	Query 2: Closed	Response satisfies query
Mar-04-2021 11:28:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Mar-04-2021 11:28:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: : YES Date of Collection: Ma	Transcription Error

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001
Visit: V4_MONTH6_L
Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Frozen, Verified
Site No: 1081
Site Name: (1081) Sterling Research Group - Mt. Auburn
Subject No: 10811026
Subject Initials: ---
Generated By: pfe.levisse
Generated Time (GMT): 29-Mar-2021 10:11

			r/3 /20 21	
Mar-04-2021 01:32:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 2: Opened	DMW7592611;Date of Collection is not equal to Date of Visit. Please clarify or correct.
Mar-03-2021 16:24:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-03-2021 16:24:28 (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.
Mar-03-2021 16:24:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry : YES Date of Collection: Mar/2/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-03-2021 16:24:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BRM4MH	Initial Entry

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Mar-03-2021 16:24:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	<u>Data Entry:</u> BRM4MH	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-03-2021 16:25:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BRM4MJ	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-03-2021 16:25:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	<u>Data Entry:</u> BRM4MJ	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-03-2021 16:25:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BKZ4HV	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-03-2021 16:25:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	<u>Data Entry:</u> BKZ4HV	Initial Entry

5.d

Date	Location	User	Value	Reason
Mar-03-2021 16:25:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BKZ4HW	Initial Entry

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

5.d Sample ID

Date	Location	User	Value	Reason
Mar-03-2021 16:25:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	<u>Data Entry:</u> BKZ4HW	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Oct/01/2020**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:** 10811026**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Date of Visit**

Date	Location	User	Value	Reason
Oct-05-2020 13:44:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-05-2020 13:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Oct-05-2020 13:42:33 (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-05-2020 13:42:33 (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 missing. Please review and update as appropriate.
Oct-05-2020 13:42:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Oct/1/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Oct-05-2020 13:42:33 (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 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF on Oct/01/2020
Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811026**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Oct-05-2020 13:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Oct/1/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Oct-05-2020 13:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sep/2/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Nov-03-2020 14:20:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Stephen Paolini (pfe.paolis01)	Query 1: Closed	Response satisfies query
Nov-03-2020 12:43:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Nov-03-2020 12:43:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO Date of Last Symptom Resolv ed: Oct/5/2020	New Information
Oct-30-2020 15:00:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Stephen Paolini (pfe.paolis01)	Query 1: Opened	CLINQUERY: Please clarify whether the reported symptoms are still ongoing? If symptoms have ended, please update 'Symptoms Ongoing' on to

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/01/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

				'NO' and add Date of Last Symptom Resolved on the CRF.
Oct-05-2020 13:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Oct-05-2020 13:43:28 (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-05-2020 13:43:28 (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-05-2020 13:43:28 (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-05-2020 13:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Present: NO	Initial Entry

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
on Oct/01/2020 Audit Trail History**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811026**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11**4.b Symptoms:**

Date	Location	User	Value	Reason
Oct-05-2020 13:43:28 (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-05-2020 13:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Oct-05-2020 13:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptoms: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: NO	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Oct-05-2020 13:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Oct-05-2020 13:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

4.d

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
on Oct/01/2020 Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levissc

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

Date	Location	User	Value	Reason
Oct-05-2020 13:43:28 (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-05-2020 13:43:28 (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-05-2020 13:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Oct-05-2020 13:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptom NEW OR INCREAS s: ED MUSCLE PAIN Symptom NO Present:	Initial Entry

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
on Oct/01/2020 Audit Trail History**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811026**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11**4.e Symptoms:**

Date	Location	User	Value	Reason
Oct-05-2020 13:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NEW OR INCREASED MUSCL E PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Oct-05-2020 13:43:28 (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-05-2020 13:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptoms NEW LOSS OF TAS : TE OR SMELL Symptom NO Present:	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Oct-05-2020 13:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NEW LOSS OF TASTE OR SME LL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Oct-05-2020 13:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
on Oct/01/2020 Audit Trail History**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811026**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11

Oct-05-2020 13:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptom NEW OR INCREAS s: ED SORE THROAT Symptom NO Present:	Initial Entry
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4.g Symptoms:

Date	Location	User	Value	Reason
Oct-05-2020 13:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NEW OR INCREASED SORE T HROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Oct-05-2020 13:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Oct-05-2020 13:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptoms: DIARRHEA Symptom Present: YES	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Oct-05-2020 13:43:28 (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-05-2020 13:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
on Oct/01/2020 Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

4.i

Date	Location	User	Value	Reason
Oct-05-2020 13:43:28 (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-05-2020 13:43:28 (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-05-2020 13:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Oct/01/2020

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: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Oct-05-2020 13:44:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> Not Done	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Oct-05-2020 13:44:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> Not Done	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Oct-05-2020 13:44:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> Not Done	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Oct-05-2020 13:44:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> Not Done	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Oct-05-2020 13:44:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> Not Done	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
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090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Oct/01/2020

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: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

Oct-05-2020 13:44:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Done	Initial Entry
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7. Test Result:

Date	Location	User	Value	Reason
Oct-05-2020 13:44:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Done	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Oct-05-2020 13:44:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Done	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Oct-05-2020 13:44:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Done	Initial Entry

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History
on Oct/01/2020**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:** 10811026**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-05-2020 13:44:46 (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-05-2020 13:44:46 (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-05-2020 15:03:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-05-2020 13:44:46 (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-05-2020 13:44:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES Date of Collection: Oct/5/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-05-2020 15:03:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: RW79396	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - on Oct/01/2020 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: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Oct-05-2020 15:03:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawynn Ebner (pfe.tebner)	<u>Data Entry:</u> RW79396	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit
on Oct/01/2020**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:** 10811026**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-05-2020 13:45:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-05-2020 13:45:08 (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
Oct-05-2020 15:04:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Oct-05-2020 15:04:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	Response to "Sample Collected?" is No, but Barcodes are present on the page.
Oct-05-2020 15:04:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Oct-05-2020 15:04:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: NO	Transcription Error
Oct-05-2020 15:01:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Date of Collection 05/Oct/2020 is different from Date of Visit 01/Oct /2020. Please review and update

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
on Oct/01/2020 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:** 10811026**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11

				as appropriate, else clarify.
Oct-05-2020 15:01:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-05-2020 15:01:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Oct/5/2020	Transcription Error
Oct-05-2020 15:01:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Sample Collected?" is No, but Barcodes are present on the page.
Oct-05-2020 13:45:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-05-2020 13:45:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Telehealth visit	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-05-2020 15:04:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID:	Transcription Error
Oct-05-2020 15:01:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: RW79396	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 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
on Oct/01/2020 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: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

Oct-05-2020 15:04:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-05-2020 15:04:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry:	Transcription Error
Oct-05-2020 15:01:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Barcode is not 6 characters in length. Please review and correct as appropriate.
Oct-05-2020 15:01:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: RW79396	Initial Entry

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Oct/01/2020

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

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I.a

Date	Location	User	Value	Reason
Oct-05-2020 13:45:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-05-2020 13:45:37 (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-05-2020 13:45:37 (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-05-2020 13:45:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Oct/01/2020

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-05-2020 13:45:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: EMERGENCY ROOM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-05-2020 13:45:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

1.c

Date	Location	User	Value	Reason
Oct-05-2020 13:45:37 (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: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Oct/01/2020**Form Version:** 15-Sep-2020 21:53**Form Status:** Data Complete, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811026**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11***1.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Oct-05-2020 13:45:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-05-2020 13:45:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

1.d

Date	Location	User	Value	Reason
Oct-05-2020 13:45:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Type of Practitioner URGENT : CARE Occurrence of Visits NO or Contacts:	Initial Entry

1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-05-2020 13:45:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-05-2020 13:45:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

1.e

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Oct/01/2020

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Oct-05-2020 13:45:37 (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-05-2020 13:45:37 (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-05-2020 13:45:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

I.f

Date	Location	User	Value	Reason
Oct-05-2020 13:45:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Type of Practitioner: OTH ER Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Oct/01/2020

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-05-2020 13:45:37 (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-05-2020 13:45:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

2. Other Type of Practitioner Specify:

Date	Location	User	Value	Reason
Nov-06-2020 15:36:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Behnaz Yousefzadeh-Khiabani (pfe.youseb01)	Query 1: Closed	Response satisfies query
Nov-06-2020 11:56:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-06-2020 11:56:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Changed Information
Nov-06-2020 04:35:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi (pfe.suryas18)	Query 1: Opened	Other Type of Practitioner Specify” is expected to be completed only when the “Type of Practioner” is OTHER and response for “Occurrence of Visits or Contacts” is answered as Yes. Hence, please verify and remove

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Oct/01/2020

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

				the specification comment if not relevant
Oct-05-2020 13:45:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Family Practice	Initial Entry

3. Has the subject been hospitalized due to potential COVID-19 illness?

Date	Location	User	Value	Reason
Oct-05-2020 13:45:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History on Oct/01/2020**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:** 10811026**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. What is the treatment Identifier?**

Date	Location	User	Value	Reason
Oct-05-2020 13:45:51 (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-05-2020 13:45:51 (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-05-2020 13:45:51 (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-05-2020 13:45:51 (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-05-2020 13:45:51 (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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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History on Oct/01/2020

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: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

Oct-05-2020 13:45:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry
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090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: ILLNESS DETAILS - eCRF Audit Trail History
on Oct/01/2020

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: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Oct-05-2020 13:46:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNES S	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Oct-05-2020 13:46:15 (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-13-2020 09:41:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nicholas Roosa (pfe.roosan)	Query 1: Closed	Response satisfies query
Oct-12-2020 07:52:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	Tox Grade is noted on progress note dated 06Oct2020. This will be uploaded into Complion
Oct-09-2020 13:22:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nicholas Roosa (pfe.roosan)	Query 1: Opened	Please confirm where this is COVID illness visit tox grade is recorded in source?
Oct-05-2020 13:46:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: 2	Initial Entry

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: ILLNESS DETAILS - SEVERE - eCRF Audit Trail History on Oct/01/2020

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: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Oct-05-2020 13:46:25 (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-05-2020 13:46:25 (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-05-2020 13:46:25 (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-05-2020 13:46:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/01/2020**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811026**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Oct-05-2020 13:46:57 (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-05-2020 13:46:57 (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-05-2020 13:46:57 (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-05-2020 13:46:57 (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-05-2020 13:46:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sponsor-Defined Id Not Applic entifier: able Test:: Not Applic able Result:: Not Applic able	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/01/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

			Not Done::	Not Applicable
			Lab Normal Range:	Not Applicable

5.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-05-2020 13:46:57 (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-05-2020 13:46:57 (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-05-2020 13:46:57 (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-05-2020 13:46:57 (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-05-2020 13:46:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.b

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/01/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levissc

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

Date	Location	User	Value	Reason
Oct-05-2020 13:46:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sponsor-Defined Id entifier: Not Applic able Test:: Not Applic able Result:: Not Applic able Not Done:: Not Applic able Lab Normal Range: Not Applic able	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History
on Oct/01/2020**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811026**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11**5.b Sponsor ID:**

Date	Location	User	Value	Reason
Oct-05-2020 13:46:57 (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-05-2020 13:46:57 (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-05-2020 13:46:57 (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-05-2020 13:46:57 (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-05-2020 13:46:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-05-2020 13:46:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sponsor-Defined Id Not Applic entifier: able	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/01/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

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	

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History
on Oct/01/2020**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811026**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11**5.c Sponsor ID:**

Date	Location	User	Value	Reason
Oct-05-2020 13:46:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Oct-05-2020 13:46:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Oct-05-2020 13:46:57 (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-05-2020 13:46:57 (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-05-2020 13:46:57 (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-05-2020 13:46:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sponsor-Defined Id Not Applic entifier: able	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/01/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

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	

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History
on Oct/01/2020**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811026**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11**5.d Sponsor ID:**

Date	Location	User	Value	Reason
Oct-05-2020 13:46:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Oct-05-2020 13:46:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Oct-05-2020 13:46:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Oct-05-2020 13:46:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Oct-05-2020 13:46:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-05-2020 13:46:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sponsor-Defined Id Not Applic entifier: able	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/01/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

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	

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History
on Oct/01/2020**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811026**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11**5.e Sponsor ID:**

Date	Location	User	Value	Reason
Oct-05-2020 13:46:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Oct-05-2020 13:46:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Oct-05-2020 13:46:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Oct-05-2020 13:46:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Oct-05-2020 13:46:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.f

Date	Location	User	Value	Reason
Oct-05-2020 13:46:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sponsor-Defined Id Not Applic entifier: able	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/01/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

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	

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History
on Oct/01/2020**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811026**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11**5.f Sponsor ID:**

Date	Location	User	Value	Reason
Oct-05-2020 13:46:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Oct-05-2020 13:46:57 (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-05-2020 13:46:57 (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-05-2020 13:46:57 (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-05-2020 13:46:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.g

Date	Location	User	Value	Reason
Oct-05-2020 13:46:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sponsor-Defined Id Not Applic entifier: able	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/01/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

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	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/01/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

5.g Sponsor ID:

Date	Location	User	Value	Reason
Oct-05-2020 13:46:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Oct-05-2020 13:46:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Oct-05-2020 13:46:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Oct-05-2020 13:46:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Oct-05-2020 13:46:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> Not Applicable	Initial Entry

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History on Oct/01/2020**Form Version:** 30-Jul-2020 21:28**Form Status:** Data Complete, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811026**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Oct-05-2020 13:47:18 (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-05-2020 13:47:18 (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-05-2020 13:47:18 (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-05-2020 13:47:18 (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-05-2020 13:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sponsor-Defined Id Not Applic entifier: able Test:: Not Applic able Result:: Not Applic able	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History on Oct/01/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

			Not Done::	Not Applicable
			Lab Normal Range:	Not Applicable

5.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-05-2020 13:47:18 (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-05-2020 13:47:18 (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-05-2020 13:47:18 (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-05-2020 13:47:18 (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-05-2020 13:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.b

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History on Oct/01/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levissc

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

Date	Location	User	Value	Reason
Oct-05-2020 13:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sponsor-Defined Id entifier: Not Applic able Test:: Not Applic able Result:: Not Applic able Not Done:: Not Applic able Lab Normal Range: Not Applic able	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History
on Oct/01/2020**Form Version:** 30-Jul-2020 21:28**Form Status:** Data Complete, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811026**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11**5.b Sponsor ID:**

Date	Location	User	Value	Reason
Oct-05-2020 13:47:18 (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-05-2020 13:47:18 (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-05-2020 13:47:18 (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-05-2020 13:47:18 (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-05-2020 13:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-05-2020 13:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sponsor-Defined Id Not Applic entifier: able	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/01/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

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

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range:	Not Applicable	

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History
on Oct/01/2020**Form Version:** 30-Jul-2020 21:28**Form Status:** Data Complete, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811026**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11**5.c Sponsor ID:**

Date	Location	User	Value	Reason
Oct-05-2020 13:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Oct-05-2020 13:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Oct-05-2020 13:47:18 (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-05-2020 13:47:18 (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-05-2020 13:47:18 (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-05-2020 13:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sponsor-Defined Id Not Applic entifier: able	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/01/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

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	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History on Oct/01/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

5.d Sponsor ID:

Date	Location	User	Value	Reason
Oct-05-2020 13:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Oct-05-2020 13:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Oct-05-2020 13:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Oct-05-2020 13:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Oct-05-2020 13:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-05-2020 13:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> Sponsor-Defined Id Not Applicable entifier: able	Initial Entry

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/01/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

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	

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History
on Oct/01/2020**Form Version:** 30-Jul-2020 21:28**Form Status:** Data Complete, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811026**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11**5.e Sponsor ID:**

Date	Location	User	Value	Reason
Oct-05-2020 13:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Oct-05-2020 13:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Oct-05-2020 13:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Oct-05-2020 13:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Oct-05-2020 13:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.f

Date	Location	User	Value	Reason
Oct-05-2020 13:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sponsor-Defined Id Not Applic entifier: able	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/01/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

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	

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History
on Oct/01/2020**Form Version:** 30-Jul-2020 21:28**Form Status:** Data Complete, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811026**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11**5.f Sponsor ID:**

Date	Location	User	Value	Reason
Oct-05-2020 13:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Oct-05-2020 13:47:18 (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-05-2020 13:47:18 (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-05-2020 13:47:18 (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-05-2020 13:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.g

Date	Location	User	Value	Reason
Oct-05-2020 13:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sponsor-Defined Id Not Applic entifier: able	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/01/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

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	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/01/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

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Generated By: pfe.levisse

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

5.g Sponsor ID:

Date	Location	User	Value	Reason
Oct-05-2020 13:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Oct-05-2020 13:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Oct-05-2020 13:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Oct-05-2020 13:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Oct-05-2020 13:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.h

Date	Location	User	Value	Reason
Oct-05-2020 13:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> Sponsor-Defined Id Not Applicable entifier: able	Initial Entry

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/01/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

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	

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History
on Oct/01/2020**Form Version:** 30-Jul-2020 21:28**Form Status:** Data Complete, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811026**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11**5.h Sponsor ID:**

Date	Location	User	Value	Reason
Oct-05-2020 13:47:18 (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-05-2020 13:47:18 (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-05-2020 13:47:18 (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-05-2020 13:47:18 (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-05-2020 13:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.i

Date	Location	User	Value	Reason
Oct-05-2020 13:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sponsor-Defined Id Not Applic entifier: able	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/01/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

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	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History on Oct/01/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

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-05-2020 13:47:18 (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-05-2020 13:47:18 (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-05-2020 13:47:18 (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-05-2020 13:47:18 (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-05-2020 13:47:18 (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-05-2020 13:47:18	ACV0PFEINFP6000	James	Data Entry:	Initial Entry

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/01/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

(UTC-05:00) Eastern Time (US & Canada)		Fry (pfe.jfry)	Sponsor-Defined Identifier:	Not Applicable	
			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range:	Not Applicable	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History
on Oct/01/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

5.j Sponsor ID:

Date	Location	User	Value	Reason
Oct-05-2020 13:47:18 (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-05-2020 13:47:18 (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-05-2020 13:47:18 (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-05-2020 13:47:18 (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-05-2020 13:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History on Oct/01/2020

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Date:

Date	Location	User	Value	Reason
Oct-05-2020 13:48:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Unknown	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-05-2020 13:48:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Record Identifier:: Unkn own Systolic:: Unkn own Diastolic:: Unkn own Respiratory Rate in resp Unkn irations/minute: own Heart Rate in beats/min Unkn ute: own	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-05-2020 13:48:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Unknown	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Oct-05-2020 13:48:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Unknown	Initial Entry

2.a Diastolic:

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History on Oct/01/2020

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisc

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

Date	Location	User	Value	Reason
Oct-05-2020 13:48:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Unknown	Initial Entry

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Oct-05-2020 13:48:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Unknown	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Oct-05-2020 13:48:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Unknown	Initial Entry

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail on Oct/01/2020 History**Form Version:** 30-Jul-2020 21:28**Form Status:** Data Complete, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811026**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**I. Date:**

Date	Location	User	Value	Reason
Oct-05-2020 13:48:28 (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-05-2020 13:48:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Record Identifier Not Applicab :: le Oxygen Saturatio Not Applicab n: le	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-05-2020 13:48:28 (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-05-2020 13:48:28 (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 Form: OXYGENATION PARAMETERS - eCRF Audit Trail History on Oct/01/2020

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: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Date Time of Assessment:

Date	Location	User	Value	Reason
Oct-05-2020 13:48:51 (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-05-2020 13:48:51 (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-05-2020 13:48:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit
on Oct/01/2020**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:** 10811026**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Oct-05-2020 13:49:07 (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-05-2020 13:49:07 (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-05-2020 13:49:07 (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-05-2020 13:49:07 (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-05-2020 13:49:07 (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/01/2020

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: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

6. Ongoing?

Date	Location	User	Value	Reason
Oct-05-2020 13:49:07 (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 Form: IMAGING - eCRF Audit Trail History on Oct/01/2020

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: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Date of Assessment:

Date	Location	User	Value	Reason
Oct-05-2020 13:49:31 (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-05-2020 13:49:31 (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-05-2020 13:49:31 (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-05-2020 13:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Oct/29/2020

Form: DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-29-2020 13:46:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Oct/29/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Oct-29-2020 13:46:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: COVID_A1	Initial Entry

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled
Visit on Oct/29/2020**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
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:** 10811026**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-29-2020 13:46:16 (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-29-2020 13:46:16 (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-29-2020 13:46:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-29-2020 13:46:16 (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-29-2020 13:46:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES Date of Collection: Oct/29/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-29-2020 13:46:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sample ID: BS64MV	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Oct/29/2020

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
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: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Oct-29-2020 13:46:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: BS64MV	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-29-2020 13:46:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sample ID: BS64MW	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-29-2020 13:46:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: BS64MW	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-29-2020 13:46:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sample ID: BRDCR7	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-29-2020 13:46:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: BRDCR7	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-29-2020 13:47:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sample ID: BRDCR8	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Oct/29/2020

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
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: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

5.d Sample ID

Date	Location	User	Value	Reason
Oct-29-2020 13:47:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: BRDCR8	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Sep-30-2020 10:58:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sep/30/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-30-2020 10:58:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-30-2020 10:58:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: COMPLETED	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811026

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
Oct-01-2020 14:10:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811026

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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

Subject Initials: ---

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Date	Location	User	Value	Reason
Oct-05-2020 13:51:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Form Created	

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811026

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
Oct-19-2020 15:53:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811026

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
Oct-21-2020 18:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Form Created	

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

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

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Date	Location	User	Value	Reason
Nov-05-2020 07:55:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Form Deleted	Changed Information
Nov-03-2020 14:16:26 (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: 10811026

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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

Subject Initials: ---

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Date	Location	User	Value	Reason
Nov-05-2020 15:20:07 (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: 10811026

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Queries, Verified

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

Subject Initials: ---

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1. Category:

Date	Location	User	Value	Reason
Oct-01-2020 14:10:07 (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
Oct-01-2020 14:10:07 (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-11-2021 07:00:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (pfe.PFESDQ_PROD)	Query 3 : Opened	eDiary: AE Diarrhea reported with start date 13 Aug 2020 and End Date 17 Aug 2020 seems to be same as e Diary occurrence Diarrhea reported on 13 Aug 2020 . Please reconcile or confirm in the query response as appropriate "[ks66 SDQ=152635]"
Oct-08-2020 06:28:39 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Aanchal Asthana (pfe.asthaa03)	Query 2 : Closed	Response satisfies query

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811026

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Queries, Verified

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

Subject Initials: ---

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

(US & Canada)				
Oct-07-2020 11:39:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 2 : Answered	Data for AE has been updated
Oct-06-2020 12:58:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (pfe.PFESDQ_PROD)	Query 2 : Opened	eDiary: AE Diarrhea reported with start date 03-Sep-2020 and End Date null seems to be same as e-Diary occurrence Diarrhea reported on 13-Aug-2020. Please reconcile or confirm in the query response as appropriate. "[cefall01 SDQ=13763]"
Oct-05-2020 14:29:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1 : Closed	Response satisfies query
Oct-05-2020 13:52:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Query 1 : Answered	COVID Illness completed and nasal swab requested. Pending arrival at site for processing.
Oct-02-2020 07:37:31	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1 : Opened	CLINQUERY: Diarrhea

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Site No: 1081

Subject No: 10811026

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Queries, Verified

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

Subject Initials: ---

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(UTC-05:00) Eastern Time (US & Canada)			d	reported as “not related” from 03Sep20-ongoing. Please complete a COVID illness CRF with all possible information gathered by the PI. Nasal Swab to be collected if event has not ceased >4days prior.
Oct-01-2020 14:10:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Diarrhea	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-07-2020 11:37:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Aug/13/2020 UNK:UNK	New Information
Oct-01-2020 14:10:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sep/3/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-12-2020 12:02:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nicholas Roosa (pfe.roosan)	Query 1: Closed	Response satisfies query
Oct-12-2020 08:07:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	The ongoing diarrhea is captured in the COVID Illness pages

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1081

Subject No: 10811026

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Queries, Verified

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

Subject Initials: ---

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

Oct-09-2020 13:20:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nicholas Roosa (pfe.roosan)	Query 1: Opened	Per TrialManager and COVID illness visit source, patient diarrhea is ongoing. Please confirm and update as applicable.
Oct-07-2020 11:38:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO End Date Time: Aug/17/2020 UNK:UNK	New Information
Oct-01-2020 14:10:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-01-2020 14:10:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-01-2020 14:10:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Oct-01-2020 14:10:07 (UTC-05:00) Eastern	ACV0PFEINFP6000	James Fry	Data Entry: NO	Initial Entry

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Form Status: Data Complete, Queries, Verified

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

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Time (US & Canada)		(pfe.jfry)	
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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-01-2020 14:10:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NOT RELATED If Not Related to study treatment (s), this event is due to: OTHER If Other, specify: idiopathic	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-01-2020 14:10:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-01-2020 14:10:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-01-2020 14:10:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 11:40:48 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1081

Subject No: 10811026

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Queries, Verified

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

Subject Initials: ---

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

Time (US & Canada)				
Oct-07-2020 11:40:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: RECOVERED/RESOLVED	New Information
Oct-07-2020 11:38:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Diarrhea: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Oct-01-2020 14:10:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: RECOVERING/RESOLVING	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-01-2020 14:10:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

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

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1. Category:

Date	Location	User	Value	Reason
Oct-05-2020 13:51:55 (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
Oct-05-2020 13:51:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-05-2020 13:51:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Urinary Tract Infection	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-13-2020 09:53:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nicholas Roosa (pfe.roosan)	Query 2: Closed	Response satisfies query
Oct-07-2020 12:08:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Closed	Response satisfies query
Oct-06-2020 13:15:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 2: Answered	This has been corrected on the source document as of early this morning 10/6/2020
Oct-06-2020 13:00:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nicholas Roosa (pfe.roosan)	Query 2: Opened	Per source AE log, start date is unk-Sep, please

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				update or confirm date as applicable
Oct-06-2020 10:30:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Oct/5/2020 UNK:UNK	Changed Information
Oct-06-2020 10:28:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-06-2020 10:28:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sep/5/2020 UNK:UNK	Changed Information
Oct-06-2020 07:33:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	CLINQUERY: A complete start date for AEs is required. Per CRF guidelines, if an exact date is unknown please provide best estimate
Oct-05-2020 13:51:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sep/UNK/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-03-2020 12:43:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO End Date Time: Oct/16/2020 UNK:UNK	New Information
Oct-05-2020 13:51:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-05-2020 13:51:55 (UTC-05:00) Eastern	ACV0PFEINFP6000	James Fry	Data Entry: 1	Initial Entry

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Time (US & Canada)		(pfe.jfry)	
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-05-2020 13:51:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Oct-05-2020 13:51:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-05-2020 13:51:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NOT RELATED If Not Related to study treatment (s), this event is due to: OTHER If Other, specify: Idiopathic	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-05-2020 13:51:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NOT APPLICABLE	Initial Entry

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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-05-2020 13:51:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-05-2020 13:51:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-03-2020 14:12:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-03-2020 14:12:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: RECOVERED/RESOLVED	New Information
Nov-03-2020 12:43:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Urinary Tract Infection: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Oct-05-2020 13:51:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: RECOVERING/RESOLVING	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-05-2020 13:51:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Oct-19-2020 15:53:12 (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
Oct-19-2020 15:53:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-04-2020 11:23:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Serous borderline tumor of le ft ovary	changed data to correspond with SAE report
Oct-26-2020 13:59:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Oct-26-2020 07:13:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.QUITOR)	Query 1: Closed	term updated in SDB. Issue resolved
Oct-23-2020 13:48:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 1: Reissued:Candidate	Left query open until ARGUS gets updated as of 10/23/2020 not updated yet.
Oct-23-2020 10:12:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Query 1: Answered	Update sent to Safety 22 Oct 2020, 1640
Oct-22-2020 06:50:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.QUITOR)	Query 1: Reissued:Opened	SAE RECON 1: The term in AE CRF was updated to "Neoplasm of uncertain behavior

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				of left ovary, however, still reported as LARGE PELVIC MASS in Safety database. Please confirm if a follow up AEM form was submitted to Safety to update term.
Oct-21-2020 23:51:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Reissued: Candidate	SAE recon: to check next SAE listing of term will also be updated
Oct-21-2020 18:54:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Oct-21-2020 18:54:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Oct-21-2020 18:54:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Neoplasm of uncertain behavior of left ovary	New Information
Oct-20-2020 12:51:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	CLINICAL SAE report reports subject had Abdominal Pain from Oct 11 to 16, 2020. Please assess for safety impact, and update with an event for this complaint if appropriate
Oct-20-2020 06:17:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON: AER#2020405804, the term was reported as 'large pelvic mass' in Safety database while recorded as 'Ovarian Mass' in AE CRF. Please confirm correct term. If safety update is required, please

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				submit a follow-up form.
Oct-19-2020 15:53:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Ovarian Mass	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-05-2020 16:20:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 5: Closed	Response satisfies query
Nov-05-2020 16:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Nov-05-2020 15:21:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 5: Answered	oversight on site end, this has now been added to AE CRF
Nov-05-2020 15:07:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 5: Opened	Clinical - Perhaps 'scanned' means a SAE update. This query is for an Adverse Event entered directly into the clinical trial system Inform.
Nov-05-2020 01:14:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 4: Closed	Response satisfies query
Nov-04-2020 12:19:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 2: Answered	Yes, it was scanned in on 03Nov2020. the is titled 'AE document - 03Nov2020.pdf Current Source Document 03 Nov 2020
Nov-04-2020 12:05:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Reissued:Opened	Clinical - as of noon 11/4; no AE for anemia is present; thank you for your review
Nov-04-2020 12:01:37	ACV0PFEINFP6000	Lora Morris	Query 2: Answered	Yes the anemia is on the

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(UTC-05:00) Eastern Time (US & Canada)		(pfe.lmorris)		AE SD, in Complion this was added 03Nov2020
Nov-04-2020 11:54:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Reissued:Opened	Clinical - No anemia event recorded on the AE CRF; please address to close this for upcoming safety report
Nov-04-2020 11:20:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	Start date of symptoms has been entered to match with SAE report, which requires this to be the start date
Nov-04-2020 11:20:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Oct/11/2020 UNK:UNK	Start date of symptoms has been entered to match with SAE report, which requires this to be the start date
Nov-04-2020 05:12:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 4: Opened	SAE RECON: AER#2020405804,onset date was updated to 16Oct2020 in AE CRF while retained as 11Oct2020 in safety database. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form.
Nov-04-2020 05:12:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 3: Closed	CORRECTED QUERY TEXT
Nov-04-2020 05:11:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 3: Opened	SAE RECON: AER#2020405804,onset date was updated to 16Oct2020 in AE CRF while retained as 11Oct2020 in AE CRF. Please confirm correct Onset Date. If safety update is required,

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				please submit a follow-up SAE form.
Nov-03-2020 12:45:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Nov-03-2020 12:45:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Oct/16/2020 UNK:UNK	Transcription Error
Nov-02-2020 23:53:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Reissued:Opened	Clinical - No anemia event recorded on the AE CRF; please address to close this for upcoming safety report
Oct-29-2020 16:18:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Query 2: Answered	Sounds like you want this added as an AE. Will do.
Oct-27-2020 22:34:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Reissued:Opened	CLINICAL Thank you; anemia event likely secondary to abd mass. Per Protocol Sects 10.3.1/10.3.3, all non-serious AEs are recorded on AE CRF, defined as 'any untoward medical occurrence temporally associated with drug administration'
Oct-27-2020 15:51:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 1: Closed	Response satisfies query
Oct-27-2020 14:29:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-27-2020 14:29:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Oct/11/2020 UNK:UNK	Changed Information
Oct-27-2020 14:16:44 (UTC-05:00) Eastern	ACV0PFEINFP6000	James Fry (pfe.jfry)	Query 2: Answered	No further information was reported in the

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Time (US & Canada)				surgical report. Felt to be secondary to the abdominal mass.
Oct-26-2020 14:10:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	CLINICAL - SAE report states subject's Hgb test result was 9.8 (nl 11.2-15.7); please review for safety significance and update with an event of anemia, if appropriate
Oct-26-2020 07:03:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON: AER#2020405804, onset date was reported as 11Oct2020 in Safety database however, recorded as 16Oct2020 on AE CRF. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form.
Oct-19-2020 15:53:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Oct/16/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-11-2021 11:10:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Opened	Clinical SAE end date is 16Oct20; however, SAE report end date is 29Oct20. Please review, harmonize reporting, and update where applicable
Mar-11-2021 11:10:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	rewording

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Mar-11-2021 11:09:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	Clinical SAE end date is 16Oct20; however, SAE report end date is 10Oct20. Please review, harmonize reporting, and update where applicable
Mar-08-2021 07:58:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (pfe.gayedj)	Query 1: Closed	Response satisfies query
Mar-05-2021 12:03:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	subject was discharged from hospital on 19Oct2020
Mar-04-2021 16:41:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (pfe.gayedj)	Query 1: Opened	Clin: please confirm in response to this query, the discharge date from hospital
Nov-03-2020 12:45:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO End Date Time: Oct/16/2020 UNK:UNK	New Information
Oct-27-2020 14:28:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES	Changed Information
Oct-19-2020 15:53:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO End Date Time: Oct/16/2020 UNK:UNK	Initial Entry

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6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-05-2020 15:06:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Nov-05-2020 12:19:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-05-2020 12:19:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: 3	Transcription Error
Nov-05-2020 11:24:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nandini Cossons (pfe.cossons_n)	Query 1: Opened	GPD CLINQUERY: Please confirm adverse event toxicity grade of 2 (as defined per protocol), given that the AE is reported as serious.
Oct-19-2020 15:53:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: 2	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-04-2020 11:51:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Query closed; will follow for SAE update with the requested COVID test info

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Queries, Frozen, Verified

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

Subject Initials: ---

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Nov-04-2020 11:07:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 2: Answered	COVID testing results have been reported in the most recent SAE, per SI Jim Fry, MS, PA-C
Oct-23-2020 17:11:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	Clinical COVID testing has not been reported in the SAE submitted to safety. Please submit a follow-up SAE form [#2020405804] to provide whether COVID testing was performed (yes/no) and if yes, the results.
Oct-20-2020 06:17:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-19-2020 15:53:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Ovarian Mass: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Oct-19-2020 15:53:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES Is this serious event associat ed with congenital anomaly or birth defect? NO Did this serious event result i n death? NO Did this serious event requir	Initial Entry

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			e or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO	
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8. Is this adverse event the result of a study Medication Error?

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

Date	Location	User	Value	Reason
Oct-19-2020 15:53:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-04-2020 15:32:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 1: Closed	Response satisfies query
Nov-04-2020 11:20:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information

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<p>Nov-04-2020 11:20:14 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>Lora Morris (pfe.lmorris)</p>	<p>Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Canada</p>	<p>New Information</p>
<p>Nov-04-2020 04:03:36 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>Roshni Nair (pfe.nairr29)</p>	<p>Query 1: Reissued :Opened</p>	<p>DM: Per previous query response, please confirm if the pathology results are available and update the data as per the query. Thank you.</p>
<p>Oct-23-2020 13:50:44 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>Ute Frantz (pfe.frantu)</p>	<p>Query 1: Reissued :Candidate</p>	<p>results are not available yet - check again in a couple of weeks 10/23/2020</p>

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<p>Oct-23-2020 10:17:48 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>James Fry (pfe.jfry)</p>	<p>Query 1: Answered</p>	<p>Pathology is not available yet as to whether this is cancerous or benign.</p>
<p>Oct-22-2020 19:33:51 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000.InFormAdapter.Discrepancy</p>	<p>PFE SDQ PROD (pfe.PFESDQ_PROD)</p>	<p>Query 1: Opened</p>	<p>Please review "If not related to study treatment other" field, the following text was indicated in the comment field [idiopathic]. Any symptoms, AEs or other key data should be collected on the appropriate page. Please review and update as necessary. "[nedrickc SDQ=20702]"</p>
<p>Oct-19-2020 15:53:12 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>James Fry (pfe.jfry)</p>	<p>Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to:</p>	<p>Initial Entry</p>

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				OTHER If Other, specify: idiopathic
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-19-2020 15:53:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-22-2020 01:49:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pratiksha Mahadik (pfe.mahadp07)	Query 1: Closed	Closed as data entered.
Oct-21-2020 18:50:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Oct-21-2020 18:50:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES	New Information
Oct-21-2020 00:59:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rajashekhar Reddy (pfe.reddy51)	Query 1: Opened	DM: The response for "Was a Concomitant Medication given?" is missing. Kindly review and update.

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
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Oct-19-2020 15:53:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES	Initial Entry
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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Nov-05-2020 05:20:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 5: Closed	Response satisfies query
Nov-04-2020 11:25:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 6: Closed	Close Auto Query
Nov-04-2020 11:25:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: RECOVERED/RESOLV ED	Transcription Error
Nov-04-2020 11:24:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 6: Opened	For AE Serous borderline tumor of left ovary: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Nov-04-2020 11:24:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Answered	Changed Information
Nov-04-2020 11:24:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: RECOVERING/RESOL VING	Changed Information
Nov-04-2020 05:14:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 5: Opened	SAE RECON:AER#2020405804 outcome was updated to RECOVERED/RESOLVED on AE CRF while reported as RECOVERING/RESOLVING in SAE form. Please confirm

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				correct outcome. If safety update is required, please submit a follow-up form.
Nov-03-2020 14:21:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Closed	Close Auto Query
Nov-03-2020 14:21:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: RECOVERED/RESOLVED	New Information
Nov-03-2020 12:45:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Opened	For AE Neoplasm of uncertain behavior of left ovary: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Oct-27-2020 15:49:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 2: Closed	Response satisfies query
Oct-27-2020 14:28:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Oct-27-2020 14:17:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	For AE Neoplasm of uncertain behavior of left ovary: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Oct-27-2020 14:17:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Oct-27-2020 14:17:42 (UTC-05:00) Eastern	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: RECOVERING/RESOLVING	Changed Information

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Time (US & Canada)				
Oct-26-2020 07:05:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Opened	SAE RECON:AER#2020405804 outcome was updated to RECOVERED/RESOLVED on AE CRF while reported as RECOVERING/RESOLVING in SAE form. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Oct-20-2020 10:21:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-20-2020 10:21:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: RECOVERED/RESOLV ED	New Information
Oct-19-2020 15:53:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Ovarian Mass: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Oct-19-2020 15:53:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: RECOVERING/RESOL VING	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-19-2020 15:53:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
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Oct-20-2020 06:17:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Data Entry: 2020405804	Initial Entry
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1. Category:

Date	Location	User	Value	Reason
Oct-21-2020 18:56:17 (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
Oct-21-2020 18:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-21-2020 18:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: lower abdominal pain	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-21-2020 18:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Oct/11/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-03-2020 11:37:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO End Date Time: Oct/16/2020 UNK:UNK	New Information
Oct-27-2020 14:32:03 (UTC-05:00) Eastern	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES	Transcription Error

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Time (US & Canada)				
Oct-27-2020 14:31:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO End Date Time:	Changed Information
Oct-21-2020 18:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO End Date Time: Oct/16/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-03-2020 11:38:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: 3	Transcription Error
Oct-21-2020 18:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-31-2020 09:55:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 4: Closed	Response satisfies query
Oct-30-2020 10:28:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	Per query response, downgraded to non-serious
Oct-30-2020 10:28:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Per query response, downgraded to non-serious

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Oct-30-2020 08:07:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 4: Opened	SAE RECON: lower abdominal pain is marked serious on AE CRF.Per query response 'The abdominal pain is part of the SAE of the abdominal neoplasm.Per review, please consider to downgrade event to non serious and keep the ovarian neoplasm as the SAE.
Oct-27-2020 15:52:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 3: Closed	Response satisfies query
Oct-27-2020 14:31:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Query 3: Answered	The abdominal pain is part of the SAE of the abdominal neoplasm.
Oct-22-2020 07:29:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 3: Opened	SAE RECON: lower abdominal pain(Onset date:11Oct2020) is not reported to Safety database but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF
Oct-22-2020 07:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Deleted	Query can be addressed internally
Oct-21-2020 18:56:46 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query

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Time (US & Canada)				
Oct-21-2020 18:56:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<p>Data Entry:</p> <p>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>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</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>NO</p> <p>Other medically important serious event</p> <p>NO</p>	Transcription Error
Oct-21-2020 18:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	For AE lower abdominal pain: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Oct-21-2020 18:56:17	ACV0PFEINFP6000	auto query	Query 1: Opened	'Is the adverse event

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(UTC-05:00) Eastern Time (US & Canada)		(autoquery)		serious?' is marked as YES, but responses to all of the seriousness criteria are NO. At least one seriousness criterion is expected to be YES for serious events. Please review and update as appropriate.
Oct-21-2020 18:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<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>NO</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>NO</p> <p>Other medically important serious event</p> <p>NO</p>	Initial Entry

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Date	Location	User	Value	Reason
Oct-21-2020 18:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-21-2020 18:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NOT RELATED If Not Related to study treatment (s), this event is due to: OTHER <i>If Other, specify:</i> Neoplasm of uncertain beha vior of left ovary	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-21-2020 18:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-21-2020 18:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-21-2020 18:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES	Initial Entry

Header Text: c4591001

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Subject No: 10811026

Generated By: pfe.levisse

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Form Status: Data Complete, Frozen

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

Date	Location	User	Value	Reason
Nov-03-2020 14:22:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Nov-03-2020 14:22:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: RECOVERED/RESOLVED	New Information
Nov-03-2020 11:37:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE lower abdominal pain: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Oct-27-2020 14:31:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-21-2020 18:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE lower abdominal pain: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Oct-21-2020 18:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: RECOVERING/RESOLVING	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-21-2020 18:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

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Subject No: 10811026

Generated By: pfe.levisse

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1. Category:

Date	Location	User	Value	Reason
Nov-03-2020 14:16:26 (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-03-2020 14:16:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-05-2020 09:15:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Closed	Response satisfies query
Nov-05-2020 07:55:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-05-2020 07:45:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	CLINQUERY: Diarrhea of 02Sep- 05Oct20 appears to be captured in the COV ILL CRFs. If this is the same event, please capture only in the COV ILL SOD and not as duplicate in the AE listing.
Nov-03-2020 14:16:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Diarrhea	Initial Entry

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1081**Subject No:** 10811026**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Deleted, Frozen, Verified**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:11

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4. Start Date Time:

Date	Location	User	Value	Reason
Nov-03-2020 14:18:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-03-2020 14:18:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sep/2/2020 16:00	Changed Information
Nov-03-2020 14:16:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Diarrhea: Start Date is the same as a Vaccination Date, but time is not provided. Please review and update as appropriate.
Nov-03-2020 14:16:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sep/2/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-03-2020 14:16:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO End Date Time: Oct/5/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-03-2020 14:16:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?**If Yes, NOTIFY PFIZER IMMEDIATELY.**

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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-03-2020 14:16:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Nov-03-2020 14:16:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-05-2020 12:31:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 1: Closed	Response satisfies query
Nov-05-2020 07:19:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed data per query response, should not list Neoplasm as the cause.
Nov-05-2020 07:19:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NOT RELATED If Not Related to study treatment	Changed data per query response, should not list Neoplasm as the cause.

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			<p>nt(s), this event is due to:</p> <p>OTHER</p> <p><i>If Other, specify:</i></p> <p>Idiopathic</p>	
<p>Nov-05-2020 06:26:09 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000.InFormAdapter.Discrepancy</p>	<p>PFE SDQ PROD (pfe.PFESDQ_PROD)</p>	<p>Query 1: Opened</p>	<p>Please review "If not related to study treatment other" field, the following text was indicated in the comment field [Neoplasm]. Any symptoms, AEs or other key data should be collected on the appropriate page. Please review and update as necessary. "[lv04 SDQ=39086]"</p>
<p>Nov-03-2020 14:16:26 (UTC-05:00)</p>	<p>ACV0PFEINFP6000</p>	<p>Lora Morris (pfe.lmorris)</p>	<p>Data Entry: NOT RE</p>	<p>Initial Entry</p>

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Eastern Time (US & Canada)			LATED If Not R elated t o study treatme nt(s), thi s event i s due to: OTHE R <i>If Ot her, s pecif y:</i> Ne opl as m o fle ft o var y
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-03-2020 14:16:26 (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
Nov-03-2020 14:16:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
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Nov-03-2020 14:16:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry
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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Nov-03-2020 14:16:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Nov-03-2020 14:16:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Nov-05-2020 15:20:07 (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-05-2020 15:20:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-07-2020 15:54:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laurie Hawes (pfe.hawesl01)	Query 1: Closed	Response satisfies query
Nov-07-2020 14:14:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-07-2020 14:14:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Worsening of Anemia	Changed Information
Nov-07-2020 05:23:43 (UTC-05:00)	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi (pfe.suryas18)	Query 1: Reissued :Opened	Thanks for your response, kindly update

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Eastern Time (US & Canada)				wording worsening if this event is baseline condition of Anemia. Thank you.
Nov-06-2020 16:19:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	This event was specifically asked to be noted as an AE, per data management, due to subjects lab results during her hospitalization for the abdominal mass. Please clarify if this event should still be captured as an AE or do we need to just change wording
Nov-06-2020 12:32:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (pfe.PFESDQ_PROD)	Query 1: Opened	The AE Anemia was reported but is also listed in Medical History. Please clarify if this is a worsening of the baseline condition, and if so, please consider adding "worsening" to the AE term. AE as baseline

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				conditions should only be reported as AEs if they worsen. "[vathm SDQ=40955]"
Nov-05-2020 15:20:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Anemia	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-05-2020 15:20:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Oct/11/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-05-2020 15:20:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO End Date Time: Oct/29/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-05-2020 15:20:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: 3	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

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Date	Location	User	Value	Reason
Nov-06-2020 12:24:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nandini Cossons (pfe.cossons_n)	Query 1: Closed	Response satisfies query
Nov-06-2020 11:53:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	This should not be documented as an SAE, the anemia is directly related to the tumor and has been captured as an AE at the request of data management
Nov-06-2020 11:32:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nandini Cossons (pfe.cossons_n)	Query 1: Opened	GPD CLINQUERY: Given AE grade of 3 and that non-drug treatment was given, please confirm that this is not considered a serious AE as defined per protocol.
Nov-05-2020 15:20:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?*If Yes, record the type of medication error on the Medication Error Log.*

Date	Location	User	Value	Reason
Nov-05-2020 15:20:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-07-2020 16:44:26	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 1: Closed	Response satisfies query

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Nov-07-2020 14:15:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	what would you like for us to change the reasoning to? per the SI, the anemia is due to the tumor
Nov-07-2020 07:31:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sonal K (pfe.ks66)	Query 1: Reissued: Opened	DM:Please review "If not related to study treatment other" field, the following text was indicated in the comment field [Tumor]. Any symptoms, AEs or other key data should be collected on the appropriate page. Please review and update as necessary.
Nov-06-2020 11:53:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	the direct cause of the anemia was the tumor. Data should be left as is
Nov-06-2020 04:48:31 (UTC-05:00)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (pfe.PFESDQ_PROD)	Query 1: Opened	Please review "If not related to study

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Eastern Time (US & Canada)				treatment other" field, the following text was indicated in the comment field [Tumor]. Any symptoms, AEs or other key data should be collected on the appropriate page. Please review and update as necessary. "[birads02 SDQ=40565]"
Nov-05-2020 15:20:07 (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> Tumor of left	Initial Entry

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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-05-2020 15:20:07 (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
Nov-05-2020 15:20:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-06-2020 19:01:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Closed	Response satisfies query
Nov-06-2020 16:22:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Will update SD and have uploaded in Complion by Monday
Nov-06-2020 16:22:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Will update SD and have uploaded in Complion by Monday
Nov-06-2020 12:44:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Reissued:Opened	CLINQUERY: Thanks for clarifying. If the surgery or any other non-drug treatment was not aimed at anemia per se, please look to update this field. The tumour entry

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				has captured its surgery
Nov-06-2020 11:54:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	No transfusion was given. Subject underwent surgery to remove the tumor which caused the anemia
Nov-06-2020 08:24:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	CLINQUERY: Please clarify if any transfusion given. If a transfusion was given please add to TRANSFUSE page within the Logs folder.
Nov-05-2020 15:20:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Nov-05-2020 15:20:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Nov-05-2020 15:20:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-07-2021 15:20:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Dec/16/2020	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Jan-08-2021 13:16:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-08-2021 00:53:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madhan Babu (pfe.babum05)	Query 1: Opened	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-07-2021 15:20:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-07-2021 15:20:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Participant is willing to return f or Vaccination 3 Participant is: eligible and NOT confirme d to have received only plac ebo at Vaccination 1/2	Initial Entry

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811026

Generated By: pfe.levisse

Form: TREATMENT UNBLINDED - 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

[Back to Form](#)

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-08-2021 13:16:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Dec/16/2020	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-08-2021 13:16:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: ASSESS ELIGIBILITY FOR A DDITIONAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811026

Generated By: pfe.levisse

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Sep-30-2020 10:58:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-12-2020 13:59:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-12-2020 12:16:50 (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
Sep-30-2020 10:58:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/30/2020	Initial Entry
Aug-12-2020 13:59:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/12/2020	Initial Entry
Aug-12-2020 12:16:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/12/2020	Initial Entry

090177e196ae3f01\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1081

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

Subject No: 10811026

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

I. Casebook Signature

Date	Location	User	Value	Reason
Sep-14-2020 16:02:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Click Here to Enable	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1081

Subject No: 10811030

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: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/12/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10811030]
2.	Birth Date:	(b) (6)/1945
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae3f00\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: 10811030

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	Aug/12/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1081

Subject No: 10811030

Generated By: pfe.levisse

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: 10811030

Generated By: pfe.levisse

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	Aug/12/2020
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: 10811030

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:	[Hypertension]
	Start Date:	UNK/UNK/2002
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Coronary Artery Disease]
	Start Date:	UNK/UNK/2006
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Coronary Artery bypass graft]
	Start Date:	UNK/UNK/2006
	Ongoing:	NO End Date: UNK/UNK/2006

090177e196ae3f00\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: 10811030

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

1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Angina-Stable]
	Start Date:	UNK/UNK/2006
	Ongoing:	YES
1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Dyslipidemia]
	Start Date:	UNK/UNK/2006
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Obesity]
	Start Date:	UNK/UNK/2009
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Fracture-Left foot]
	Start Date:	UNK/UNK/1970
	Ongoing:	YES

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL 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: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

1.h	Line/MH Number:	[8]	
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Fracture-left fingers/thumb]	
	Start Date:	UNK/UNK/1965	
	Ongoing:	YES	
1.i	Line/MH Number:	[9]	Comments
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Fracture Left foot. Duplicate entry error]	Comments
	Start Date:	UNK/UNK/1970	Comments
	Ongoing:	YES	Comments

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1081

Subject No: 10811030

Generated By: pfe.levisse

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:	Aug/12/2020
2.	Weight:	[217.2]
3.	Unit:	LB
4.	Height:	[68.0]
5.	Unit:	in
6.	Body Mass Index:	[33.0]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.5]
	Unit:	F
	Temperature Location:	FOREHEAD

090177e196ae3f00\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: 10811030

Generated By: pfe.levisse

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 :	Aug/12/2020
2.	Randomization Number:	[226846]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

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: Aug/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	[BP1J5K]
5.b	Sample ID	[BP1J5L]
5.c	Sample ID	[BP1J5M]
5.d	Sample ID	[BPHZFN]
5.e	Sample ID	[BPHZFP]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811030

Generated By: pfe.levisse

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: Aug/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	[BP1J3Y]
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090177e196ae3f00\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: 10811030

Generated By: pfe.levisse

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:	Aug/12/2020 13:57
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

090177e196ae3f00\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: 10811030

Generated By: pfe.levisse

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	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
----	--	--

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811030

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/1/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

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

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

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

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/1/2020
----	-------	------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.7]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811030

Generated By: pfe.levisse

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/1/2020
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	[BP97LK]
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090177e196ae3f00\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: 10811030

Generated By: pfe.levisse

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/1/2020 13:11
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

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

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	Sep/29/2020
2.	Erroneous Visit	

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

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

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

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

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: 10811030

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: 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	[BRTXPH]
5.b	Sample ID	[BRTXPJ]
5.c	Sample ID	[BP1HSD]

090177e196ae3f00\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: 10811030

Generated By: pfe.levisse

Form: DATE OF VISIT

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](#)

Date of Visit

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

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

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: Mar/2/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRM4LV]
5.b	Sample ID	[BRM4LW]
5.c	Sample ID	[BKZ4C6]
5.d	Sample ID	[BKZ4C7]

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811030

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: 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: 10811030

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	[]
----	-----------	-----

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811030

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: 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: 10811030

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	[]
----	-----------	-----

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1081

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

Subject No: 10811030

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:	
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Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

Signs and Symptoms

1.	Date of Assessment:	//
2.	Date of First Symptom Started:	//
3.	Symptoms Ongoing?	

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

5.	Symptoms - Other Text:	[]
----	------------------------	-----

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB
SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1081

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

Subject No: 10811030

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: POT_COVID_ILL - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1081

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

Subject No: 10811030

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	[]
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090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

Health Care Utilization

1.	Physician or Healthcare Professional:	
	Occurrence of Visits or Contacts:	

Health Care Utilization Other

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

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	
----	--	--

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

Illness Details

1.	Category of Clinical Event:	
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	
3.	Toxicity Grade:	

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1081

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

Subject No: 10811030

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 Visit

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: 10811030

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	[]
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090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1081

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

Subject No: 10811030

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: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

Unplanned Assessments

1.	Assessments	
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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: 10811030

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 :	Sep/29/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

Disposition - Follow-Up

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB -
New 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: 10811030

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:	
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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: 10811030

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	[]
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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: 10811030

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 Ongoing	Form Instance
1.	ADVERSE EVENT	1	Prostate Cancer	Sep/10/2020 UNK:UNK	YES	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811030

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Queries

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

Subject Initials: ---

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

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Prostate Cancer]
4.	Start Date Time:	Sep/10/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? NO Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event YES

090177e196ae3f00\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:** 10811030**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Queries**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:11

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: [Unknown]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021247314]

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: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

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

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1081

Subject No: 10811030

Generated By: pfe.levisse

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

[Back to Form](#)

Medication Error

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

090177e196ae3f00\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: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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: 10811030

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:	//

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: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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: 10811030

Generated By: pfe.levisse

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?	

090177e196ae3f00\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: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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: 10811030

Generated By: pfe.levisse

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: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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: 10811030

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: 10811030

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: 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: 10811030

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: 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: 10811030

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?	

090177e196ae3f00\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: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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: 10811030

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: 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: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

Informed Consent - Asymptomatic Surveillance

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

Header Text: c4591001**Visit:** V201_SURVEIL_CONSENT -
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811030**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: 10811030

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	[]
----	-----------	-----

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

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	Jan/20/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2
----	---	---

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811030

Generated By: pfe.levisse

Form: TREATMENT UNBLINDED

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](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/20/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Sep/29/2020

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levissc

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, Verified

Site No: 1081

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

Subject No: 10811030

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
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1081

Subject No: 10811030

Generated By: pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-12-2020 13:28:47 (UTC-05:00) Eastern Time (US & Canada)	Tawnyn Ebner (pfe.tebner)	all inclusion and exclusion met <hr/> Not Done

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811030

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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

[Back to Form](#)

Item	Date	User	Comment
1.i	Aug-13-2020 14:15:00 (UTC-05:00) Eastern Time (US & Canada)	Phillip Ross (pfe.pross)	Duplicate entry error

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811030

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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

[Back to Form](#)

Item	Date	User	Comment
1.i	Aug-13-2020 14:15:00 (UTC-05:00) Eastern Time (US & Canada)	Phillip Ross (pfe.pross)	Duplicate entry error

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811030

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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

[Back to Form](#)

Item	Date	User	Comment
1.i	Aug-13-2020 14:15:00 (UTC-05:00) Eastern Time (US & Canada)	Phillip Ross (pfe.pross)	Duplicate entry error

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811030

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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
1.i	Aug-13-2020 14:15:00 (UTC-05:00) Eastern Time (US & Canada)	Phillip Ross (pfe.pross)	Duplicate entry error

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1081

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

Subject No: 10811030

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
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
Lora Morris	N/A	Jan-22-2021 07:29:42 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

Michael Butcher	Approved	Oct-13-2020 11:56:36 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
-----------------	----------	--	------	--------

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.

Tawnyn Ebner	N/A	Sep-29-2020 12:37:19 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

James Fry	Approved	Sep-14-2020 16:04:12 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae3f00\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, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

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: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1081

Subject No: 10811030

Generated By: pfe.levisse

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

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-12-2020 13:27:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn 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
Aug-12-2020 13:27:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

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I. Consent Was:

Date	Location	User	Value	Reason
Aug-12-2020 13:28:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: OBTAINED Date Written Consent Obtained Aug/12/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Subject ID

Date	Location	User	Value	Reason
Aug-12-2020 13:27:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10811030	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-12-2020 13:27:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1945	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-12-2020 13:28:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-12-2020 13:28:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: NOT HISPANIC OR LATI NO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1081

Subject No: 10811030

Generated By: pfe.levisse

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

Aug-12-2020 13:28:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: WHITE	Initial Entry
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811030

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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1. Date of Visit

Date	Location	User	Value	Reason
Aug-12-2020 13:28:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: Aug/12/2020	Initial Entry

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - 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: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-12-2020 13:29:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: Aug/12/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-12-2020 13:29:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-12-2020 13:29:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: COMPLETED	Initial Entry

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811030**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**I.a**

Date	Location	User	Value	Reason
Aug-12-2020 15:48:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 1 ber: Medical Histo Hypertensi ry Term: on Start Date: UNK/UN K/2002 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-12-2020 15:48:54 (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
Aug-12-2020 15:48:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Hypertension	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Aug-12-2020 15:48:54	ACV0PFEINFP6000	Phillip Ross	Data Entry: UNK/UNK/2002	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

(UTC-05:00) Eastern Time (US & Canada)		(pfe.pross)		
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1.a Ongoing:

Date	Location	User	Value	Reason
Aug-12-2020 15:48:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Aug-12-2020 15:49:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 2 Medical History Term: Coronary Artery Disease Start Date: UNK/UNK/2006 Ongoing: YES	Initial Entry

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811030**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11***1.b Line/MH Number:***

Date	Location	User	Value	Reason
Aug-12-2020 15:49:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 15:49:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Coronary Artery Disease	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-12-2020 15:49:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2006	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-12-2020 15:49:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

1.c

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811030

Generated By: pfe.levisse

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

Aug-12-2020 15:49:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 3 Number: Medical History Term Coronary Artery bypass graft : Start Date: UNK/UNK/2006 Ongoing: NO End Date: UNK/UNK/2006	Initial Entry
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090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811030**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11***I.c Line/MH Number:***

Date	Location	User	Value	Reason
Aug-12-2020 15:49:51 (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
Aug-12-2020 15:49:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Coronary Artery bypass gra ft	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Aug-12-2020 15:49:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2006	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Aug-12-2020 15:49:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO End Date: UNK/UNK/2006	Initial Entry

I.d

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

<p>Aug-13-2020 14:13:00 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>Phillip Ross (pfe.pross)</p>	<p>Data Entry: Line/MH Number: 4 Medical History Term: Angina-Stable Start Date: UNK/UNK/2006 Ongoing: YES</p>	<p>Stable. No worsening within 6 weeks of enrollment</p>
<p>Aug-12-2020 15:50:18 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>auto calc (autocalc)</p>	<p>Data Entry: Line/MH Number: 4 Medical History Term: Angina Start Date: UNK/UNK/2006 Ongoing: YES</p>	<p>Initial Entry</p>

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

1.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-12-2020 15:50:18 (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
Aug-14-2020 01:41:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Katherine Liau (pfe.liaukf)	Query 1: Closed	Response satisfies query
Aug-13-2020 14:13:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Stable. No worsening within 6 weeks of enrollment
Aug-13-2020 14:13:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Angina-Stable	Stable. No worsening within 6 weeks of enrollment
Aug-13-2020 11:44:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	GPD Clin: Per IC3 and Criteria for Temporary Delay of Enrolment (Protocol 5.5), please confirm stability of symptoms within

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

				6 weeks of enrolment and no acute event within 48h before study intervention administration
Aug-12-2020 15:50:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Angina	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Aug-12-2020 15:50:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2006	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Aug-12-2020 15:50:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

1.e

Date	Location	User	Value	Reason
Aug-12-2020 15:50:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 5 ber:	Initial Entry

090177e196ae3f00\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: 10811030

Generated By: pfe.levisse

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:	Dyslipidemia	
			Start Date:	UNK/UNK/2006	
			Ongoing:	YES	

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811030**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11***I.e Line/MH Number:***

Date	Location	User	Value	Reason
Aug-12-2020 15:50:40 (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
Aug-12-2020 15:50:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Dyslipidemia	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Aug-12-2020 15:50:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2006	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Aug-12-2020 15:50:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811030

Generated By: pfe.levisse

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

Aug-12-2020 15:50:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 6 ber: Medical History Term: Obesity Start Date: UNK/UNK/2009 Ongoing: YES	Initial Entry
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090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

1.f Line/MH Number:

Date	Location	User	Value	Reason
Aug-12-2020 15:50:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 15:50:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Obesity	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Aug-12-2020 15:50:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2009	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Aug-12-2020 15:50:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

1.g

Date	Location	User	Value	Reason
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090177e196ae3f00\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: 10811030

Generated By: pfe.levisse

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

Aug-12-2020 15:51:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 7 mber: Medical Histo Fracture-L ry Term: eft foot Start Date: UNK/UN K/1970 Ongoing: YES	Initial Entry
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Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811030**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11***1.g Line/MH Number:***

Date	Location	User	Value	Reason
Aug-12-2020 15:51:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 15:51:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Fracture-Left foot	Initial Entry

1.g Start Date:

Date	Location	User	Value	Reason
Aug-12-2020 15:51:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/1970	Initial Entry

1.g Ongoing:

Date	Location	User	Value	Reason
Aug-12-2020 15:51:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

1.h

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811030

Generated By: pfe.levisse

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

Aug-12-2020 15:52:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 8 Medical History Term: Fracture-left fingers/thumb Start Date: UNK/UNK/1965 Ongoing: YES	Initial Entry
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Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811030**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 10:11***1.h Line/MH Number:***

Date	Location	User	Value	Reason
Aug-12-2020 15:52:00 (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
Aug-12-2020 15:52:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Fracture-left fingers/thumb	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Aug-12-2020 15:52:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/1965	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Aug-12-2020 15:52:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

1.i

Date	Location	User	Value	Reason
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Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811030**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11

Aug-14-2020 07:35:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Line/MH 9 Number: Medical History Term: Fracture Left foot. Duplicate entry error Start Date: UNK/UNK/1970 Ongoing: YES	Duplicate entry (DELETED)
Aug-13-2020 16:51:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 9 Number: Medical History Term: Fracture-Left foot. Duplicate entry error Start Date: UNK/UNK/1970 Ongoing: YES	Transcription Error
Aug-13-2020 14:13:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu Number: Medical History Term: Start Date: UNK/UNK/1970 Ongoing: YES	Duplicate entry by error
Aug-12-2020 15:52:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 9 Number: Medical History Term: Fractured Left foot Start Date: UNK/UNK/1970	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811030

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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

			Ongoing: YES	
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

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Generated By: pfe.levisse

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

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1.i Line/MH Number:

Date	Location	User	Value	Reason
Aug-14-2020 07:35:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> 9	Duplicate entry (DELETED)
Aug-13-2020 16:51:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 9	Transcription Error
Aug-13-2020 14:13:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Duplicate entry by error
Aug-12-2020 15:52:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 9	Initial Entry

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

Date	Location	User	Value	Reason
Aug-14-2020 13:04:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Closed	Response satisfies query
Aug-14-2020 07:35:20 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> Fractur	Duplicate entry (DELETED)

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

(US & Canada)			re-Left foot. Duplicate entry error	
Aug-14-2020 07:35:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Duplicate entry
Aug-14-2020 01:44:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Katherine Liao (pfe.liaukf)	Query 1: Reissued: Opened	GPD Clin: Thank you for your response. Please delete the duplicate entry per original query. Thank you.
Aug-13-2020 17:54:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 2: Closed	Discrepancy has been closed.
Aug-13-2020 16:51:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Aug-13-2020	ACV0PFEINFP6000	Phillip Ross	Data	Transcription

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811030**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11

16:51:44 (UTC-05:00) Eastern Time (US & Canada)		(pfe.pross)	Entry : Fracture-Left foot. Duplicate entry error	Error
Aug-13-2020 15:57:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 2: Opened	Null Term: Verbatim term must not be null/blank.
Aug-13-2020 14:13:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Duplicate entry by error
Aug-13-2020 14:13:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry :	Duplicate entry by error
Aug-13-2020 11:17:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	GPD Clin: Fracture - left foot has been reported twice in MH listing for same date. Please review

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

				entries and correct duplication
Aug-12-2020 15:52:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry : Fractured Left foot	Initial Entry

1.i Start Date:

Date	Location	User	Value	Reason
Aug-14-2020 07:35:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/1970	Duplicate entry (DELETED)
Aug-12-2020 15:52:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/1970	Initial Entry

1.i Ongoing:

Date	Location	User	Value	Reason
Aug-14-2020 07:35:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Duplicate entry (DELETED)
Aug-12-2020 15:52:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Date:

Date	Location	User	Value	Reason
Aug-12-2020 15:52:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Aug/12/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-12-2020 15:52:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: 217.2	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-12-2020 15:52:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-12-2020 15:52:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: 68.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
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090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

Aug-12-2020 15:52:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: in	Initial Entry
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6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-12-2020 15:52:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 33.0	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-12-2020 15:52:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Record Identifier:: 1 Temperature: 97.5 Temperature Unit: F Temperature Location: FOREHEAD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-12-2020 15:52:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
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090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

Aug-12-2020 15:52:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: 97.5	Initial Entry
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7.a Unit:

Date	Location	User	Value	Reason
Aug-12-2020 15:52:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-12-2020 15:52:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: FOREHEAD	Initial Entry

090177e196ae3f00\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: 10811030

Generated By: pfe.levisse

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
Aug-12-2020 15:53:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Aug/12/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-12-2020 15:53:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: 226846	Initial Entry

090177e196ae3f00\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: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Data Origin

Date	Location	User	Value	Reason
Aug-12-2020 13:29:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-12-2020 13:29:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-12-2020 13:29:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-12-2020 13:29:38 (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.
Aug-12-2020 13:29:38	ACV0PFEINFP6000	Tawyn Ebner	Data Entry: YES	Initial Entry

090177e196ae3f00\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: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

(UTC-05:00) Eastern Time (US & Canada)		(pfe.tebner)	Date of Collection:	
			Aug/12/2020	

5.a

Date	Location	User	Value	Reason
Aug-12-2020 13:29:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: Sample ID: BP1J5K	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-12-2020 13:29:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: BP1J5K	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-12-2020 13:29:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: Sample ID: BP1J5L	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-12-2020 13:29:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: BP1J5L	Initial Entry

090177e196ae3f00\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: 10811030

Subject Initials: ---

Generated By: pfe.lewissc

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

5.c

Date	Location	User	Value	Reason
Aug-12-2020 13:30:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BP1J5M	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-12-2020 13:30:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BP1J5M	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-12-2020 13:30:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BPHZFN	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-12-2020 13:30:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BPHZFN	Initial Entry

5.e

Date	Location	User	Value	Reason
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090177e196ae3f00\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: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

Aug-12-2020 13:30:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BPHZFP	Initial Entry
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5.e Sample ID

Date	Location	User	Value	Reason
Aug-12-2020 13:30:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BPHZFP	Initial Entry

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: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Data Origin

Date	Location	User	Value	Reason
Aug-12-2020 15:33:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-12-2020 15:33:35 (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
Aug-12-2020 15:33:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-12-2020 15:33:35 (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.
Aug-12-2020 15:33:35	ACV0PFEINFP6000	Tawnyn Ebner	Data Entry: YES	Initial Entry

090177e196ae3f00\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: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

(UTC-05:00) Eastern Time (US & Canada)		(pfe.tebner)	Date of Collection:	
			Aug/12/2020	

5.a

Date	Location	User	Value	Reason
Aug-12-2020 15:33:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: Sample ID: BP1J3Y	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-12-2020 15:33:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: BP1J3Y	Initial Entry

090177e196ae3f00\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: 10811030

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
Aug-12-2020 15:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-12-2020 15:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-12-2020 15:53:23 (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
Aug-12-2020 15:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Aug/12/2020 13:57	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
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090177e196ae3f00\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: 10811030

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

Aug-12-2020 15:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry
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6. Body Side:

Date	Location	User	Value	Reason
Aug-12-2020 15:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-12-2020 15:53:23 (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
Aug-12-2020 15:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 15:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

090177e196ae3f00\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: 10811030

Generated By: pfe.levisse

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
Aug-12-2020 15:53:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> YES - REACTOGENICIT Y E-DIARY 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: 10811030

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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1. Date of Visit

Date	Location	User	Value	Reason
Sep-01-2020 14:04:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> Sep/1/2020	Initial Entry

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811030**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Sep-01-2020 14:04:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-01-2020 14:04:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Symptom:: FE V E R Were fever or systemi N c symptoms present o O n the last day the Sub ject Diary was compl eted?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 14:04:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: FEVER	Initial Entry

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

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

Sep-01-2020 14:04:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO	Initial Entry
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2.b

Date	Location	User	Value	Reason
Sep-01-2020 14:04:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Symptom:: FA TI GU E Were fever or system NO ic symptoms present on the last day the Su bject Diary was com pleted?:	Initial Entry

2.b Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 14:04:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 14:04:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO	Initial Entry

2.c

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Sep-01-2020 14:04:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Symptom:: HE AD AC HE Were fever or syste mic symptoms prese nt on the last day the Subject Diary was c ompleted?: NO	Initial Entry

2.c Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 14:04:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 14:04:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-01-2020 14:04:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Symptom:: C HI LL	Initial Entry

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

			S	
Were fever or systemic symptoms present on the last day the Subject Diary was completed?:				

2.d Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 14:04:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 14:04:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Sep-01-2020 14:04:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Symptom:: VO MI TIN G Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

2.e Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 14:04:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 14:04:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Sep-01-2020 14:04:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Symptom:: DI AR RH EA Were fever or system NO ic symptoms present on the last day the S ubject Diary was co mpleted?:	Initial Entry

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.lewissc

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

2.f Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 14:04:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 14:04:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-01-2020 14:04:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Symptom:: NEW O R WOR SENED MUSCL E PAIN Were fever or sy NO stemic symptom s present on the last day the Subj ect Diary was co mpleted?:	Initial Entry

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

2.g Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 14:04:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NEW OR WORSENE M USCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 14:04:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Sep-01-2020 14:04:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Symptom:: NEW O R WOR SENE D JOINT PAIN Were fever or sy NO stemic symptoms present on the la st day the Subjec t Diary was com pleted?:	Initial Entry

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.lewissc

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

2.h Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 14:04:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NEW OR WORSENEED JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 14:04:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-01-2020 14:04:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-01-2020 14:04:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
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090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

Sep-01-2020 14:04:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Injection Site Reaction: RE DN ES S Were injection site reactions present on the last day the Subject Diary was completed?:	Initial Entry
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5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-01-2020 14:04:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 14:04:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-01-2020 14:04:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Injection Site Reaction: SW ELL ING	Initial Entry

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.lewissc

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

			Were injection site reactions present on the last day the Subject Diary was completed?:	
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5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-01-2020 14:04:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 14:04:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-01-2020 14:04:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> Injection Site Reaction: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-01-2020 14:04:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: PAIN AT INJECTION SIT E	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 14:04:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO	Initial Entry

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Sep-01-2020 14:04:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Sep/1/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-01-2020 14:04:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Record Identifier:: Temperature: 97.7 Temperature Unit: F Temperature Location:: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-01-2020 14:04:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-01-2020 14:04:55 (UTC-05:00) Eastern	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: 97.7	Initial Entry

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

Time (US & Canada)				
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2.a Unit:

Date	Location	User	Value	Reason
Sep-01-2020 14:04:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-01-2020 14:04:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3f00\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:** 10811030**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-01-2020 14:42:00 (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-01-2020 14:42:00 (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-01-2020 14:42:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-01-2020 14:42:00 (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-01-2020 14:42:00	ACV0PFEINFP6000	Tawyn Ebner	Data Entry: YES	Initial Entry

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: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

(UTC-05:00) Eastern Time (US & Canada)		(pfe.tebner)	Date of Collection: Sep/1/2020	
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5.a

Date	Location	User	Value	Reason
Sep-01-2020 14:42:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BP97LK	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-01-2020 14:42:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BP97LK	Initial Entry

090177e196ae3f00\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: 10811030

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-01-2020 14:05:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-01-2020 14:05:18 (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-01-2020 14:05:18 (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-01-2020 14:05:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Sep/1/2020 13:11	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
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090177e196ae3f00\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: 10811030

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

Sep-01-2020 14:05:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry
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6. Body Side:

Date	Location	User	Value	Reason
Sep-01-2020 14:05:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-01-2020 14:05:18 (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-01-2020 14:05:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFI ED OBSERVATION PERIO D	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-01-2020 14:05:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

090177e196ae3f00\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: 10811030

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Sep-29-2020 12:37:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: Sep/29/2020	Initial Entry

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811030**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Sep-29-2020 13:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-29-2020 13:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom:: FE V E R Were fever or syste mic symptoms prese nt on the last day the Subject Diary was co mpleted?: N O	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 13:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: FEVER	Initial Entry

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

Date	Location	User	Value	Reason
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Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811030**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11

Sep-29-2020 13:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry
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2.b

Date	Location	User	Value	Reason
Sep-29-2020 13:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom:: FA TI G UE Were fever or syste N mic symptoms prese O nt on the last day th e Subject Diary was completed?:	Initial Entry

2.b Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 13:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 13:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

2.c

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Sep-29-2020 13:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.c Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 13:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 13:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-29-2020 13:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> Symptom:: C HI LL	Initial Entry

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

			S Were fever or systemic symptoms present on the last day the Subject Diary was completed?:
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2.d Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 13:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 13:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Sep-29-2020 13:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> Symptom:: VO MI TIN G Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

2.e Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 13:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 13:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Sep-29-2020 13:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom:: DI AR RH EA Were fever or syste NO mic symptoms pres ent on the last day t he Subject Diary w as completed?:	Initial Entry

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

2.f Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 13:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 13:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-29-2020 13:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> Symptom:: NEW O R WOR SENED MUSC LE PAI N Were fever or s NO ystemic sympto ms present on t he last day the Subject Diary w as completed?:	Initial Entry

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

2.g Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 13:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NEW OR WORSENERD M USCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 13:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Sep-29-2020 13:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom:: NEW OR W ORSE NED J OINT P AIN Were fever or sy NO stemic symptom s present on the last day the Sub ject Diary was c ompleted?:	Initial Entry

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811030**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11**2.h Symptom:**

Date	Location	User	Value	Reason
Sep-29-2020 13:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NEW OR WORSENERD J OINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 13:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-29-2020 13:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-29-2020 13:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

Sep-29-2020 13:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Injection Site Reaction: RE DN ES S Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry
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5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-29-2020 13:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 13:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-29-2020 13:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Injection Site Reaction: SW EL LIN G	Initial Entry

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.lewissc

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

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

Date	Location	User	Value	Reason
Sep-29-2020 13:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 13:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-29-2020 13:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> Injection Site Reaction: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-29-2020 13:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: PAIN AT INJECTION SIT E	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 13:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

090177e196ae3f00\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: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Data Origin

Date	Location	User	Value	Reason
Sep-29-2020 12:37:42 (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 12:37:42 (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-29-2020 12:37:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-29-2020 12:37:42 (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 12:37:42	ACV0PFEINFP6000	Tawyn Ebner	Data Entry: YES	Initial Entry

090177e196ae3f00\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: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

(UTC-05:00) Eastern Time (US & Canada)		(pfe.tebner)	Date of Collection: Sep/29/2020	
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5.a

Date	Location	User	Value	Reason
Sep-29-2020 12:37:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: Sample ID: BRTXPH	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-29-2020 12:37:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: BRTXPH	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-29-2020 12:38:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: Sample ID: BRTXPJ	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-29-2020 12:38:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: BRTXPJ	Initial Entry

090177e196ae3f00\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: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

5.c

Date	Location	User	Value	Reason
Sep-29-2020 12:38:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BP1HSD	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-29-2020 12:38:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BP1HSD	Initial Entry

090177e196ae3f00\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: 10811030

Generated By: pfe.levisse

Form: DATE OF VISIT - 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 Visit

Date	Location	User	Value	Reason
Mar-02-2021 13:30:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Mar/2/2021	Initial Entry

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Data Origin

Date	Location	User	Value	Reason
Mar-02-2021 13:30:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-02-2021 13:30:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-02-2021 13:30:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-02-2021 13:30:33 (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.
Mar-02-2021 13:30:33	ACV0PFEINFP6000	Tawyn Ebner	Data Entry: YES	Initial Entry

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

(UTC-05:00) Eastern Time (US & Canada)		(pfe.tebner)	Date of Collection: Mar/2/2021	
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5.a

Date	Location	User	Value	Reason
Mar-02-2021 13:30:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: Sample ID: BRM4LV	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-02-2021 13:30:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: BRM4LV	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-02-2021 13:30:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: Sample ID: BRM4LW	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-02-2021 13:30:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: BRM4LW	Initial Entry

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

5.c

Date	Location	User	Value	Reason
Mar-02-2021 13:31:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: Sample ID: BKZ4C6	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-02-2021 13:31:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: BKZ4C6	Initial Entry

5.d

Date	Location	User	Value	Reason
Mar-02-2021 13:31:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: Sample ID: BKZ4C7	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Mar-02-2021 13:31:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: BKZ4C7	Initial Entry

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Sep-29-2020 13:47:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sep/29/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-29-2020 13:47:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-29-2020 13:47:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: COMPLETED	Initial Entry

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

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Date	Location	User	Value	Reason
Mar-05-2021 14:40:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Queries

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Category:

Date	Location	User	Value	Reason
Mar-05-2021 14:40:16 (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
Mar-05-2021 14:40:16 (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-10-2021 13:23:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical SAE report also includes a diagnosis of 'metastases to bladder'; please review for safety and severity, and report as either AE or SAE (this is prior to Visit 3).
Mar-05-2021 14:40:16	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Prostate Cancer	Initial Entry

090177e196ae3f00\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, Queries

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

(UTC-05:00) Eastern Time (US & Canada)				
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4. Start Date Time:

Date	Location	User	Value	Reason
Mar-05-2021 14:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sep/10/2020 UNK:UNK	Transcription Error
Mar-05-2021 14:40:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Feb/10/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-05-2021 14:40:16 (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
Mar-05-2021 14:40:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

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090177e196ae3f00\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, Queries

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Mar-08-2021 04:29:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-05-2021 14:40:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Prostate Cancer: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Mar-05-2021 14:40:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization?	Initial Entry

090177e196ae3f00\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, Queries**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811030**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11

			NO	
			Did this serious event result in persistent or significant disability/incapacity?	
			NO	
			Is this serious event life threatening?	
			NO	
			Other medically important serious event	
			YES	

8. Is this adverse event the result of a study Medication Error?*If Yes, record the type of medication error on the Medication Error Log.*

Date	Location	User	Value	Reason
Mar-05-2021 14:40:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-05-2021 14:40:16 (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:	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Queries

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.lewissc

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

			OTHER <i>If Other, specify:</i> Unknown	
--	--	--	---	--

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-05-2021 14:40:16 (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
Mar-05-2021 14:40:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-05-2021 14:40:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Mar-05-2021 14:40:16	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: RECOVERING/RESOLVI	Initial Entry

090177e196ae3f00\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, Queries

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

(UTC-05:00) Eastern Time (US & Canada)			NG	
--	--	--	----	--

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Mar-05-2021 14:40:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Mar-08-2021 04:29:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Data Entry: 2021247314	Initial Entry

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Jan-22-2021 07:29:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> Jan/20/2021	Initial Entry

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1081

Subject No: 10811030

Generated By: pfe.levisse

Form: FURTHER VACCINATION CONFIRMATION - 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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Jan-22-2021 07:30:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-22-2021 07:30:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-22-2021 07:30:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Participant is willing to r eturn for Vaccination 3 Participant is: eligible and NOT conf irmed to have receive d only placebo at Vacc ination 1/2	Initial Entry

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-22-2021 07:30:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Jan/20/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-22-2021 07:30:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: ASSESS ELIGIBILITY F OR ADDITIONAL VACC INATION	Initial Entry

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1081

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

Subject No: 10811030

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Sep-29-2020 13:47:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-12-2020 15:53:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-12-2020 13:29:15 (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
Sep-29-2020 13:47:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/29/2020	Initial Entry
Aug-12-2020 15:53:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/12/2020	Initial Entry
Aug-12-2020 13:29:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/12/2020	Initial Entry

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811030

Generated By: pfe.levisse

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail
History

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Casebook Signature

Date	Location	User	Value	Reason
Sep-14-2020 16:04:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> Click Here to Enable	Initial Entry

090177e196ae3f00\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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: 10811036

Generated By: pfe.lewissc

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 Aug/13/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1081

Subject No: 10811036

Generated By: pfe.lewissc

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	[10811036]
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):	BLACK OR AFRICAN AMERICAN
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811036

Generated By: pfe.lewissc

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	Aug/13/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1081

Subject No: 10811036

Generated By: pfe.lewissc

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 _____
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Exclusion Criteria Met

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

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811036

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	Aug/13/2020
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: 10811036

Generated By: pfe.lewissc

Form: GENERAL MEDICAL 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

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Asthma-Stable, No change within 6 weeks of screening]
	Start Date:	UNK/UNK/1980
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Seasonal Allergies]
	Start Date:	UNK/UNK/1980
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Bilateral Tubal Ligation]
	Start Date:	UNK/UNK/1991
	Ongoing:	NO End Date: UNK/UNK/1991
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[C-Section]
	Start Date:	UNK/UNK/1991
	Ongoing:	NO End Date: UNK/UNK/1991

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811036

Generated By: pfe.levisse

Form: GENERAL MEDICAL 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

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[COPD]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1081

Subject No: 10811036

Generated By: pfe.levisse

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:	Aug/13/2020
2.	Weight:	[160.2]
3.	Unit:	LB
4.	Height:	[62.5]
5.	Unit:	in
6.	Body Mass Index:	[28.8]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[98.2]
	Unit:	F
	Temperature Location:	FOREHEAD

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1081

Subject No: 10811036

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:	Aug/13/2020
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: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811036

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 :	Aug/13/2020
2.	Randomization Number:	[47787]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811036

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: Aug/13/2020
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	[BP1J6N]
5.b	Sample ID	[BP1J6P]
5.c	Sample ID	[BP1J6R]
5.d	Sample ID	[BPHZG4]
5.e	Sample ID	[BPHZG5]

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:03
Site No: 1081
Subject No: 10811036
Generated By: pfe.lewissc

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: Aug/13/2020
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	[BP1J5Y]
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090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811036

Generated By: pfe.lewissc

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:	Aug/13/2020 15:09
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1081

Subject No: 10811036

Generated By: pfe.lewissc

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	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
----	--	---

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811036

Generated By: pfe.lewissc

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/3/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811036

Subject Initials: ---

Generated By: pfe.lewissc

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

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

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

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	RIGHT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1081

Subject No: 10811036

Generated By: pfe.lewissc

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/3/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.0]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 30-Jul-2020 21:27**Site No:** 1081**Subject No:** 10811036**Generated By:** pfe.levisse**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

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

Lab Urinalysis

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

Lab Result

6.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____ _____	Comments
	Not Done:	Not Applicable _____	Comments

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811036

Generated By: pfe.lewissc

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/3/2020
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	[BP97NC]
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090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811036

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/3/2020 15:38
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811036

Generated By: pfe.lewissc

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/1/2020
2.	Erroneous Visit	

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811036

Subject Initials: ---

Generated By: pfe.lewissc

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

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

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

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	RIGHT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811036

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: Oct/1/2020
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	[BRTXRX]
5.b	Sample ID	[BRTXRY]
5.c	Sample ID	[BP1HT3]

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811036

Generated By: pfe.lewissc

Form: DATE OF VISIT

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

Date of Visit

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

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811036

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BSFNXS]
5.b	Sample ID	[BSFNXT]
5.c	Sample ID	[BRM4MZ]
5.d	Sample ID	[BRM4N0]

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811036

Generated By: pfe.lewissc

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: 10811036

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: 10811036

Generated By: pfe.levisc

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: 10811036

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 **Form:** DATE OF VISIT - ILLNESS ONSET
on Nov/03/2020

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: 10811036

Subject Initials: ---

Generated By: pfe.lewissc

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Nov/3/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Nov/03/2020

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: 10811036

Subject Initials: ---

Generated By: pfe.lewissc

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

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Nov/3/2020
2.	Date of First Symptom Started:	Oct/19/2020
3.	Symptoms Ongoing?	NO
	Date of Last Symptom Resolved:	Nov/9/2020

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?	YES
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?	NO
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	YES

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
on Nov/03/2020

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: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

Symptoms - Other

5.a	Symptoms - Other Text:	[Chest Tightness]
5.b	Symptoms - Other Text:	[Nasal Congestion]
5.c	Symptoms - Other Text:	[Chest Congestion]
5.d	Symptoms - Other Text:	[Sputum Production]
5.e	Symptoms - Other Text:	[Nausea]
5.f	Symptoms - Other Text:	[Wheezing]

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: 10811036

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.	Nov/2/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN
on Nov/03/2020

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: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

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[Form Comments](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Microbiology Specimen

1.	Actual Date of Collection:	Nov/2/2020	Comments
2.	Specimen Type:	SWABBED MATERIAL	Comments
3.	Specimen Collection Location:	NASOPHARYNX	Comments
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	Comments
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST	Comments
6.	Trade Name:	OTHER	Comments
7.	Test Result:	NEGATIVE	Comments
8.	Comments/Findings/Details:	[Per medical records- "this test has been authorized by the FDA under EUA. Test performed at UC Health Hospital in the UC Health Lab]	Comments
9.	Trade Name Other, Specify:	[NALT Unknown]	Comments

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Nov/03/2020

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: 10811036

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?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[On site swab performed]

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 Nov/03/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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: 10811036

Subject Initials: ---

Generated By: pfe.lewissc

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: Nov/3/2020
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	[BP1HZ9]
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090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION
on Nov/03/2020**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:** 10811036**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11[Form Comments](#)
[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:	YES Number of Visits or Contacts: [1]
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
----	--	----

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: 10811036

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.						Repeating Pages

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT
on Nov/03/2020

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1081

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

Subject No: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Respiratory Treatment

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS
on Nov/03/2020

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: 10811036

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?	YES Respiratory Illness Diagnosis: [COPD Exacerbation & upper respiratory infection] Date of Diagnosis: Nov/2/2020
3.	Toxicity Grade:	1

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1081

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

Subject No: 10811036

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.					Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE
on Nov/03/2020

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1081

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

Subject No: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Illness Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 30-Jul-2020 21:27

Site No: 1081

Subject No: 10811036

Generated By: pfe.levissc

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

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

Subject Initials: ---

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

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Nov/03/2020

Form Version: 30-Jul-2020 21:27

Form Status: Not Started

Site No: 1081

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

Subject No: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Lab Chemistry Details

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

Lab Result

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

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 30-Jul-2020 21:28

Site No: 1081

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

Subject No: 10811036

Subject Initials: ---

Generated By: pfe.levissc

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

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
on Nov/03/2020

Form Version: 30-Jul-2020 21:28

Form Status: Not Started

Site No: 1081

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

Subject No: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Laboratory Data Hematology

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

Lab Result

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

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 30-Jul-2020 21:27

Site No: 1081

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

Subject No: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Nov/03/2020

Form Version: 30-Jul-2020 21:27

Form Status: Not Started

Site No: 1081

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

Subject No: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 30-Jul-2020 21:28

Site No: 1081

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

Subject No: 10811036

Subject Initials: ---

Generated By: pfe.levissc

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

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Nov/03/2020

Form Version: 30-Jul-2020 21:28

Form Status: Not Started

Site No: 1081

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

Subject No: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

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Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1081

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

Subject No: 10811036

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.				Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS
on Nov/03/2020

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1081

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

Subject No: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

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Oxygenation Parameters

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1081

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

Subject No: 10811036

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: POT_COVID_ILL 1 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
on Nov/03/2020

Form Version: 06-Jul-2020 21:55

Form Status: Not Started

Site No: 1081

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

Subject No: 10811036

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.	Start Date:	//
6.	Ongoing?	

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (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: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Nov/2/2020	CHEST	X-RAY	NORMAL	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING
on Nov/03/2020

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: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

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Imaging

1.	Date of Assessment:	Nov/2/2020
2.	Location of Assessment:	CHEST
3.	Type of Imaging Exam:	X-RAY
4.	Assessment:	NORMAL

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Dec/07/2020

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811036

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Dec/7/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A1
----	-------------------------	----------

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Dec/07/2020

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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: 10811036

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	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/7/2020
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	[BS64RW]
5.b	Sample ID	[BS64RX]
5.c	Sample ID	[BKN9N4]
5.d	Sample ID	[BKN9N5]

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1081

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

Subject No: 10811036

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: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

Unplanned Assessments

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1081

Subject No: 10811036

Generated By: pfe.lewissc

Form: DISPOSITION - TREATMENT

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 - Treatment

1.	Date of Completion/Discontinuation/Death :	Oct/1/2020
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: 10811036

Generated By: pfe.levissc

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

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

Subject Initials: ---

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

Disposition - Follow-Up

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
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: 10811036

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 Repeat Swab

3.	COVID-19 Repeat Swab:	
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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: 10811036

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	[]
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090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

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: 10811036

Subject Initials: ---

Generated By: pfe.levissc

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Appendicitis	Aug/21/2020 UNK:UNK	NO End Date Time: Aug/23/2020 UNK:UNK	Repeating Pages
2. DELETED	ADVERSE EVENT	2	COPD exacerbation	Nov/2/2020 UNK:UNK	YES	Repeating Pages
3.	ADVERSE EVENT	3	Anemia	Nov/2/2020 UNK:UNK	YES	Repeating Pages

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811036

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

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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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Appendicitis]
4.	Start Date Time:	Aug/21/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/23/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO 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

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811036

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

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

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: [Acute Infection]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020336178]

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811036

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted

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

Subject Initials: ---

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

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

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Adverse Event Report

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

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811036

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted

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

Subject Initials: ---

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

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811036

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

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Adverse Event Report

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

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811036

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

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: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

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

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1081

Subject No: 10811036

Generated By: pfe.levisse

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	[]

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (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: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

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: 10811036

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:	//

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (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: 10811036

Subject Initials: ---

Generated By: pfe.lewissc

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

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811036

Generated By: pfe.levisse

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?	

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (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: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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: 10811036

Generated By: pfe.levisse

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: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

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

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811036

Generated By: pfe.levisse

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: 10811036

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: 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: 10811036

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: 10811036

Subject Initials: ---

Generated By: pfe.lewissc

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:	

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

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:** 10811036**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?	

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: 10811036

Subject Initials: ---

Generated By: pfe.lewissc

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: 10811036

Subject Initials: ---

Generated By: pfe.lewissc

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: 10811036

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: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

Informed Consent - Asymptomatic Surveillance

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1081

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

Subject No: 10811036

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: 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: 10811036

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: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

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: 10811036

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	Feb/8/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1081

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

Subject No: 10811036

Subject Initials: ---

Generated By: pfe.lewissc

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

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2
----	---	--

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811036

Generated By: pfe.lewissc

Form: TREATMENT UNBLINDED

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

Treatment Unblinded

1.	Date Treatment Unblinded :	Feb/8/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811036

Generated By: pfe.lewissc

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: 10811036

Generated By: pfe.levissc

Form: DEATH DETAILS CODED

Form Status: Not Started

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

Subject Initials: ---

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

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811036

Generated By: pfe.levissc

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

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1081

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

Subject No: 10811036

Subject Initials: ---

Generated By: pfe.lewissc

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, Verified

Site No: 1081

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

Subject No: 10811036

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
- CRF_Sign_1

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1081

Subject No: 10811036

Generated By: pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-13-2020 14:27:14 (UTC-05:00) Eastern Time (US & Canada)	Tawny Ebner (pfe.tebner)	all inclusion and exclusion met <hr/> Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1081

Subject No: 10811036

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-03-2020 16:34:32 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	surgically sterile <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1081

Subject No: 10811036

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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
1	Sep-03-2020 16:34:32 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	surgically sterile <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1081

Subject No: 10811036

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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
2	Sep-03-2020 16:34:32 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	surgically sterile <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1081

Subject No: 10811036

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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
3	Sep-03-2020 16:34:32 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	surgically sterile <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1081

Subject No: 10811036

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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
4	Sep-03-2020 16:34:32 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	surgically sterile <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1081

Subject No: 10811036

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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

[Back to Form](#)

Item	Date	User	Comment
5	Sep-03-2020 16:34:32 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	surgically sterile <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1081

Subject No: 10811036

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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
6.a	Sep-03-2020 16:34:32 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	surgically sterile <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1081

Subject No: 10811036

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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

[Back to Form](#)

Item	Date	User	Comment
6.a	Sep-03-2020 16:34:32 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	surgically sterile <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1081

Subject No: 10811036

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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
6.a	Sep-03-2020 16:34:32 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	surgically sterile <hr/> Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Nov/03/2020

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: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
Form	Dec-04-2020 11:59:18 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	COVID Test was performed 02Nov2020 at ER. Records will be requested and data will be updated at that time. 19Nov2020: COVID test result re-requested. ML 03Dec2020 - Data will be entered upon receipt of medical records
Form	Dec-03-2020 07:32:06 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	COVID Test was performed 02Nov2020 at ER. Records will be requested and data will be updated at that time. 19Nov2020: COVID test result re-requested. ML 03Dec2020 - Data will be entered upon receipt of medical records <hr/> Not Done
Form	Nov-19-2020 13:53:17 (UTC-05:00) Eastern Time (US & Canada)	Marcel Lanton (pfe.mlanton)	COVID Test was performed 02Nov2020 at ER. Records will be requested and data will be updated at that time. 19Nov2020: COVID test result re-requested. ML
Form	Nov-04-2020 07:46:03 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	COVID Test was performed 02Nov2020 at ER. Records will be requested and data will be updated at that time
Form	Nov-03-2020 10:39:40 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	COVID Test was performed 02Nov2020 at ER. Records will be requested and data will be updated at that time <hr/> Unknown
Form	Nov-03-2020 10:17:11 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Applicable

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Nov/03/2020

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: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
1	Dec-04-2020 11:59:18 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	COVID Test was performed 02Nov2020 at ER. Records will be requested and data will be updated at that time. 19Nov2020: COVID test result re-requested. ML 03Dec2020 - Data will be entered upon receipt of medical records
1	Dec-03-2020 07:32:06 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	COVID Test was performed 02Nov2020 at ER. Records will be requested and data will be updated at that time. 19Nov2020: COVID test result re-requested. ML 03Dec2020 - Data will be entered upon receipt of medical records <hr/> Not Done
1	Nov-04-2020 07:46:03 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	COVID Test was performed 02Nov2020 at ER. Records will be requested and data will be updated at that time
1	Nov-03-2020 10:39:40 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	COVID Test was performed 02Nov2020 at ER. Records will be requested and data will be updated at that time <hr/> Unknown
1	Nov-03-2020 10:17:11 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Applicable

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Nov/03/2020

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: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
2	Dec-04-2020 11:59:18 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	COVID Test was performed 02Nov2020 at ER. Records will be requested and data will be updated at that time. 19Nov2020: COVID test result re-requested. ML 03Dec2020 - Data will be entered upon receipt of medical records
2	Dec-03-2020 07:32:06 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	COVID Test was performed 02Nov2020 at ER. Records will be requested and data will be updated at that time. 19Nov2020: COVID test result re-requested. ML 03Dec2020 - Data will be entered upon receipt of medical records <hr/> Not Done
2	Nov-04-2020 07:46:03 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	COVID Test was performed 02Nov2020 at ER. Records will be requested and data will be updated at that time
2	Nov-03-2020 10:39:40 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	COVID Test was performed 02Nov2020 at ER. Records will be requested and data will be updated at that time <hr/> Unknown
2	Nov-03-2020 10:17:11 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Applicable

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Nov/03/2020

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: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
3	Dec-04-2020 11:59:18 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	COVID Test was performed 02Nov2020 at ER. Records will be requested and data will be updated at that time. 19Nov2020: COVID test result re-requested. ML 03Dec2020 - Data will be entered upon receipt of medical records
3	Dec-03-2020 07:32:06 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	COVID Test was performed 02Nov2020 at ER. Records will be requested and data will be updated at that time. 19Nov2020: COVID test result re-requested. ML 03Dec2020 - Data will be entered upon receipt of medical records <hr/> Not Done
3	Nov-04-2020 07:46:03 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	COVID Test was performed 02Nov2020 at ER. Records will be requested and data will be updated at that time
3	Nov-03-2020 10:39:40 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	COVID Test was performed 02Nov2020 at ER. Records will be requested and data will be updated at that time <hr/> Unknown
3	Nov-03-2020 10:17:11 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Applicable

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Nov/03/2020

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: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
4	Dec-04-2020 11:59:18 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	COVID Test was performed 02Nov2020 at ER. Records will be requested and data will be updated at that time. 19Nov2020: COVID test result re-requested. ML 03Dec2020 - Data will be entered upon receipt of medical records
4	Dec-03-2020 07:32:06 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	COVID Test was performed 02Nov2020 at ER. Records will be requested and data will be updated at that time. 19Nov2020: COVID test result re-requested. ML 03Dec2020 - Data will be entered upon receipt of medical records <hr/> Not Done
4	Nov-04-2020 07:46:03 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	COVID Test was performed 02Nov2020 at ER. Records will be requested and data will be updated at that time
4	Nov-03-2020 10:39:40 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	COVID Test was performed 02Nov2020 at ER. Records will be requested and data will be updated at that time <hr/> Unknown
4	Nov-03-2020 10:17:11 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Applicable

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Nov/03/2020

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: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
5	Dec-04-2020 11:59:18 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	COVID Test was performed 02Nov2020 at ER. Records will be requested and data will be updated at that time. 19Nov2020: COVID test result re-requested. ML 03Dec2020 - Data will be entered upon receipt of medical records
5	Dec-03-2020 07:32:06 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	COVID Test was performed 02Nov2020 at ER. Records will be requested and data will be updated at that time. 19Nov2020: COVID test result re-requested. ML 03Dec2020 - Data will be entered upon receipt of medical records <hr/> Not Done
5	Nov-04-2020 07:46:03 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	COVID Test was performed 02Nov2020 at ER. Records will be requested and data will be updated at that time
5	Nov-03-2020 10:39:40 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	COVID Test was performed 02Nov2020 at ER. Records will be requested and data will be updated at that time <hr/> Unknown
5	Nov-03-2020 10:17:11 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Applicable

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Nov/03/2020

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: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
6	Dec-04-2020 11:59:18 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	COVID Test was performed 02Nov2020 at ER. Records will be requested and data will be updated at that time. 19Nov2020: COVID test result re-requested. ML 03Dec2020 - Data will be entered upon receipt of medical records
6	Dec-03-2020 07:32:06 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	COVID Test was performed 02Nov2020 at ER. Records will be requested and data will be updated at that time. 19Nov2020: COVID test result re-requested. ML 03Dec2020 - Data will be entered upon receipt of medical records <hr/> Not Done
6	Nov-04-2020 07:46:03 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	COVID Test was performed 02Nov2020 at ER. Records will be requested and data will be updated at that time
6	Nov-03-2020 10:39:40 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	COVID Test was performed 02Nov2020 at ER. Records will be requested and data will be updated at that time <hr/> Unknown
6	Nov-03-2020 10:17:11 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Applicable

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Nov/03/2020

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: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
7	Dec-04-2020 11:59:18 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	COVID Test was performed 02Nov2020 at ER. Records will be requested and data will be updated at that time. 19Nov2020: COVID test result re-requested. ML 03Dec2020 - Data will be entered upon receipt of medical records
7	Dec-03-2020 07:32:06 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	COVID Test was performed 02Nov2020 at ER. Records will be requested and data will be updated at that time. 19Nov2020: COVID test result re-requested. ML 03Dec2020 - Data will be entered upon receipt of medical records <hr/> Not Done
7	Nov-04-2020 07:46:03 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	COVID Test was performed 02Nov2020 at ER. Records will be requested and data will be updated at that time
7	Nov-03-2020 10:39:40 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	COVID Test was performed 02Nov2020 at ER. Records will be requested and data will be updated at that time <hr/> Unknown
7	Nov-03-2020 10:17:11 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Applicable

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Nov/03/2020

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: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
8	Dec-04-2020 11:59:18 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	COVID Test was performed 02Nov2020 at ER. Records will be requested and data will be updated at that time. 19Nov2020: COVID test result re-requested. ML 03Dec2020 - Data will be entered upon receipt of medical records
8	Dec-03-2020 07:32:06 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	COVID Test was performed 02Nov2020 at ER. Records will be requested and data will be updated at that time. 19Nov2020: COVID test result re-requested. ML 03Dec2020 - Data will be entered upon receipt of medical records <hr/> Not Done
8	Nov-04-2020 07:46:03 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	COVID Test was performed 02Nov2020 at ER. Records will be requested and data will be updated at that time
8	Nov-03-2020 10:39:40 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	COVID Test was performed 02Nov2020 at ER. Records will be requested and data will be updated at that time <hr/> Unknown
8	Nov-03-2020 10:17:11 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Applicable

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Nov/03/2020

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: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
9	Dec-04-2020 11:59:18 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	COVID Test was performed 02Nov2020 at ER. Records will be requested and data will be updated at that time. 19Nov2020: COVID test result re-requested. ML 03Dec2020 - Data will be entered upon receipt of medical records
9	Dec-03-2020 07:32:06 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	COVID Test was performed 02Nov2020 at ER. Records will be requested and data will be updated at that time. 19Nov2020: COVID test result re-requested. ML 03Dec2020 - Data will be entered upon receipt of medical records <hr/> Not Done
9	Nov-04-2020 07:46:03 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	COVID Test was performed 02Nov2020 at ER. Records will be requested and data will be updated at that time
9	Nov-03-2020 10:39:40 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	COVID Test was performed 02Nov2020 at ER. Records will be requested and data will be updated at that time <hr/> Unknown
9	Nov-03-2020 10:17:11 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Applicable

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - Comments
on Nov/03/2020

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: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
Form	Nov-03-2020 10:47:22 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Records have been requested, all data will be updated once received

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1081

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

Subject No: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
Lora Morris	N/A	Jan-29-2021 11:40:26 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

James Fry	Approved	Jan-23-2021 11:55:05 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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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	Dec-03-2020 13:39:45 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

James Fry	Approved	Dec-03-2020 07:50:11 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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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.

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1081

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

Subject No: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

Marcel Lanton	N/A	Nov-19-2020 13:53:17 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:
N/A

Michael Butcher	Approved	Nov-17-2020 14:13:15 (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-03-2020 10:16:48 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:
N/A

Michael Butcher	Approved	Oct-13-2020 11:59:53 (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.

Tawnyn Ebner	N/A	Oct-01-2020 11:30:16 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:
N/A

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1081

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

Subject No: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

James Fry	Approved	Sep-14-2020 16:17:12 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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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: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1081

Subject No: 10811036

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
Aug-13-2020 14:26:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn 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
Aug-13-2020 14:26:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811036

Generated By: pfe.lewissc

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
Aug-13-2020 14:28:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-13-2020 14:28:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	<u>Data Entry:</u> OBTAINED Date Written Consent Obtained Aug/13/2020	Transcription Error
Aug-13-2020 14:27:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date Informed Consent Obtained is not the same as the Date of Visit. Please correct as necessary.
Aug-13-2020 14:26:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	<u>Data Entry:</u> OBTAINED Date Written Consent Obtained Aug/12/2020	Initial Entry

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001**Visit:** COHORT_SELECTION**Form Version:** 06-Jul-2020 21:55**Site No:** 1081**Subject No:** 10811036**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[Back to Form](#)**1. Subject ID**

Date	Location	User	Value	Reason
Sep-02-2020 07:49:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Closed	confirmed event added in AE CRF
Sep-02-2020 07:12:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Query 2: Answered	Confirmed as serious. Awaiting medical records report for appendicitis event for subject. Patient recovering and discharged from hospital.
Sep-01-2020 07:39:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Opened	SAE RECON:AER#2020336178 APPENDICITIS(onset date:21Aug2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Sep-01-2020 07:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	revised query text. new query issued
Sep-01-2020 07:38:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON:AER#2020326724 APPENDICITIS(onset date:21Aug2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Aug-13-2020 14:26:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10811036	Item copied from previous form

2. Birth Date:

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Aug-13-2020 14:25:58 (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
Aug-13-2020 14:26:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-13-2020 14:26:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 14:26:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BLACK OR AFRICAN AMERIC AN	Initial Entry

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811036

Generated By: pfe.lewissc

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
Aug-13-2020 14:27:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Aug/13/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811036

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
Aug-13-2020 14:27:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Aug/13/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-13-2020 14:27:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-13-2020 14:27:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: COMPLETED	Initial Entry

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811036

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - 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.a

Date	Location	User	Value	Reason
Aug-13-2020 16:30:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: Line/MH 1 Number: Medical History Term: Asthma-Stable, No change within 6 weeks of screening Start Date: UNK/UNK/1980 : Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-13-2020 16:30:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 16:30:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Asthma-Stable, No change within 6 weeks of screening	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Aug-13-2020 16:30:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/1980	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-13-2020 16:30:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811036

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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

I.b

Date	Location	User	Value	Reason
Aug-13-2020 16:30:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 2 : Medical History T Seasonal Allergies: Start Date: UNK/UNK/1980 Ongoing: YES	Initial Entry

I.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-13-2020 16:30:38 (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
Aug-13-2020 16:30:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Seasonal Allergies	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Aug-13-2020 16:30:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/1980	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Aug-13-2020 16:30:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

I.c

Date	Location	User	Value	Reason
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090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811036

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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

Aug-17-2020 08:58:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Line/MH Number: 3 Medical History Term: Bilateral Tubal Ligation Start Date: UNK/UNK/1991 Ongoing: NO End Date: UNK/UNK/1991	New Information
Aug-13-2020 16:31:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Term: Bilateral Tubal Ligation Start Date: UNK/UNK/1991 Ongoing: YES	Initial Entry

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811036

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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

I.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-13-2020 16:31:04 (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
Aug-13-2020 16:31:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Bilateral Tubal Ligation	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Aug-13-2020 16:31:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/1991	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 10:42:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Closed	Response satisfies query
Aug-17-2020 08:58:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Aug-17-2020 08:58:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO End Date: UNK/UNK/1991	New Information
Aug-17-2020 08:50:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	GPD Clin: Please review the Ongoing status of this surgery/procedure and update as appropriate

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811036

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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

Aug-13-2020 16:31:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry
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I.d

Date	Location	User	Value	Reason
Aug-17-2020 08:35:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Line/MH Number 4 er: Medical History C-Section Term: Start Date: UNK/UNK/19 91 Ongoing: NO End Date: UNK/UNK/ 1991	Transcription Error
Aug-13-2020 16:31:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 4 : Medical History T C-Section erm: Start Date: UNK/UNK/1 991 Ongoing: YES	Initial Entry

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811036

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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

I.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-13-2020 16:31:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 16:31:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: C-Section	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Aug-13-2020 16:31:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/1991	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 10:42:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Closed	Response satisfies query
Aug-17-2020 08:35:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Aug-17-2020 08:35:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: NO End Date: UNK/UNK/1991	Transcription Error
Aug-17-2020 07:44:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	GPD Clin: Please review the Ongoing status of this surgery/procedure and update as appropriate

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811036

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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

Aug-13-2020 16:31:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry
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I.e

Date	Location	User	Value	Reason
Dec-03-2020 13:39:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Term: COPD Start Date: UNK/UNK/2018 Ongoing: YES	Initial Entry

I.e Line/MH Number:

Date	Location	User	Value	Reason
Dec-03-2020 13:39:45 (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
Dec-03-2020 13:39:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: COPD	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Dec-03-2020 13:39:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: UNK/UNK/2018	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Dec-03-2020 13:39:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1081

Subject No: 10811036

Generated By: pfe.lewissc

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
Aug-13-2020 16:32:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> Aug/13/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-13-2020 16:32:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> 160.2	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-13-2020 16:32:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-13-2020 16:32:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> 62.5	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-13-2020 16:32:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-13-2020 16:32:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 28.8	Initial Entry

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1081

Subject No: 10811036

Generated By: pfe.levisse

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

7.a

Date	Location	User	Value	Reason
Aug-13-2020 16:32:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Record Identifier:: 1 Temperature: 98.2 Temperature Unit: F Temperature Location: FOREHEAD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-13-2020 16:32:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-13-2020 16:32:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: 98.2	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-13-2020 16:32:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-13-2020 16:32:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: FOREHEAD	Initial Entry

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811036

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
Aug-13-2020 16:32:53 (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
Aug-13-2020 16:32:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-23-2020 11:20:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Closed	PD to be reported
Oct-23-2020 10:03:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	No other information available, missed pregnancy tests will be documented as deviations
Oct-22-2020 17:56:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	CLINQUERY: Is there any other information available on the subject's childbearing potential status that may be added to the MH listing? (no pregnancy testing)
Aug-13-2020 16:32:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Aug/13/2020	Initial Entry

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Aug-13-2020 16:32:53 (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
Aug-13-2020 16:32:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-13-2020 16:32:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin in Beta_PX113 Result:: Not Done:: NOT DONE	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-13-2020 16:32:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-13-2020 16:32:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
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090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

Aug-13-2020 16:32:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NOT DONE	Initial Entry
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811036

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
Aug-13-2020 16:34:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Aug/13/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-13-2020 16:34:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: 47787	Initial Entry

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1081**Subject No:** 10811036**Generated By:** pfe.lewissc**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-13-2020 16:41:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-13-2020 16:41:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-13-2020 16:41:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-13-2020 16:41:36 (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.
Aug-13-2020 16:41:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Aug/13/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-13-2020 16:41:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BP1J6N	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: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Aug-13-2020 16:41:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> BP1J6N	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-13-2020 16:41:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BP1J6P	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-13-2020 16:41:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> BP1J6P	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-13-2020 16:42:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BP1J6R	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-13-2020 16:42:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> BP1J6R	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-13-2020 16:42:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BPHZG4	Initial Entry

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (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: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

5.d Sample ID

Date	Location	User	Value	Reason
Aug-13-2020 16:42:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BPHZG4	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-13-2020 16:42:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BPHZG5	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-13-2020 16:42:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BPHZG5	Initial Entry

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (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:** 10811036**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
Aug-13-2020 15:31:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-13-2020 15:31:31 (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
Aug-13-2020 15:31:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-13-2020 15:31:31 (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.
Aug-13-2020 15:31:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Aug/13/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-13-2020 15:31:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BP1J5Y	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811036

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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

5.a Sample ID

Date	Location	User	Value	Reason
Aug-13-2020 15:31:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BP1J5Y	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811036

Generated By: pfe.lewissc

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
Aug-13-2020 16:37:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-13-2020 16:34:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-13-2020 16:34:22 (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
Aug-13-2020 16:34:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Aug/13/2020 15:09	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-13-2020 16:34:22 (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
Aug-13-2020 16:34:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: RIGHT	Initial Entry

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811036

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

7. Route:

Date	Location	User	Value	Reason
Aug-13-2020 16:34:22 (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
Aug-13-2020 16:34:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 16:34:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1081

Subject No: 10811036

Generated By: pfe.lewissc

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-09-2020 09:35:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Premraj Bhoyar (pfe.bhoyap)	Query 1: Closed	Query closed per site response.
Sep-08-2020 07:29:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Query 1: Answered	Subject mistakenly completed weekly illness diary instead of reactogenicity diary for Vax 2
Sep-07-2020 08:26:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Premraj Bhoyar (pfe.bhoyap)	Query 1: Opened	eDiary: Per Trial Max Attributes, Vaccination eDiary is needed and REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT is 'Yes'. However eDiary records for Vax 2 is not available. Please verify and clarify in query response.
Aug-13-2020 16:34:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES - REACTOGENICITY E- DIARY COLLECTED FOR TH IS SUBJECT	Initial Entry

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811036

Generated By: pfe.lewissc

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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1. Date of Visit

Date	Location	User	Value	Reason
Sep-03-2020 16:33:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sep/3/2020	Initial Entry

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811036**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Sep-03-2020 16:33:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-03-2020 16:33:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptom:: FE VE R Were fever or systemic symp toms present on the last day the Subject Diary was compl eted?: NO	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Sep-03-2020 16:33:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 16:33:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-03-2020 16:33:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptom:: FAT IG	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

			UE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	
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2.b Symptom:

Date	Location	User	Value	Reason
Sep-03-2020 16:33:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 16:33:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-03-2020 16:33:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptom:: HEA DA CHE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811036**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11**2.c Symptom:**

Date	Location	User	Value	Reason
Sep-03-2020 16:33:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 16:33:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-03-2020 16:33:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptom:: CH IL LS Were fever or systemic symp NO toms present on the last day the Subject Diary was compl eted?:	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Sep-03-2020 16:33:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 16:33:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

Sep-03-2020 16:33:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptom:: VO MIT ING Were fever or systemic sym ptoms present on the last d ay the Subject Diary was co mpleted?:	Initial Entry
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2.e Symptom:

Date	Location	User	Value	Reason
Sep-03-2020 16:33:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 16:33:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Sep-03-2020 16:33:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic sym ptoms present on the last d ay the Subject Diary was co mpleted?:	Initial Entry

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001
Visit: V2_VAX2_L
Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History
Form Version: 30-Jul-2020 21:30
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1081
Site Name: (1081) Sterling Research Group - Mt. Auburn
Subject No: 10811036
Subject Initials: ---
Generated By: pfe.levisse
Generated Time (GMT): 29-Mar-2021 10:11

2.f Symptom:

Date	Location	User	Value	Reason
Sep-03-2020 16:33:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 16:33:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-03-2020 16:33:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptom:: NEW OR WORSE ED MUSC LE PAIN Were fever or systemi NO c symptoms present o n the last day the Sub ject Diary was comple ted?::	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Sep-03-2020 16:33:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NEW OR WORSE NED MUSCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 16:33:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

2.h

Date	Location	User	Value	Reason
Sep-03-2020 16:33:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptom:: NEW OR WORSE NED JOI NT PAIN Were fever or systemi c symptoms present o n the last day the Subj ect Diary was complet ed?: NO	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Sep-03-2020 16:33:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NEW OR WORSE NED JOI NT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 16:33:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-03-2020 16:33:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-03-2020 16:33:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: RIGHT	Initial Entry

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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5.a

Date	Location	User	Value	Reason
Sep-03-2020 16:33:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactions NO present on the last day the S ubject Diary was completed ?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-03-2020 16:33:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 16:33:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-03-2020 16:33:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reaction NO s present on the last day th e Subject Diary was compl eted?:	Initial Entry

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-03-2020 16:33:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 16:33:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-03-2020 16:33:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Injection Site Reaction:: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?:	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-03-2020 16:33:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 16:33:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1081

Subject No: 10811036

Generated By: pfe.levisse

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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1. Date:

Date	Location	User	Value	Reason
Sep-03-2020 16:34:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sep/3/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-03-2020 16:34:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Record Identifier:: 1 Temperature: 98.0 Temperature Unit: F Temperature Locat ion:: ORAL CAVI TY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-03-2020 16:34:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-03-2020 16:34:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: 98.0	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-03-2020 16:34:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: F	Initial Entry

2.a Temperature Location:

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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1081

Subject No: 10811036

Generated By: pfe.levisse

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: ---

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Date	Location	User	Value	Reason
Sep-03-2020 16:34:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: ORAL CAVITY	Initial Entry

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811036**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
Sep-03-2020 16:34:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-03-2020 16:34:32 (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
Sep-03-2020 16:34:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-03-2020 16:34:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-03-2020 16:34:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-03-2020 16:34:32 (UTC-05:00) Eastern	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

Time (US & Canada)			Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable	
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-03-2020 16:34:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-03-2020 16:34:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-03-2020 16:34:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-03-2020 16:34:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (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:** 10811036**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
Sep-03-2020 16:56:21 (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-03-2020 16:56:21 (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-03-2020 17:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-03-2020 16:56:21 (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-03-2020 16:56:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Sep/3/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-03-2020 17:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: Sample ID: BP97NC	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811036

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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

5.a Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 17:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BP97NC	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811036

Generated By: pfe.lewissc

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-03-2020 16:35:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-03-2020 16:35:10 (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-03-2020 16:35:10 (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-03-2020 16:35:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sep/3/2020 15:38	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-03-2020 16:35:10 (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-03-2020 16:35:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: RIGHT	Initial Entry

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811036

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

7. Route:

Date	Location	User	Value	Reason
Sep-03-2020 16:35:10 (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-03-2020 16:35:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION 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-03-2020 16:35:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES	Initial Entry

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811036

Generated By: pfe.lewissc

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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1. Date of Visit

Date	Location	User	Value	Reason
Oct-01-2020 11:51:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: Oct/1/2020	Initial Entry

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811036**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Oct-01-2020 11:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-01-2020 11:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom:: FE VE R Were fever or systemic symptoms present on the last day the Subject Diary was completed?: N O	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Oct-01-2020 11:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 11:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Oct-01-2020 11:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom:: FA TIG	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

			UE	
Were fever or systemic symptoms present on the last day the Subject Diary was completed?:				

2.b Symptom:

Date	Location	User	Value	Reason
Oct-01-2020 11:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 11:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Oct-01-2020 11:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811036**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11**2.c Symptom:**

Date	Location	User	Value	Reason
Oct-01-2020 11:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 11:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Oct-01-2020 11:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom:: CH IL LS Were fever or systemic sym ptoms present on the last d ay the Subject Diary was co mpleted?: NO	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Oct-01-2020 11:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 11:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

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Subject Initials: ---

Generated By: pfe.levisse

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

Oct-01-2020 11:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom:: VO MIT ING Were fever or systemic sy mptoms present on the las t day the Subject Diary wa s completed?:	Initial Entry
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2.e Symptom:

Date	Location	User	Value	Reason
Oct-01-2020 11:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 11:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Oct-01-2020 11:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic sy mptoms present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811036**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11**2.f Symptom:**

Date	Location	User	Value	Reason
Oct-01-2020 11:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 11:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Oct-01-2020 11:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom:: NEW OR WORSE NED MUS CLE PAI N Were fever or system NO ic symptoms present on the last day the Su bject Diary was com pleted?:	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Oct-01-2020 11:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NEW OR WORSE NED MUSCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 11:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

2.h

Date	Location	User	Value	Reason
Oct-01-2020 11:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom:: NEW OR WORSE NED JOI NT PAIN Were fever or systemi NO c symptoms present o n the last day the Sub ject Diary was compl eted?:	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Oct-01-2020 11:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NEW OR WORSE NED JOINT P AIN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 11:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Oct-01-2020 11:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Oct-01-2020 11:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: RIGHT	Initial Entry

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

5.a

Date	Location	User	Value	Reason
Oct-01-2020 11:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-01-2020 11:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 11:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-01-2020 11:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811036**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11**5.b Injection Site Reaction:**

Date	Location	User	Value	Reason
Oct-01-2020 11:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 11:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-01-2020 11:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Injection Site Reaction PAIN AT INJECTION SITE : Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-01-2020 11:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 11:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	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:** 10811036**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-01-2020 11:30:16 (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-01-2020 11:30:16 (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-01-2020 11:30:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-01-2020 11:30:16 (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-01-2020 11:30:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Oct/1/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-01-2020 11:30:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: Sample ID: BRTXRX	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Oct-01-2020 11:30:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	<u>Data Entry:</u> BRTXRX	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-01-2020 11:30:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BRTXRY	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-01-2020 11:30:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	<u>Data Entry:</u> BRTXRY	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-01-2020 11:30:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BP1HT3	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-01-2020 11:30:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	<u>Data Entry:</u> BP1HT3	Initial Entry

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Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811036

Generated By: pfe.lewissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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I. Date of Visit

Date	Location	User	Value	Reason
Mar-04-2021 16:09:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Mar/4/2021	Initial Entry

Header Text: c4591001

Visit: V4_MONTH6_L

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

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Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811036

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Mar-04-2021 16:10:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-04-2021 16:10:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-04-2021 16:10:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-04-2021 16:10:14 (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.
Mar-04-2021 16:10:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Mar/4/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-04-2021 16:10:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BSFNXS	Initial Entry

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811036

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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

5.a Sample ID

Date	Location	User	Value	Reason
Mar-04-2021 16:10:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> BSFNXS	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-04-2021 16:10:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BSFNXT	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-04-2021 16:10:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> BSFNXT	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-04-2021 16:10:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BRM4MZ	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-04-2021 16:10:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> BRM4MZ	Initial Entry

5.d

Date	Location	User	Value	Reason
Mar-04-2021 16:11:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BRM4N0	Initial Entry

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811036

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
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

5.d Sample ID

Date	Location	User	Value	Reason
Mar-04-2021 16:11:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BRM4N0	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Nov/03/2020**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:** 10811036**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)***1. Date of Visit***

Date	Location	User	Value	Reason
Nov-03-2020 14:20:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-03-2020 10:38:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Nov-03-2020 10:16:46 (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.
Nov-03-2020 10:16:46 (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 missing. Please review and update as appropriate.
Nov-03-2020 10:16:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Nov/3/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Nov-03-2020 10:16:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: COVID_A	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1081**Subject No:** 10811036**Generated By:** pfe.lewissc**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Nov-03-2020 10:38:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Nov/3/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Dec-03-2020 14:51:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Oct/19/2020	New Information
Nov-03-2020 10:38:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Oct/27/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Dec-07-2020 10:52:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO Date of Last Symptom Resolved : Nov/9/2020	New Information
Nov-03-2020 10:38:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Nov-03-2020 10:38:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry

4.a Symptoms:

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1081**Subject No:** 10811036**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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

Date	Location	User	Value	Reason
Nov-03-2020 10:38:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Nov-03-2020 10:38:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Nov-03-2020 10:38:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom P YES resent:	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Nov-03-2020 10:38:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Nov-03-2020 10:38:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

4.c

Date	Location	User	Value	Reason
Dec-03-2020 14:36:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms: NEW OR INCREASED SHORTNESS OF BREATH	New Information

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

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: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

			REATH Symptom Present: YES	
Nov-03-2020 10:38:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: NO	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Nov-03-2020 10:38:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Dec-03-2020 14:36:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	New Information
Nov-03-2020 10:38:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Nov-03-2020 10:38:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1081**Subject No:** 10811036**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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**4.d Symptoms:**

Date	Location	User	Value	Reason
Nov-03-2020 10:38:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Nov-03-2020 10:38:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Nov-03-2020 10:38:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom NEW OR INCREAS s: ED MUSCLE PAIN Symptom NO Present:	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Nov-03-2020 10:38:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NEW OR INCREASED MUSCL E PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Nov-03-2020 10:38:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Nov-03-2020 10:38:31 (UTC-05:00) Eastern	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

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: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

Time (US & Canada)			Symptoms NEW LOSS OF TASTE OR SMELL Symptom Present: NO
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4.f Symptoms:

Date	Location	User	Value	Reason
Nov-03-2020 10:38:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Nov-03-2020 10:38:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Nov-03-2020 10:38:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NEW OR INCREASED SORE THROAT Symptom Present: NO	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Nov-03-2020 10:38:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Nov-03-2020 10:38:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

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: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

4.h

Date	Location	User	Value	Reason
Nov-03-2020 10:38:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms: DIARRHEA Symptom Present: NO	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Nov-03-2020 10:38:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Nov-03-2020 10:38:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Dec-03-2020 14:38:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms: VOMITING Symptom Present: YES	New Information
Nov-03-2020 10:38:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms: VOMITING Symptom Present: NO	Initial Entry

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1081**Subject No:** 10811036**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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**4.i Symptoms:**

Date	Location	User	Value	Reason
Nov-03-2020 10:38:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Dec-03-2020 14:38:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	New Information
Nov-03-2020 10:38:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-03-2020 10:38:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms - Other: Chest Tightness	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Nov-03-2020 10:38:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Chest Tightness	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-03-2020 14:36:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms - Other: Nasal Congestion	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1081**Subject No:** 10811036**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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**5.b Symptoms - Other Text:**

Date	Location	User	Value	Reason
Dec-03-2020 14:36:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Nasal Congestion	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-03-2020 14:36:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms - Other: Chest Congestion	Initial Entry

5.c Symptoms - Other Text:

Date	Location	User	Value	Reason
Dec-03-2020 14:36:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Chest Congestion	Initial Entry

5.d

Date	Location	User	Value	Reason
Dec-03-2020 14:38:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms - Other: Sputum Production	Initial Entry

5.d Symptoms - Other Text:

Date	Location	User	Value	Reason
Dec-03-2020 14:38:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sputum Production	Initial Entry

5.e

Date	Location	User	Value	Reason
Dec-03-2020 14:38:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms - Other: Nausea	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

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: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

5.e Symptoms - Other Text:

Date	Location	User	Value	Reason
Dec-03-2020 14:38:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Nausea	Initial Entry

5.f

Date	Location	User	Value	Reason
Dec-03-2020 14:54:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms - Other: Wheezing	Initial Entry

5.f Symptoms - Other Text:

Date	Location	User	Value	Reason
Dec-03-2020 14:54:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Wheezing	Initial Entry

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020 **Form:** MICROBIOLOGY SPECIMEN - Audit Trail

Form Version: 06-Jul-2020 21:54

Form Status:

Site No: 1081

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

Subject No: 10811036

Subject Initials: ---

Generated By: pfe.levissc

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

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Date	Location	User	Value	Reason
Nov-05-2020 12:19:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Nov/03/2020

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: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

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I. Actual Date of Collection:

Date	Location	User	Value	Reason
Dec-04-2020 12:02:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Nov/2/2020	Initial Entry
Dec-04-2020 11:59:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry
Dec-03-2020 07:32:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Done	Initial Entry
Dec-03-2020 07:31:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Changed Information
Nov-05-2020 12:19:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Nov/2/2020	Initial Entry
Nov-04-2020 09:26:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gbenga Akinkunmi (pfe.akinkg)	Query 1: Closed	Response satisfies query
Nov-04-2020 07:46:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	Removed 'unknown' since records have still not been received. Data will be updated upon receipt of records
Nov-04-2020 07:46:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry
Nov-04-2020 06:11:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Teena Patra (pfe.patrat02)	Query 1: Opened	DM: Please confirm if Comment entered needs to be recorded in appropriate data point. Please confirm and correct else clarify, thank you.

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
on Nov/03/2020

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: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

Nov-03-2020 10:39:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Unknown	Initial Entry
Nov-03-2020 10:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Applicable	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Dec-04-2020 12:02:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: SWABBED MATERIAL	Initial Entry
Dec-04-2020 11:59:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry
Dec-03-2020 09:04:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 2: Closed	Response satisfies query
Dec-03-2020 07:32:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 2: Answered	Page marked as not done per query response
Dec-03-2020 07:32:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Done	Initial Entry
Nov-30-2020 14:05:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Behnaz Yousefzadeh- Khiabani (pfe.youseb01)	Query 2: Reissued:Opened	Response to Data item#2,3 and 7 are missing. Please review and update the data if available with site and respond to the query once data is updated. Thank you.
Nov-17-2020 17:08:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pamela Benne prod (pfe.bennep07)	Query 2: Reissued:Candidate	We still have not received the records. Data will be updated upon receipt of those

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
on Nov/03/2020**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:** 10811036**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11

				records
Nov-17-2020 15:30:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 2: Answered	We still have not received the records. Data will be updated upon receipt of those records
Nov-12-2020 00:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 2: Reissued:Opened	DM : Response to Data item#2,3 and 7 are missing. Please review and update the data if available with site and respond to the query once data is updated. Thank you.
Nov-11-2020 12:12:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 2: Answered	It is out of our hand to give you a date. We hope to have it asap however it seems like most places are taking 1-2 months to get records to us
Nov-11-2020 11:48:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 2: Reissued:Opened	In order to put this issue on hold we need an date (or estimated date) as to when the missing information is available. Please a DATE as to when we can expect the missing information. Thank you!
Nov-07-2020 16:46:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 2: Reissued:Candidate	DM keep this candidate query open until medical records come in and data can be updated

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
on Nov/03/2020**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:** 10811036**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11

				so issue will not get lost
Nov-07-2020 14:12:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 2: Answered	NO data available. per site monitor, only the available data was to be entered until records will be received, at which time, data will be updated
Nov-07-2020 13:18:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cheryl Haseman (pfe.hasemc)	Query 2: Opened	DM: The response for Data item#2,3 and 7 are missing. Kindly review and update.
Nov-07-2020 13:17:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cheryl Haseman (pfe.hasemc)	Query 1: Closed	Will create better query.
Nov-07-2020 06:19:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Vijay Venugopal (pfe.venugv04)	Query 1: Reissued:Candidate	Site awaiting medical records to update data.
Nov-06-2020 11:57:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	This data is currently unknown, no records have been received. Known data was entered at the request of the site monitor. All other data will be updated upon receipt of the medical records
Nov-06-2020 03:06:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rajashekhar Reddy (pfe.reddy51)	Query 1: Opened	DM: The response for Data item#2,3 and 7 are missing. Kindly review and update.
Nov-04-2020 07:46:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Nov/03/2020**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:** 10811036**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11

Nov-03-2020 10:39:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Unknown	Initial Entry
Nov-03-2020 10:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Applicable	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Dec-04-2020 12:02:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NASOPHARYNX	Initial Entry
Dec-04-2020 11:59:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry
Dec-03-2020 07:32:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Done	Initial Entry
Nov-04-2020 07:46:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry
Nov-03-2020 10:39:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Unknown	Initial Entry
Nov-03-2020 10:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Applicable	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Dec-04-2020 12:02:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYNDR OME CORONAVIRUS 2	Initial Entry
Dec-04-2020 11:59:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Nov/03/2020**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:** 10811036**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11

Dec-03-2020 07:32:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Done	Initial Entry
Dec-03-2020 07:31:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Changed Information
Nov-05-2020 12:19:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYNDR OME CORONAVIRUS 2	Initial Entry
Nov-04-2020 07:46:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry
Nov-03-2020 10:39:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Unknown	Initial Entry
Nov-03-2020 10:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Applicable	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Dec-04-2020 12:02:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC TES T	Initial Entry
Dec-04-2020 11:59:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry
Dec-03-2020 07:32:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Done	Initial Entry
Dec-03-2020 07:31:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Changed Information

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Nov/03/2020

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: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

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5. Device Type:

Date	Location	User	Value	Reason
Nov-05-2020 12:19:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC TE ST	Initial Entry
Nov-04-2020 07:46:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry
Nov-03-2020 10:39:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Unknown	Initial Entry
Nov-03-2020 10:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Applicable	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Dec-04-2020 12:02:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: OTHER	Initial Entry
Dec-04-2020 11:59:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry
Dec-03-2020 07:32:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Done	Initial Entry
Dec-03-2020 07:30:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Changed Information
Nov-05-2020 12:19:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: OTHER	Initial Entry
Nov-04-2020 07:46:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Nov/03/2020

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: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

Nov-03-2020 10:39:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Unknown	Initial Entry
Nov-03-2020 10:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Applicable	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Dec-04-2020 12:02:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NEGATIVE	Initial Entry
Dec-04-2020 11:59:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry
Dec-03-2020 07:32:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Done	Initial Entry
Nov-04-2020 07:46:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry
Nov-03-2020 10:39:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Unknown	Initial Entry
Nov-03-2020 10:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Applicable	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Dec-04-2020 12:02:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Per medical records- "this test has been authorized by the FDA under EUA. Test performed at UC Health Hospital in the UC Health Lab	Initial Entry
Dec-04-2020 11:59:18 (UTC-05:00) Eastern	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Nov/03/2020

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Site No: 1081

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

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Subject Initials: ---

Generated By: pfe.levisse

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

Time (US & Canada)				
Dec-03-2020 07:32:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Done	Initial Entry
Dec-03-2020 07:31:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Changed Information
Nov-05-2020 12:19:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: all missing data will be updated u pon receipt of records	Initial Entry
Nov-04-2020 07:46:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry
Nov-03-2020 10:39:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Unknown	Initial Entry
Nov-03-2020 10:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Applicable	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Dec-04-2020 12:02:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NALT Unknown	Initial Entry
Dec-04-2020 11:59:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry
Dec-03-2020 07:32:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Done	Initial Entry
Dec-03-2020 07:31:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Changed Information
Nov-05-2020 12:19:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NALT Unknown	Initial Entry

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
on Nov/03/2020

Form Version: 06-Jul-2020 21:54

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Site No: 1081

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

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Generated By: pfe.levisse

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

Nov-04-2020 07:46:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry
Nov-03-2020 10:39:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Unknown	Initial Entry
Nov-03-2020 10:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811036

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - 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. Data Origin

Date	Location	User	Value	Reason
Nov-03-2020 10:46:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-03-2020 10:46:19 (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
Nov-03-2020 10:46:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-03-2020 10:46:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: On site swab performed	Initial Entry

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit
on Nov/03/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1081**Subject No:** 10811036**Generated By:** pfe.lewissc**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Nov-03-2020 14:20:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-03-2020 14:20:10 (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
Nov-03-2020 14:20:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-03-2020 14:20:10 (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.
Nov-03-2020 14:20:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Nov/3/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-03-2020 14:20:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BP1HZ9	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Nov/03/2020

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: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Nov-03-2020 14:20:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BP1HZ9	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/03/2020

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: 10811036

Subject Initials: ---

Generated By: pfe.lewissc

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

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1.a

Date	Location	User	Value	Reason
Nov-03-2020 10:46:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

1.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-03-2020 10:46:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: SPECIALIST	Initial Entry

1.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-03-2020 10:46:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

1.b

Date	Location	User	Value	Reason
Nov-03-2020 10:46:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: YES Number of Visits or Contacts: 1	Initial Entry

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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/03/2020**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:** 10811036**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11***1.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-03-2020 10:46:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: EMERGENCY ROOM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-03-2020 10:46:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

1.c

Date	Location	User	Value	Reason
Nov-03-2020 10:46:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN N Occurrence of Visits or Contacts: NO	Initial Entry

1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-03-2020 10:46:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-03-2020 10:46:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

1.d

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/03/2020

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: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Nov-03-2020 10:46:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: NO	Initial Entry

1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-03-2020 10:46:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-03-2020 10:46:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Nov-03-2020 10:46:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/03/2020**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:** 10811036**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11***1.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-03-2020 10:46:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-03-2020 10:46:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

1.f

Date	Location	User	Value	Reason
Nov-03-2020 10:46:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Type of Practitioner: OTHER Occurrence of Visits or Contacts: NO	Initial Entry

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-03-2020 10:46:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-03-2020 10:46:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

3. Has the subject been hospitalized due to potential COVID-19 illness?

Date	Location	User	Value	Reason
Nov-03-2020 10:46:43 (UTC-05:00) Eastern	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
on Nov/03/2020

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: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

Time (US & Canada)				
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090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History
on Nov/03/2020**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:** 10811036**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Nov-03-2020 10:47:00 (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
Dec-11-2020 02:02:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Clo sed	Discrepancy has been closed.
Dec-04-2020 11:54:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Ans wered	How would I 'submit separately'? This is all under the single illness visit? Please advise, thank you
Dec-03-2020 17:29:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Op ened	Multiple concepts in the term COPD EXACERBATION & UPPER RESPIRATORY INFECTION. Split the term into COPD EXACERBATION and UPPER RESPIRATORY INFECTION and submit separately. Thank you.
Dec-03-2020 14:55:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES <i>Respiratory Illness Dia gnosis:</i>	New Information

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: ILLNESS DETAILS - eCRF Audit Trail History on Nov/03/2020

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: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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			COPD Exacerbation & upper respiratory infection	
			Date of Diagnosis: Nov/2/2020	
Dec-03-2020 14:35:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES <i>Respiratory Illness Diagnosis:</i> COPD Exacerbation Date of Diagnosis: Nov/2/2020	Changed Information
Nov-03-2020 10:47:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-03-2020 10:47:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: 1	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Audit Trail
on Nov/03/2020

Form Version: 06-Jul-2020 21:53

Form Status:

Site No: 1081

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

Subject No: 10811036

Subject Initials: ---

Generated By: pfe.lewissc

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

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Date	Location	User	Value	Reason
Jan-29-2021 11:40:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: IMAGING - eCRF Audit Trail History on Nov/03/2020

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: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Date of Assessment:

Date	Location	User	Value	Reason
Feb-03-2021 13:21:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nicholas Roosa (pfe.roosan)	Query 1: Closed	Response satisfies query
Jan-29-2021 11:40:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Jan-29-2021 11:40:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Nov/2/2020	Changed Information
Jan-26-2021 13:53:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nicholas Roosa (pfe.roosan)	Query 1: Opened	Per source, chest x-ray completed on 02Nov2020. Please enter details as applicable.

2. Location of Assessment:

Date	Location	User	Value	Reason
Jan-29-2021 11:41:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: CHEST	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Jan-29-2021 11:41:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: X-RAY	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Jan-29-2021 11:41:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NORMAL	Initial Entry

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Dec/07/2020

Form: DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit
Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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

Subject No: 10811036

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Date of Visit

Date	Location	User	Value	Reason
Dec-07-2020 10:52:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Dec/7/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Dec-07-2020 10:52:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: COVID_A1	Initial Entry

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled
Visit on Dec/07/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1081**Subject No:** 10811036**Generated By:** pfe.lewissc**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
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[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Dec-07-2020 14:04:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-07-2020 14:04:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-07-2020 14:05:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-07-2020 14:04:54 (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.
Dec-07-2020 14:04:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Dec/7/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-07-2020 14:05:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: Sample ID: BS64RW	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Dec/07/2020

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Dec-07-2020 14:05:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> BS64RW	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-07-2020 14:05:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BS64RX	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-07-2020 14:05:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> BS64RX	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-07-2020 14:05:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BKN9N4	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-07-2020 14:05:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> BKN9N4	Initial Entry

5.d

Date	Location	User	Value	Reason
Dec-07-2020 14:05:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BKN9N5	Initial Entry

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Dec/07/2020

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
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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: 10811036

Subject Initials: ---

Generated By: pfe.levisse

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

5.d Sample ID

Date	Location	User	Value	Reason
Dec-07-2020 14:05:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BKN9N5	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811036

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-01-2020 11:52:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Oct/1/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-01-2020 11:52:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-01-2020 11:52:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: COMPLETED	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811036

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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

Subject Initials: ---

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Date	Location	User	Value	Reason
Sep-01-2020 16:38:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811036

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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Subject Initials: ---

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

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Date	Location	User	Value	Reason
Dec-03-2020 14:15:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Form Deleted	this event is captured in the illness visit
Nov-23-2020 10:00:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Form Created	

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811036

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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

Subject Initials: ---

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Date	Location	User	Value	Reason
Dec-11-2020 12:08:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1081

Subject No: 10811036

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - 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. Category:

Date	Location	User	Value	Reason
Sep-01-2020 16:38:24 (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
Sep-01-2020 16:38:24 (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
Sep-01-2020 16:38:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Appendicitis	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-01-2020 16:44:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Aug/21/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-01-2020 16:46:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO End Date Time: Aug/23/2020 UNK:UNK	New Information
Sep-01-2020 16:38:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1081

Subject No: 10811036

Generated By: pfe.levisse

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Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-01-2020 16:44:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: 3	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-05-2020 14:51:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Closed	Query closed; will follow for SAE update with the requested COVID test info
Nov-04-2020 13:52:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 3: Answered	this has been noted in the most recent SAE update, as of 04Nov2020
Nov-04-2020 11:59:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Reissued:Opened	Clinical - Thank you. Please document in SAE report that you are awaiting medical records to determine if a COVID test was performed (DMC request)
Nov-04-2020 09:09:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 3: Answered	It is still unknown if COVID testing was performed. Still awaiting records. Data will be updated once records are received. Please clarify if 'unknown if COVID testing was performed at time of

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1081**Subject No:** 10811036**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - 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

				hospitalization' needs to be added to SAE form
Oct-25-2020 21:30:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Opened	COVID testing has not been reported in the SAE submitted to safety. Please submit a follow-up SAE form [#2020336178] to provide whether COVID testing was performed (yes/no) and if yes, the results.
Sep-02-2020 07:36:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-01-2020 16:41:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Sep-01-2020 16:41:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO	Changed Information

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			<p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	
Sep-01-2020 16:38:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Is this adverse event serious?' is reported 'Yes', but at least one seriousness criteria is missing. Please review and update as appropriate.
Sep-01-2020 16:38:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Appendicitis : Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Sep-01-2020 16:38:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<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>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
Sep-01-2020 16:44:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<p>Data Entry: NO</p>	Initial Entry

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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-10-2020 13:16:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Closed	Response satisfies query
Sep-10-2020 06:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Sep-10-2020 06:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NOT RELATED If Not Related to study treatmen t(s), this event is due to: OTHER <i>If Other, specify:</i> Acute Infection	Changed Information
Sep-10-2020 04:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Reissued:Opened	CLINQUERY: Thank you for the review. In the meantime, an entry of 'infection' or 'acute infection' is sufficient
Sep-08-2020 07:52:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	No cause for appendicitis known. Awaiting medical records
Sep-08-2020 07:52:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NOT RELATED If Not Related to study treatmen t(s), this event is due to: OTHER <i>If Other, specify:</i> Acute Event not related to s tudy treatment.	No cause for appendicitis known. Awaiting medical records
Sep-08-2020 07:43:14	ACV0PFEINFP6000	Hayley	Query 1: Reissued:Opened	CLINQUERY:

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(UTC-05:00) Eastern Time (US & Canada)		Wyper (pfe.wyperh)		Thank you for the response. Please enter a possible cause for the appendicitis in this entry eg infection, or cause that led to infection if known/part of MH
Sep-03-2020 13:34:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Acute Event not related to study treatment	Changed Information
Sep-03-2020 13:33:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Sep-03-2020 13:33:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to:	Changed Information
Sep-03-2020 10:41:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	CLINQUERY: 'Other, specify' entry is the same as the AE term (Appendicitis). Please review and amend as appropriate
Sep-01-2020 16:44:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i>	Initial Entry

Header Text: c4591001

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			Appendicitis	
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-01-2020 16:44:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-12-2020 15:29:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Query closed; will follow for SAE safety update on medical treatment
Oct-09-2020 10:34:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	SAE report will be updated with con med information from medical records report and then the report will be re-submitted
Oct-09-2020 08:54:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL Response to Con Med Treatment is YES; however, SAE report does not report any antibiotic or other con med usage. Please review and submit a SAE safety update if appropriate.
Sep-01-2020 16:45:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
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Sep-01-2020 16:45:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry
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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Sep-03-2020 07:48:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Closed	outcome matched in both database.
Sep-02-2020 09:45:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Sep-02-2020 09:45:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: RECOVERED/RESOLVE D	Transcription Error
Sep-02-2020 07:41:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Opened	SAE RECON:AER#2020336178 ,outcome was reported as RECOVERING/RESOLVING in SAE form however, was left blank on AE CRF. Please confirm correct outcome and update CRF. If safety update is required, please submit a follow-up form.
Sep-02-2020 07:05:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-02-2020 07:05:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry:	Changed Information
Sep-01-2020 16:46:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Appendicitis : Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Sep-01-2020 16:44:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: RECOVERING/RESOLVI NG	Initial Entry

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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Sep-01-2020 16:38:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Sep-02-2020 07:36:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Data Entry: 2020336178	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Nov-23-2020 10:00:56 (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-23-2020 10:00:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-03-2020 14:46:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Closed	Response satisfies query
Dec-03-2020 13:40:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	thank you, COPD has been added to MH
Dec-03-2020 12:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Reissued:Opened	CLINQUERY: MH page is unlocked and can be updated with the MH of COPD
Dec-03-2020 07:56:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	spoke with subject, COPD began in 2018. Please unlock MH page so that this can be added
Nov-27-2020 06:43:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Reissued:Opened	CLINQUERY: Thank you, please leave query in open status. Reply when information retrieved

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				and page can be unlocked for updating if needed
Nov-24-2020 15:21:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	awaiting call back from subject to confirm start date of COPD, her medical record only stated "PMH COPD" but did not have the start date of Dx. Will update as soon as subject calls office back
Nov-24-2020 06:58:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	CLINQUERY: COPD has not been captured in the MH of this subject. Please review and confirm if MH is to be updated
Nov-23-2020 10:00:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: COPD exacerbation	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-23-2020 10:00:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Nov/2/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-23-2020 10:00:56 (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
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Nov-23-2020 10:00:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: 2	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Nov-23-2020 10:00:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Nov-23-2020 10:00:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-23-2020 10:00:56 (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> COPD	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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Nov-23-2020 10:00:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NOT APPLICABLE	Initial Entry
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-23-2020 10:00:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-23-2020 10:00:56 (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-23-2020 10:00:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: RECOVERING/RESOLVING	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Nov-23-2020 10:00:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Dec-11-2020 12:08:14 (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
Dec-11-2020 12:08:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-11-2020 12:08:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Anemia	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-11-2020 12:08:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Nov/2/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-11-2020 12:08:14 (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
Dec-11-2020 12:08:14 (UTC-05:00) Eastern	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: 2	Initial Entry

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Time (US & Canada)

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
Dec-11-2020 12:08:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Dec-11-2020 12:08:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Dec-11-2020 12:08:14 (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 If Other, specify: Unknown, no mention of ca use/disease in med record	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-11-2020 12:08:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NOT APPLICABLE	Initial Entry

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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Dec-11-2020 12:08:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-11-2020 12:08:14 (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
Dec-11-2020 12:08:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NOT RECOVERED/NOT RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Dec-11-2020 12:08:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

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Site No: 1081

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

Subject No: 10811036

Subject Initials: ---

Generated By: pfe.levissc

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

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-08-2021 18:36:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Feb/8/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1081

Subject No: 10811036

Generated By: pfe.levissc

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History

Form Status: Data Complete, Frozen

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 - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Feb-08-2021 18:36:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at V accination 1/2	Initial Entry

Header Text: c4591001**Visit:** Disposition - Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1081**Subject No:** 10811036**Generated By:** pfe.lewissc**Form:** TREATMENT UNBLINDED - 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[Back to Form](#)**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Feb-24-2021 00:29:48 (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_DS001_36
Feb-23-2021 13:11:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: An swere d	Transcription Error
Feb-23-2021 13:11:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry : Feb/8/ 2021	Transcription Error
Feb-22-2021 21:11:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Op ened	DMW7350970;Date Treatment Unblinded should be equal to or after DOV in REVAX CONTACT visit when Reason is ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION.Please review and update as appropriate.
Feb-08-2021 18:36:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry : Feb/2/ 2021	Initial Entry

2. Primary Reason for Unblinding:

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811036

Generated By: pfe.levisse

Form: TREATMENT UNBLINDED - 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

Date	Location	User	Value	Reason
Feb-08-2021 18:36:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811036

Generated By: pfe.levissc

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, 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 Status

Date	Location	User	Value	Reason
Oct-01-2020 11:52:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-13-2020 16:34:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-13-2020 14:27:36 (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
Oct-01-2020 11:52:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/1/2020	Initial Entry
Aug-13-2020 16:34:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/13/2020	Initial Entry
Aug-13-2020 14:27:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/13/2020	Initial Entry

090177e196ae3f0b\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811036

Generated By: pfe.lewissc

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

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1. Casebook Signature

Date	Location	User	Value	Reason
Sep-14-2020 16:17:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Click Here to Enable	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811045

Subject Initials: ---

Generated By: pfe.levissc

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: 10811045

Generated By: pfe.lewissc

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 Aug/17/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1081

Subject No: 10811045

Generated By: pfe.lewissc

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	[10811045]
2.	Birth Date:	(b) (6)/1956
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: 10811045

Generated By: pfe.lewissc

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	Aug/17/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1081

Subject No: 10811045

Generated By: pfe.lewissc

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: 10811045

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	Aug/17/2020
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: 10811045

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

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[myopia]
	Start Date:	UNK/UNK/1970
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[tinnitus]
	Start Date:	Jan/1/2014
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[tonsillitis]
	Start Date:	Jan/1/1964
	Ongoing:	NO End Date: UNK/UNK/1964
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[obesity]
	Start Date:	Jan/1/2001
	Ongoing:	YES

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

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

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[GERD]
	Start Date:	Jan/1/2009
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Osteoarthritis of bilateral index fingers]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[fractured right wrist]
	Start Date:	UNK/UNK/1995
	Ongoing:	NO End Date: UNK/UNK/1995
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[seasonal allergic rhinitis]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[occasional headache]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

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

1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[menopause moodiness]
	Start Date:	UNK/UNK/2008
	Ongoing:	NO End Date: UNK/UNK/2008
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[anemia]
	Start Date:	UNK/UNK/2018
	Ongoing:	NO End Date: UNK/UNK/2018
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[benign lump right breast]
	Start Date:	UNK/UNK/1998
	Ongoing:	NO End Date: UNK/UNK/1998
1.m	Line/MH Number:	[13]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[postmenopausal]
	Start Date:	Jan/1/2008
	Ongoing:	NO End Date: UNK/UNK/2008

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

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

1.n	Line/MH Number:	[14]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[C-section]
	Start Date:	UNK/UNK/1988
	Ongoing:	NO End Date: UNK/UNK/1988
1.o	Line/MH Number:	[15]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[C-section]
	Start Date:	UNK/UNK/1989
	Ongoing:	NO End Date: UNK/UNK/1989
1.p	Line/MH Number:	[16]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Lumpectomy of Right breast]
	Start Date:	UNK/UNK/1998
	Ongoing:	NO End Date: UNK/UNK/1998
1.q	Line/MH Number:	[17]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[tonsillectomy]
	Start Date:	UNK/UNK/1965
	Ongoing:	NO End Date: UNK/UNK/1965

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

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

1.r	Line/MH Number:	[18]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Fall]
	Start Date:	UNK/UNK/1995
	Ongoing:	NO End Date: UNK/UNK/1995

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1081

Subject No: 10811045

Generated By: pfe.lewissc

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:	Aug/17/2020
2.	Weight:	[180.0]
3.	Unit:	LB
4.	Height:	[61.0]
5.	Unit:	in
6.	Body Mass Index:	[34.0]

Vital Signs Details

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

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1081

Subject No: 10811045

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:	Aug/17/2020
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

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

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 :	Aug/17/2020
2.	Randomization Number:	[229862]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

Generated By: pfe.lewissc

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: Aug/17/2020
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	[BP1J7L]
5.b	Sample ID	[BP1J7M]
5.c	Sample ID	[BP1J7N]
5.d	Sample ID	[BPHZGR]
5.e	Sample ID	[BPHZGS]

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

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: Aug/17/2020
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	[BP1J7Y]
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090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811045

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:	Aug/17/2020 10:41
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

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001	Form: REACTOGENICITY DIARY
Visit: V1_DAY1_VAX1_L	Form Status: Data Complete, Locked, Frozen, Verified
Form Version: 06-Jul-2020 21:53	Site Name: (1081) Sterling Research Group - Mt. Auburn
Site No: 1081	Subject Initials: ---
Subject No: 10811045	Generated Time (GMT): 29-Mar-2021 10:11
Generated By: pfe.levissc	

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811045

Generated By: pfe.lewissc

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/9/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811045

Subject Initials: ---

Generated By: pfe.lewissc

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

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

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

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811045

Subject Initials: ---

Generated By: pfe.levisse

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

2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1081

Subject No: 10811045

Generated By: pfe.levissc

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/9/2020
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Vital Signs Details

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

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 30-Jul-2020 21:27**Site No:** 1081**Subject No:** 10811045**Generated By:** pfe.levisse**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[Form Comments](#)
[eCRF Audit Trail History](#)**Lab Urinalysis**

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

Lab Result

6.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	Comments
	Not Done:	Not Applicable _____	Comments

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

Generated By: pfe.lewissc

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/9/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP97P8]
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090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811045

Generated By: pfe.lewissc

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/9/2020 09:58
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

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811045

Generated By: pfe.lewissc

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/7/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811045

Subject Initials: ---

Generated By: pfe.lewissc

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

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

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

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

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

Subject No: 10811045

Subject Initials: ---

Generated By: pfe.levisse

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

2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

Generated By: pfe.lewissc

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: Oct/7/2020
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	[BRTXTM]
5.b	Sample ID	[BRTXTN]
5.c	Sample ID	[BP1HTZ]

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811045

Generated By: pfe.lewissc

Form: DATE OF VISIT

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

Date of Visit

1.	Date of Visit	Mar/3/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BKZ4HS]
5.b	Sample ID	[BKZ4HT]
5.c	Sample ID	[BRM4MF]
5.d	Sample ID	[BRM4MG]

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisc

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: 10811045

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: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisc

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: 10811045

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	[]
----	-----------	-----

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET
on Dec/01/2020

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: 10811045

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Date of Visit

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

COVID-19 Illness Visit

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

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Dec/01/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

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: 10811045

Subject Initials: ---

Generated By: pfe.lewissc

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

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Dec/1/2020
2.	Date of First Symptom Started:	Nov/25/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Dec/25/2020

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

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/01/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

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: 10811045

Subject Initials: ---

Generated By: pfe.levisse

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

Symptoms - Other

5.a	Symptoms - Other Text:	[Nasal Congestion]
-----	------------------------	--------------------

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: 10811045

Subject Initials: ---

Generated By: pfe.lewissc

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 Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN
on Dec/01/2020

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: 10811045

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 Applicable _____ //	Comments
2.	Specimen Type:	Not Applicable _____	Comments
3.	Specimen Collection Location:	Not Applicable _____	Comments
4.	Assay Code and Description:	Not Applicable _____	Comments
5.	Device Type:	Not Applicable _____	Comments
6.	Trade Name:	Not Applicable _____	Comments
7.	Test Result:	Not Applicable _____	Comments
8.	Comments/Findings/Details:	Not Applicable _____ []	Comments
9.	Trade Name Other, Specify:	Not Applicable _____ []	Comments

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Dec/01/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

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: 10811045

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: Dec/1/2020
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	[CV22031]
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090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
on Dec/01/2020

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: 10811045

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
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Obtaining Self Swab today]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
----	-----------	-----

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION
on Dec/01/2020**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:** 10811045**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
----	--	----

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: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT
on Dec/01/2020

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Respiratory Treatment

1.	What is the treatment Identifier?	[]
2.	Concomitant Non-drug Treatment Pre-specified:	
3.	Treatment:	
4.	Treatment:	[]
5.	Start Date:	//
6.	Ongoing?	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS
on Dec/01/2020

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: 10811045

Subject Initials: ---

Generated By: pfe.levisse

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:	1

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: 10811045

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.					Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE
on Dec/01/2020

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Illness Details

1.	Category of Clinical Event:	
2.	Subcategory of Clinical Event:	
3.	Was a diagnosis obtained?	
4.	Toxicity Grade:	

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 30-Jul-2020 21:27

Site No: 1081

Subject No: 10811045

Generated By: pfe.levissc

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Dec/01/2020

Form Version: 30-Jul-2020 21:27

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Lab Chemistry Details

1.	Lab Panel:	
2.	Laboratory Name and Address	[]
3.	Collection Date:	//
4.	Specimen Type:	

Lab Result

5.	Sponsor ID:	[]
	Test:	
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 30-Jul-2020 21:28

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811045

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

#	Category for Lab Test	Vendor Name (DE RIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	Repeating Pages

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
on Dec/01/2020

Form Version: 30-Jul-2020 21:28

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Laboratory Data Hematology

1.	Lab Panel:	
2.	Laboratory Name and Address	[]
3.	Collection Date:	//
4.	Specimen Type:	

Lab Result

5.	Sponsor ID:	[]
	Test:	
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 30-Jul-2020 21:27

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811045

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

#	Date:	Vital Signs Details			Form Instance
1.		Record Identifier:	Systolic:	Diastolic:	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Dec/01/2020

Form Version: 30-Jul-2020 21:27

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Vital Signs

1.	Date:	//
----	-------	----

Vital Signs Details

2.	Record Identifier:	
	Systolic:	[]
	Diastolic:	[]
	Respiratory Rate in respirations/minute:	[]
	Heart Rate in beats/minute:	[]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 30-Jul-2020 21:28

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811045

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

#	Date:	Vital Signs Details		Form Instance
1.		Record Identifier:	Oxygen Saturation	Repeating Pages

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Dec/01/2020

Form Version: 30-Jul-2020 21:28

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Vital Signs

1.	Date:	//
----	-------	----

Vital Signs Details

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811045

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.				Repeating Pages

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS
on Dec/01/2020

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Oxygenation Parameters

1.	Date Time of Assessment:	//
2.	Arterial Blood Gases PaO2 (mmHg):	[]
3.	FiO2 (Fraction of Inhaled Oxygen):	[]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811045

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: POT_COVID_ILL 1 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
on Dec/01/2020

Form Version: 06-Jul-2020 21:55

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811045

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.	Start Date:	//
6.	Ongoing?	

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (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: 10811045

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.					Repeating Pages

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING
on Dec/01/2020

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Imaging

1.	Date of Assessment:	//
2.	Location of Assessment:	
3.	Type of Imaging Exam:	
4.	Assessment:	

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Jan/05/2021

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811045

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Jan/5/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A1
----	-------------------------	----------

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled
Visit on Jan/05/2021**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**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:** 10811045**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	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/5/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BS64SY]
5.b	Sample ID	[BS64SZ]
5.c	Sample ID	[BKN9P6]
5.d	Sample ID	[BKN9P7]

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: 10811045

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: 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: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Unplanned Assessments

1.	Assessments	
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Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1081

Subject No: 10811045

Generated By: pfe.lewissc

Form: DISPOSITION - TREATMENT

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 - Treatment

1.	Date of Completion/Discontinuation/Death :	Oct/7/2020
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: 10811045

Generated By: pfe.levissc

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Disposition - Follow-Up

1.	Date of Completion/Discontinuation/Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[]

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
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: 10811045

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 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: 10811045

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: 10811045

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Atrial Fibrillation with Rapid Ventricular Response	Nov/17/2020 06:00	NO End Date Time: Dec/1/2020 UNK: UNK	Repeating Pages
2. DELETED	ADVERSE EVENT	2	Rapid Ventricular Response	Nov/17/2020 06:00	YES	Repeating Pages
3.	ADVERSE EVENT	3	Unspecified Sleep Apnea	Jan/5/2021 UNK:UNK	YES	Repeating Pages

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

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)	[Atrial Fibrillation with Rapid Ventricular Response]
4.	Start Date Time:	Nov/17/2020 06:00
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/1/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? NO Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event YES
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

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

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: [Idiopathic, no cause noted in medical records]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020461222]

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

*** THIS REPEATING FORM HAS BEEN DELETED ***

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Rapid Ventricular Response]
4.	Start Date Time:	Nov/17/2020 06:00
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? NO Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event YES
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

*** THIS REPEATING FORM HAS BEEN DELETED ***

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: [unknown at this time, will update once records received]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Unspecified Sleep Apnea]
4.	Start Date Time:	Jan/5/2021 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Obesity]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (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: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

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	[]

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (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: 10811045

Subject Initials: ---

Generated By: pfe.levisse

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.	1	VACCINATIONS	NO	Flu Vaccination	Nov/11/2020	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811045

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?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Flu Vaccination]
5.	Date:	Nov/11/2020

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (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: 10811045

Subject Initials: ---

Generated By: pfe.levisse

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: 10811045

Generated By: pfe.levisse

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?	

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (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: 10811045

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: 10811045

Generated By: pfe.levisse

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: 10811045

Subject Initials: ---

Generated By: pfe.levisse

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: 10811045

Generated By: pfe.levisse

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: 10811045

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: 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: 10811045

Subject Initials: ---

Generated By: pfe.lewissc

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: 10811045

Subject Initials: ---

Generated By: pfe.levissc

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: 10811045

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?	

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (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: 10811045

Subject Initials: ---

Generated By: pfe.lewissc

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: 10811045

Subject Initials: ---

Generated By: pfe.levisse

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: 10811045

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: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Informed Consent - Asymptomatic Surveillance

1.	Consent Was:	
----	--------------	--

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811045

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: 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: 10811045

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: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

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: 10811045

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Feb/4/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2
----	---	--

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

Generated By: pfe.lewissc

Form: TREATMENT UNBLINDED

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

Treatment Unblinded

1.	Date Treatment Unblinded :	Feb/4/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

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 :	//
----	------------------------------	----

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

Generated By: pfe.lewissc

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Death Details

1.	Date of Collection / Notification of Death:	//
----	---	----

Cause of Death

2.	Cause of Death Status:	
	Cause of Death:	[]

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

Generated By: pfe.lewissc

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	FOLLOW-UP
2.	Subject Status Date	Oct/7/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811045

Generated By: pfe.lewissc

Form: CASEBOOK SIGNATURE FORM

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](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
----	--------------------	--------------------------------------

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811045

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
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
------	----------------------	------	------	--------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-17-2020 10:38:08 (UTC-05:00) Eastern Time (US & Canada)	Tawny Ebner (pfe.tebner)	All inclusion and exclusion met <hr/> Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-09-2020 10:56:48 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	post-menopausal <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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

[Back to Form](#)

Item	Date	User	Comment
1	Sep-09-2020 10:56:48 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	post-menopausal _____ Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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
2	Sep-09-2020 10:56:48 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	post-menopausal <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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
3	Sep-09-2020 10:56:48 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	post-menopausal <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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
4	Sep-09-2020 10:56:48 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	post-menopausal <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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
5	Sep-09-2020 10:56:48 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	post-menopausal <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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
6.a	Sep-09-2020 10:56:48 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	post-menopausal <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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

[Back to Form](#)

Item	Date	User	Comment
6.a	Sep-09-2020 10:56:48 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	post-menopausal <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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

[Back to Form](#)

Item	Date	User	Comment
6.a	Sep-09-2020 10:56:48 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	post-menopausal <hr/> Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Dec/01/2020

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: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
Form	Dec-01-2020 09:08:15 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/01/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

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: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
1	Dec-01-2020 09:08:15 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/01/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

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: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
2	Dec-01-2020 09:08:15 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Dec/01/2020

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: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
3	Dec-01-2020 09:08:15 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/01/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

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: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
4	Dec-01-2020 09:08:15 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/01/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

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: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
5	Dec-01-2020 09:08:15 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/01/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

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: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
6	Dec-01-2020 09:08:15 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/01/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

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: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
7	Dec-01-2020 09:08:15 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/01/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

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: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
8	Dec-01-2020 09:08:15 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/01/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

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: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
9	Dec-01-2020 09:08:15 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

This form requires signing by a member of each of the following signature groups:

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
Lora Morris	N/A	Jan-28-2021 15:48:42 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

James Fry	Approved	Jan-23-2021 11:57:10 (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-23-2020 07:15:53 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
-------------	-----	---	--	-----------------------------------

Affidavit:

N/A

Michael Butcher	Approved	Oct-22-2020 15:05:17 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
-----------------	----------	---	------	--------

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.

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811045

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-17-2020 10:37:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn 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
Aug-17-2020 10:37:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811045

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
Aug-17-2020 10:37:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: OBTAINED Date Written Consent Obtained Aug/17/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1081

Subject No: 10811045

Generated By: pfe.lewissc

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
Aug-17-2020 10:37:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10811045	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-17-2020 10:37:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1956	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-17-2020 10:37:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-17-2020 10:37:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Aug-17-2020 10:37:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: WHITE	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811045

Generated By: pfe.lewissc

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
Aug-17-2020 10:37:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Aug/17/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

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
Aug-17-2020 10:38:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Aug/17/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-17-2020 10:38:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-17-2020 10:38:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: COMPLETED	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

Generated By: pfe.lewissc

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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I.a

Date	Location	User	Value	Reason
Aug-17-2020 11:53:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: Line/MH Number: 1 Medical History Term: myopia Start Date: UNK/UNK/1970 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 11:53:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: 1	Initial Entry

I.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 11:53:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: myopia	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 11:53:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: UNK/UNK/1970	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 11:53:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: YES	Initial Entry

I.b

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Aug-17-2020 11:53:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term tinnitus : Start Date: Jan/1/2014 4 Ongoing: YES	Initial Entry

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 11:53:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 11:53:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: tinnitus	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 11:53:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: Jan/1/2014	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 11:53:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Aug-17-2020 11:54:21 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numbe 3	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

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

Time (US & Canada)			r: Medical History Term: tonsillitis Start Date: Jan/1/1964 Ongoing: NO End Date: UNK/UNK/ 1964	
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I.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 11:54:21 (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
Aug-17-2020 11:54:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: tonsillitis	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 11:54:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: Jan/1/1964	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 11:54:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: NO End Date: UNK/UNK/1964	Initial Entry

I.d

Date	Location	User	Value	Reason
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090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

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

Aug-17-2020 11:54:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term obesity : Start Date: Jan/1/2001 Ongoing: YES	Initial Entry
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1.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 11:54:54 (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
Aug-17-2020 11:54:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: obesity	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 11:54:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: Jan/1/2001	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 11:54:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: YES	Initial Entry

1.e

Date	Location	User	Value	Reason
Aug-17-2020 11:55:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

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 GERD : Start Date: Jan/1/2009 Ongoing: YES	
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I.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 11:55:15 (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
Aug-17-2020 11:55:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: GERD	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 11:55:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: Jan/1/2009	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 11:55:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Aug-18-2020 13:39:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Line/MH N umber: 6 Medical History Term: Osteoarthritis of bilateral index fingers	Changed Information

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

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	
Aug-17-2020 12:02:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 6 Medical History Term: arthritis of bilateral index fingers Start Date: UNK/UNK/2018 Ongoing: YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

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

If Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 12:02:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

If Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-18-2020 15:00:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Closed	Response satisfies query
Aug-18-2020 13:39:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Aug-18-2020 13:39:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Osteoarthritis of bilateral index f ingers	Changed Information
Aug-18-2020 12:12:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	GPD Clin: Please specify in the event term the type of arthritis (eg osteo/rheumatoid)
Aug-17-2020 12:02:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: arthritis of bilateral index fingers	Initial Entry

If Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 12:02:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: UNK/UNK/2018	Initial Entry

If Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 12:02:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: YES	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

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.g

Date	Location	User	Value	Reason
Aug-17-2020 14:43:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Line/MH Number: Medical History Term: fractured right wrist Start Date: UNK/UNK/1995 Ongoing: NO End Date: UNK/UNK/1995	Changed Information
Aug-17-2020 12:03:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History Term: fractured right wrist (due to fall) Start Date: UNK/UNK/1995 Ongoing: NO End Date: UNK/UNK/1995	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

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.g Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 12:03:26 (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
Aug-17-2020 16:17:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Closed	Discrepancy has been closed.
Aug-17-2020 14:43:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Aug-17-2020 14:43:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: fractured right wrist	Changed Information
Aug-17-2020 14:06:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Opened	Multiple concepts in the term FRACTURED RIGHT WRIST (DUE TO FALL). Split the term into FRACTURED RIGHT WRIST and FALL and submit separately. Thank you.
Aug-17-2020 12:03:26 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: fractured right wrist (due to fall)	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

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

(US & Canada)

1.g Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 12:03:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: UNK/UNK/1995	Initial Entry

1.g Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 12:03:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: NO End Date: UNK/UNK/1995	Initial Entry

1.h

Date	Location	User	Value	Reason
Aug-17-2020 12:03:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 8 Medical History: seasonal allergic Term: rhinitis Start Date: UNK/UNK/200 0 Ongoing: YES	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

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
Aug-17-2020 12:03:51 (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
Aug-17-2020 12:03:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: seasonal allergic rhinitis	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 12:03:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: UNK/UNK/2000	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 12:03:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: YES	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

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.i

Date	Location	User	Value	Reason
Aug-17-2020 12:04:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: r: Medical History occasional headache Term: Start Date: UNK/UNK/2000 Ongoing: YES	Initial Entry

1.i Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 12:04:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

1.i Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 12:04:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: occasional headache	Initial Entry

1.i Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 12:04:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: UNK/UNK/2000	Initial Entry

1.i Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 12:04:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: YES	Initial Entry

1.j

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Aug-17-2020 12:05:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 10 Medical History Term: menopause moodiness Start Date: UNK/UNK/2008 Ongoing: NO End Date: UNK/UNK/2008	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

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.j Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 12:05:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: 10	Initial Entry

1.j Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 12:05:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: menopause moodiness	Initial Entry

1.j Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 12:05:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: UNK/UNK/2008	Initial Entry

1.j Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 12:05:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: NO End Date: UNK/UNK/2008	Initial Entry

1.k

Date	Location	User	Value	Reason
Aug-17-2020 12:05:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: Line/MH Numbe 11 r: Medical History anemia Term: Start Date: UNK/UNK/201 8	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

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

			Ongoing:	NO	
				End Date:	
				UNK/UNK/2018	

1.k Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 12:05:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: 11	Initial Entry

1.k Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 12:05:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: anemia	Initial Entry

1.k Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 12:05:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: UNK/UNK/2018	Initial Entry

1.k Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 12:05:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: NO End Date: UNK/UNK/2018	Initial Entry

1.l

Date	Location	User	Value	Reason
Aug-17-2020 12:06:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: Line/MH Number: 12	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

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: benign lump right breast Start Date: UNK/UNK/1998 Ongoing: NO End Date: UNK/UNK/1998	
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1.1 Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 12:06:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12	Initial Entry

1.1 Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 12:06:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: benign lump right breast	Initial Entry

1.1 Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 12:06:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: UNK/UNK/1998	Initial Entry

1.1 Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 12:06:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: NO End Date: UNK/UNK/1998	Initial Entry

1.m

Date	Location	User	Value	Reason
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090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

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

Aug-17-2020 12:07:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 13 r: Medical History Term: postmenopausal Start Date: Jan/1/2008 Ongoing: NO End Date: UNK/UNK/ 2008	Initial Entry
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1.m Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 12:07:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 13	Initial Entry

1.m Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 12:07:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: postmenopausal	Initial Entry

1.m Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 12:07:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: Jan/1/2008	Initial Entry

1.m Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 12:07:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: NO End Date: UNK/UNK/2008	Initial Entry

1.n

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Aug-17-2020 12:07:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 14 Medical History Term: C-section Start Date: UNK/UNK/1988 Ongoing: NO End Date: UNK/UNK/ 1988	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

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.n Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 12:07:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: 14	Initial Entry

1.n Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 12:07:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: C-section	Initial Entry

1.n Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 12:07:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: UNK/UNK/1988	Initial Entry

1.n Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 12:07:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: NO End Date: UNK/UNK/1988	Initial Entry

1.o

Date	Location	User	Value	Reason
Aug-17-2020 12:08:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: Line/MH Numbe 15 r: Medical History C-section Term: Start Date: UNK/UNK/198 9	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

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

			Ongoing:	NO	
				End Date:	
				UNK/UNK/	
				1989	

1.o Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 12:08:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: 15	Initial Entry

1.o Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 12:08:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: C-section	Initial Entry

1.o Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 12:08:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: UNK/UNK/1989	Initial Entry

1.o Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 12:08:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: NO End Date: UNK/UNK/1989	Initial Entry

1.p

Date	Location	User	Value	Reason
Aug-17-2020 12:08:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: Line/MH Nu 16 mber:	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

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: Lumpectomy of Right breast Start Date: UNK/UNK/1998 Ongoing: NO End Date: UNK/UNK/1998	
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1.p Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 12:08:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 16	Initial Entry

1.p Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 12:08:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: Lumpectomy of Right breast	Initial Entry

1.p Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 12:08:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: UNK/UNK/1998	Initial Entry

1.p Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 12:08:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: NO End Date: UNK/UNK/1998	Initial Entry

1.q

Date	Location	User	Value	Reason
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090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

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

Aug-17-2020 12:09:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 17 Medical History Term: tonsillectomy Start Date: UNK/UNK/1965 Ongoing: NO End Date: UNK/UNK/1965	Initial Entry
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1.q Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 12:09:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 17	Initial Entry

1.q Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 12:09:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: tonsillectomy	Initial Entry

1.q Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 12:09:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: UNK/UNK/1965	Initial Entry

1.q Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 12:09:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: NO End Date: UNK/UNK/1965	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

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>1.r</i>				
Date	Location	User	Value	Reason
Aug-17-2020 14:43:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 18 r: Medical History: Fall Term: Start Date: UNK/UNK/1995 Ongoing: NO End Date: UNK/UNK/ 1995	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

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.r Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 14:43:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: 18	Initial Entry

I.r Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 14:43:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Fall	Initial Entry

I.r Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 14:43:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: UNK/UNK/1995	Initial Entry

I.r Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 14:43:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO End Date: UNK/UNK/1995	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1081

Subject No: 10811045

Generated By: pfe.lewissc

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
Aug-17-2020 16:34:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: Aug/17/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-17-2020 16:34:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: 180.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-17-2020 16:34:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-17-2020 16:34:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: 61.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-17-2020 16:34:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-17-2020 16:34:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 34.0	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

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

7.a

Date	Location	User	Value	Reason
Aug-17-2020 16:34:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: Record Identifier:: 1 Temperature: 97.1 Temperature Unit: F Temperature Locati on:: FOREHE AD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-17-2020 16:34:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-17-2020 16:34:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: 97.1	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-17-2020 16:34:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-17-2020 16:34:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: FOREHEAD	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811045**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
Aug-17-2020 16:35:49 (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
Aug-17-2020 16:35:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-17-2020 16:35:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: Aug/17/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Aug-17-2020 16:35:49 (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
Aug-17-2020 16:35:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-17-2020 16:35:49 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Time (US & Canada)			Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: Not Done:: NOT DONE
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-17-2020 16:35:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-17-2020 16:35:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Aug-17-2020 16:35:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: NOT DONE	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

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
Aug-17-2020 16:36:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: Aug/17/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-17-2020 16:36:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: 229862	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: 10811045

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Data Origin

Date	Location	User	Value	Reason
Aug-17-2020 11:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-17-2020 11:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-17-2020 11:17:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-17-2020 11:17:11 (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.
Aug-17-2020 11:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Aug/17/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-17-2020 11:17:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BP1J7L	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (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: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.a Sample ID

Date	Location	User	Value	Reason
Aug-17-2020 11:17:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> BP1J7L	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-17-2020 11:17:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BP1J7M	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-17-2020 11:17:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> BP1J7M	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-17-2020 11:17:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BP1J7N	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-17-2020 11:17:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> BP1J7N	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-17-2020 11:17:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BPHZGR	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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

5.d Sample ID

Date	Location	User	Value	Reason
Aug-17-2020 11:17:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BPHZGR	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-17-2020 11:17:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BPHZGS	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-17-2020 11:17:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BPHZGS	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (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:** 10811045**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
Aug-17-2020 11:03:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-17-2020 11:03:46 (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
Aug-17-2020 11:03:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-17-2020 11:03:46 (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.
Aug-17-2020 11:03:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Aug/17/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-17-2020 11:03:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: Sample ID: BP1J7Y	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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

5.a Sample ID

Date	Location	User	Value	Reason
Aug-17-2020 11:03:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BP1J7Y	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811045

Generated By: pfe.lewissc

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
Aug-17-2020 16:37:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-17-2020 16:37:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-17-2020 16:37:32 (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
Aug-17-2020 16:37:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: Aug/17/2020 10:41	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-17-2020 16:37:32 (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
Aug-17-2020 16:37:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: LEFT	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811045

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

7. Route:

Date	Location	User	Value	Reason
Aug-17-2020 16:37:32 (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
Aug-17-2020 16:37:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Aug-17-2020 16:37:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: YES	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1081

Subject No: 10811045

Generated By: pfe.lewissc

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-03-2020 00:13:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pramod Margaj (pfe.margap03)	Query 1: Closed	Closed by DM: PM.
Sep-02-2020 07:10:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Sep-02-2020 07:10:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES - REACTOGENICITY E -DIARY COLLECTED FOR T HIS SUBJECT	Changed Information
Sep-02-2020 04:13:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Premraj Bhoyar (pfe.bhoyap)	Query 1: Opened	eDiary: REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT is 'No' however VAX 1 eDiary records are available for the subject. Please verify and update. Else, confirm in query response appropriately.
Aug-17-2020 16:51:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: NO - REACTOGENICITY E- DIARY NOT COLLECTED F OR THIS SUBJECT	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811045

Generated By: pfe.lewissc

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-09-2020 09:50:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sep/9/2020	Initial Entry

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:52**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811045**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Sep-09-2020 10:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-09-2020 10:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptom:: FE VE R Were fever or systemic symp NO toms present on the last day the Subject Diary was compl eted?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Sep-09-2020 10:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: FEVER	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-09-2020 10:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-09-2020 10:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptom:: FAT IG	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

			UE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	
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2.b Symptom:

Date	Location	User	Value	Reason
Sep-09-2020 10:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-09-2020 10:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-09-2020 10:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptom:: HEA DA CHE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:52**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811045**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11**2.c Symptom:**

Date	Location	User	Value	Reason
Sep-09-2020 10:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-09-2020 10:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-09-2020 10:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptom:: CH IL LS Were fever or systemic symp NO toms present on the last day the Subject Diary was compl eted?:	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Sep-09-2020 10:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-09-2020 10:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Sep-09-2020 10:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptom:: VO MIT ING Were fever or systemic sym ptoms present on the last d ay the Subject Diary was co mpleted?:	Initial Entry
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2.e Symptom:

Date	Location	User	Value	Reason
Sep-09-2020 10:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-09-2020 10:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Sep-09-2020 10:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic sym ptoms present on the last d ay the Subject Diary was co mpleted?:	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

2.f Symptom:

Date	Location	User	Value	Reason
Sep-09-2020 10:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-09-2020 10:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-09-2020 10:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptom:: NEW OR WORSE NED MUSC LE PAIN Were fever or systemi NO c symptoms present o n the last day the Sub ject Diary was comple ted?::	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Sep-09-2020 10:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NEW OR WORSE NED MUSCLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-09-2020 10:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

2.h

Date	Location	User	Value	Reason
Sep-09-2020 10:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptom:: NEW OR WORSE NED JOI NT PAIN Were fever or systemi c symptoms present o n the last day the Subj ect Diary was complet ed?: NO	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Sep-09-2020 10:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NEW OR WORSENERD JOINT PAI N	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-09-2020 10:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-09-2020 10:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-09-2020 10:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: LEFT	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.a

Date	Location	User	Value	Reason
Sep-09-2020 10:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactions NO present on the last day the S ubject Diary was completed ?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-09-2020 10:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-09-2020 10:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-09-2020 10:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reaction NO s present on the last day th e Subject Diary was compl eted?:	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-09-2020 10:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-09-2020 10:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-09-2020 10:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Injection Site Reaction:: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?:	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-09-2020 10:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-09-2020 10:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 21-Aug-2020 02:51**Site No:** 1081**Subject No:** 10811045**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[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Sep-09-2020 10:56:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sep/9/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-09-2020 10:56:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Record Identifier:: 1 Temperature: 98.3 Temperature Unit: F Temperature Locat ion:: ORAL CAVI TY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-09-2020 10:56:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-09-2020 10:56:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: 98.3	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-09-2020 10:56:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: F	Initial Entry

2.a Temperature Location:

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Sep-09-2020 10:56:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: ORAL CAVITY	Initial Entry

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811045**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-09-2020 10:56:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-09-2020 10:56:48 (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
Sep-09-2020 10:56:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-09-2020 10:56:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-09-2020 10:56:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-09-2020 10:56:48 (UTC-05:00) Eastern	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Time (US & Canada)			Sponsor-Defined Identifier: Test:: Result:: Not Done::	Not Applicable Not Applicable Not Applicable Not Applicable
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-09-2020 10:56:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-09-2020 10:56:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-09-2020 10:56:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-09-2020 10:56:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (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: 10811045

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Data Origin

Date	Location	User	Value	Reason
Sep-09-2020 09:51:05 (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-09-2020 09:51:05 (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-09-2020 09:51:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-09-2020 09:51:05 (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-09-2020 09:51:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Sep/9/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-09-2020 09:51:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: Sample ID: BP97P8	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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

5.a Sample ID

Date	Location	User	Value	Reason
Sep-09-2020 09:51:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BP97P8	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811045

Generated By: pfe.lewissc

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-09-2020 10:57:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-09-2020 10:57:54 (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-09-2020 10:57:54 (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-09-2020 10:57:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sep/9/2020 09:58	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-09-2020 10:57:54 (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-09-2020 10:57:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: LEFT	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811045

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

7. Route:

Date	Location	User	Value	Reason
Sep-09-2020 10:57:54 (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-09-2020 10:57:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION 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-09-2020 10:57:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811045

Generated By: pfe.lewissc

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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1. Date of Visit

Date	Location	User	Value	Reason
Oct-07-2020 09:24:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Oct/7/2020	Initial Entry

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:52**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811045**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Oct-07-2020 09:25:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-07-2020 09:25:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom:: FE VE R Were fever or systemic symptoms present on the last day the Subject Diary was completed?: N O	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Oct-07-2020 09:25:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: FEVER	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 09:25:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Oct-07-2020 09:25:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom:: FA TIG	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

			UE	
Were fever or systemic symptoms present on the last day the Subject Diary was completed?:				

2.b Symptom:

Date	Location	User	Value	Reason
Oct-07-2020 09:25:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 09:25:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Oct-07-2020 09:25:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:52**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811045**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11**2.c Symptom:**

Date	Location	User	Value	Reason
Oct-07-2020 09:25:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 09:25:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Oct-07-2020 09:25:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom:: CH IL LS Were fever or systemic sym ptoms present on the last d ay the Subject Diary was co mpleted?: NO	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Oct-07-2020 09:25:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 09:25:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Oct-07-2020 09:25:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom:: VO MIT ING Were fever or systemic sy mptoms present on the las t day the Subject Diary wa s completed?:	Initial Entry
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2.e Symptom:

Date	Location	User	Value	Reason
Oct-07-2020 09:25:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 09:25:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Oct-07-2020 09:25:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic sy mptoms present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

2.f Symptom:

Date	Location	User	Value	Reason
Oct-07-2020 09:25:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 09:25:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Oct-07-2020 09:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom:: NEW OR WORSEN ED MUS CLE PAI N Were fever or system ic symptoms present on the last day the Su bject Diary was com pleted?: NO	Initial Entry
Oct-07-2020 09:25:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom:: NEW OR WORSEN ED MUS CLE PAI N Were fever or system ic symptoms present on the last day the Su bject Diary was com pleted?:	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

2.g Symptom:

Date	Location	User	Value	Reason
Oct-07-2020 09:25:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NEW OR WORSE NED MUSCLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 09:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Oct-07-2020 09:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom:: NEW OR WORSE NED JOI NT PAIN Were fever or systemi c symptoms present o n the last day the Sub ject Diary was compl eted?: NO	Initial Entry
Oct-07-2020 09:25:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom:: NEW OR WORSE NED JOI NT PAIN Were fever or systemi c symptoms present o n the last day the Sub ject Diary was compl eted?:	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001
 Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History
 Form Version: 21-Aug-2020 02:52 Form Status: Data Complete, Locked, Frozen, Verified
 Site No: 1081 Site Name: (1081) Sterling Research Group - Mt. Auburn
 Subject No: 10811045 Subject Initials: ---
 Generated By: pfe.levisse Generated Time (GMT): 29-Mar-2021 10:11

2.h Symptom:

Date	Location	User	Value	Reason
Oct-07-2020 09:25:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NEW OR WORSENE D JOINT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 09:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Oct-07-2020 09:25:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Oct-07-2020 09:25:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-07-2020 09:25:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Injection Site Reaction: RE DN ESS Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
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090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:52**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811045**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11

Oct-07-2020 09:25:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: REDNESS	Initial Entry
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5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 09:25:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-07-2020 09:25:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-07-2020 09:25:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 09:25:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-07-2020 09:25:57 (UTC-05:00) Eastern	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Injection Site Reaction PAIN A	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Time (US & Canada)			::	T INJECTION SITE	
Were injection site reactions present on the last day the Subject Diary was completed?:					

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-07-2020 09:25:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 09:25:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (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:** 10811045**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-07-2020 09:55:26 (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-07-2020 09:55:26 (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-07-2020 09:55:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-07-2020 09:55:26 (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-07-2020 09:55:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Oct/7/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-07-2020 09:55:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: Sample ID: BRTXTM	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: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.a Sample ID

Date	Location	User	Value	Reason
Oct-07-2020 09:55:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: BRTXTM	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-07-2020 09:55:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: Sample ID: BRTXTN	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-07-2020 09:55:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: BRTXTN	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-07-2020 09:56:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: Sample ID: BP1HTZ	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-07-2020 09:56:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: BP1HTZ	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811045

Generated By: pfe.lewissc

Form: DATE OF VISIT - 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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I. Date of Visit

Date	Location	User	Value	Reason
Mar-03-2021 16:02:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Mar/3/2021	Initial Entry

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811045

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Data Origin

Date	Location	User	Value	Reason
Mar-03-2021 16:22:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-03-2021 16:22:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-03-2021 16:22:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-03-2021 16:22:23 (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.
Mar-03-2021 16:22:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Mar/3/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-03-2021 16:22:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BKZ4HS	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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

5.a Sample ID

Date	Location	User	Value	Reason
Mar-03-2021 16:22:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> BKZ4HS	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-03-2021 16:22:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BKZ4HT	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-03-2021 16:22:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> BKZ4HT	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-03-2021 16:23:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BRM4MF	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-03-2021 16:23:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> BRM4MF	Initial Entry

5.d

Date	Location	User	Value	Reason
Mar-03-2021 16:23:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BRM4MG	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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

5.d Sample ID

Date	Location	User	Value	Reason
Mar-03-2021 16:23:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BRM4MG	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/01/2020

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: 10811045

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Date of Visit

Date	Location	User	Value	Reason
Dec-01-2020 11:46:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-01-2020 09:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Dec-01-2020 09:07:06 (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.
Dec-01-2020 09:07:06 (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 missing. Please review and update as appropriate.
Dec-01-2020 09:07:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Dec/1/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Dec-01-2020 09:07:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/01/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1081**Subject No:** 10811045**Generated By:** pfe.lewissc**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Dec-01-2020 09:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Dec/1/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Dec-01-2020 09:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Nov/25/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Jan-05-2021 13:45:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO Date of Last Symptom Resolved : Dec/25/2020	New Information
Dec-01-2020 09:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Dec-01-2020 09:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Dec-01-2020 09:07:44 (UTC-05:00) Eastern	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: FEVER	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/01/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1081**Subject No:** 10811045**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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

Time (US & Canada)

4.a Was symptom present?

Date	Location	User	Value	Reason
Dec-01-2020 09:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Dec-01-2020 09:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom P present: YES	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Dec-01-2020 09:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Dec-01-2020 09:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

4.c

Date	Location	User	Value	Reason
Dec-01-2020 09:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: NO	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/01/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1081**Subject No:** 10811045**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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**4.c Symptoms:**

Date	Location	User	Value	Reason
Dec-01-2020 09:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NEW OR INCREASED SHORTN ESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Dec-01-2020 09:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Dec-01-2020 09:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Dec-01-2020 09:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Dec-01-2020 09:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Dec-01-2020 09:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom NEW OR INCREAS s: ED MUSCLE PAIN	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/01/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1081**Subject No:** 10811045**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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

			Symptom NO Present:	
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4.e Symptoms:

Date	Location	User	Value	Reason
Dec-01-2020 09:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Dec-01-2020 09:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Dec-01-2020 09:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms NEW LOSS OF TASTE OR SMELL Symptom NO Present:	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Dec-01-2020 09:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Dec-01-2020 09:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

4.g

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/01/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1081**Subject No:** 10811045**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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

Date	Location	User	Value	Reason
Dec-01-2020 09:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom NEW OR INCREASED SORE THROAT Symptom YES Present:	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Dec-01-2020 09:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Dec-01-2020 09:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

4.h

Date	Location	User	Value	Reason
Dec-01-2020 09:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms: DIARRHEA Symptom Present: NO	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Dec-01-2020 09:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Dec-01-2020 09:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/01/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1081**Subject No:** 10811045**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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**4.i**

Date	Location	User	Value	Reason
Dec-01-2020 09:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms: VOMITING Symptom Present: NO	Initial Entry

4.i Symptoms:

Date	Location	User	Value	Reason
Dec-01-2020 09:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Dec-01-2020 09:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-01-2020 09:08:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms - Other: Nasal Congestion	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Dec-01-2020 09:08:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Nasal Congestion	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Dec/01/2020**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:** 10811045**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
Dec-01-2020 09:08:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Applicable	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Dec-01-2020 09:08:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Applicable	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Dec-01-2020 09:08:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Applicable	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Dec-01-2020 09:08:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Applicable	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Dec-01-2020 09:08:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Applicable	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Dec-01-2020 09:08:15 (UTC-05:00) Eastern	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Dec/01/2020

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: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Time (US & Canada)				
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7. Test Result:

Date	Location	User	Value	Reason
Dec-01-2020 09:08:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Applicable	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Dec-01-2020 09:08:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Applicable	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Dec-01-2020 09:08:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Applicable	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/01/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1081**Subject No:** 10811045**Generated By:** pfe.levissc**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - 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[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Dec-01-2020 11:46:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-01-2020 11:46:58 (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
Dec-01-2020 11:47:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-01-2020 11:46:58 (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.
Dec-01-2020 11:46:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Dec/1/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-01-2020 11:47:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: Sample ID: CV22031	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/01/2020

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: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.a Sample ID

Date	Location	User	Value	Reason
Dec-01-2020 11:47:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: CV22031	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/01/2020

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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. Data Origin

Date	Location	User	Value	Reason
Dec-01-2020 09:08:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-01-2020 09:08:38 (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
Dec-01-2020 09:08:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Dec-01-2020 09:08:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Obtaining Self Swab today	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/01/2020

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: 10811045

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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1.a

Date	Location	User	Value	Reason
Dec-01-2020 09:08:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

1.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-01-2020 09:08:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: SPECIALIST	Initial Entry

1.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-01-2020 09:08:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

1.b

Date	Location	User	Value	Reason
Dec-01-2020 09:08:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/01/2020**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:** 10811045**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11***1.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-01-2020 09:08:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: EMERGENCY ROOM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-01-2020 09:08:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

1.c

Date	Location	User	Value	Reason
Dec-01-2020 09:08:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry

1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-01-2020 09:08:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-01-2020 09:08:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

1.d

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/01/2020

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: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Dec-01-2020 09:08:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: NO	Initial Entry
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1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-01-2020 09:08:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-01-2020 09:08:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Dec-01-2020 09:08:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/01/2020**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:** 10811045**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11***1.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-01-2020 09:08:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-01-2020 09:08:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

1.f

Date	Location	User	Value	Reason
Dec-01-2020 09:08:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Type of Practitioner: OTHER Occurrence of Visits or Contacts: NO	Initial Entry

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-01-2020 09:08:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-01-2020 09:08:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

3. Has the subject been hospitalized due to potential COVID-19 illness?

Date	Location	User	Value	Reason
Dec-01-2020 09:08:57 (UTC-05:00) Eastern	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
on Dec/01/2020

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: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Time (US & Canada)				
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090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History
on Dec/01/2020

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: 10811045

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
Dec-01-2020 09:09:10 (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
Dec-01-2020 09:09:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-01-2020 09:09:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: 1	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Jan/05/2021

Form: DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit
Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811045

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-05-2021 13:46:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Jan/5/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Jan-05-2021 13:46:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: COVID_A1	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Jan/05/2021

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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. Data Origin

Date	Location	User	Value	Reason
Jan-05-2021 14:28:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-05-2021 14:28:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-07-2021 00:21:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 2 : Closed	Response satisfies query
Jan-06-2021 14:30:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2 : Answered	Transcription Error
Jan-06-2021 14:30:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES Date of Collection: Jan/5/2021	Transcription Error

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Jan/05/2021

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Jan-05-2021 22:25:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 2 : Opened	DMW6706032;Date of Collection is not equal to Date of Visit. Please clarify or correct.
Jan-05-2021 14:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1 : Deleted	Close Auto Query
Jan-05-2021 14:28:47 (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.
Jan-05-2021 14:28:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawyn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Jan/5 /2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-05-2021 14:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawyn Ebner (pfe.tebner)	Data Entry: Sample ID: BS64SY	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-05-2021 14:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawyn Ebner (pfe.tebner)	Data Entry: BS64SY	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled
Visit on Jan/05/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1081**Subject No:** 10811045**Generated By:** pfe.levisse**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
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**5.b**

Date	Location	User	Value	Reason
Jan-05-2021 14:29:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: Sample ID: BS64SZ	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-05-2021 14:29:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: BS64SZ	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-05-2021 14:29:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: Sample ID: BKN9P6	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-05-2021 14:29:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: BKN9P6	Initial Entry

5.d

Date	Location	User	Value	Reason
Jan-05-2021 14:29:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: Sample ID: BKN9P7	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Jan-05-2021 14:29:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: BKN9P7	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1081

Subject No: 10811045

Generated By: pfe.levissc

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-07-2020 09:26:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Oct/7/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-07-2020 09:26:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-07-2020 09:26:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: COMPLETED	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811045

Generated By: pfe.lewissc

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Date	Location	User	Value	Reason
Nov-23-2020 07:15:53 (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: 10811045

Generated By: pfe.levisse

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Date	Location	User	Value	Reason
Nov-30-2020 09:13:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Form Deleted	Per Query- Leave as 1 AE term
Nov-23-2020 09:14:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Form Created	

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Date	Location	User	Value	Reason
Jan-28-2021 15:48:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Form Created	

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Generated By: pfe.levisse

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1. Category:

Date	Location	User	Value	Reason
Nov-23-2020 07:15:53 (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-23-2020 07:15:53 (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
Nov-30-2020 09:11:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Atrial Fibrillation with Rapid Ventricular Response	Per query response to combine terms again
Nov-23-2020 10:52:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Closed	Discrepancy has been closed.
Nov-23-2020 09:11:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-23-2020 09:11:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Atrial Fibrillation	Changed Information
Nov-23-2020 08:53:15 (UTC-05:00)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Opened	Clarify as follows... If atrial

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Eastern Time (US & Canada)					fibrillation with rapid ventricular response, edit. Otherwise, clarify the "ventricular response" portion of the term and potentially split.
Nov-23-2020 07:53:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Atrial Fibrillation with ventricular Response	Changed Information	
Nov-23-2020 07:15:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Atrial Fibrillation	Initial Entry	

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-17-2020 11:27:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Dec-07-2020 11:24:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	Updated SAE report now
Dec-06-2020 12:10:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL Please submit SAE safety followup for specific treatment of A fib (beyond ASA), and possible end date for SAE #2020461222
Nov-23-2020 09:15:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Nov/17/2020 06:00	Changed Information

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1081**Subject No:** 10811045**Generated By:** pfe.levisse**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

Nov-23-2020 07:15:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Nov/17/2020 UNK:UNK	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-07-2020 11:23:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO End Date Time: Dec/1/2020 UNK:UNK	New Information
Nov-23-2020 07:15:53 (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-23-2020 07:15:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: 2	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-25-2020 22:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Nov-25-2020 08:25:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Nov-25-2020 08:25:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES Is this serious event associated with congenital anomaly or bir th defect?	Transcription Error

Header Text: c4591001

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			<p>NO</p> <p>Did this serious event result in death?</p> <p>NO</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>NO</p> <p>Other medically important serious event</p> <p>YES</p>	
Nov-25-2020 01:39:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quoter)	Query 1: Closed	Response satisfies query
Nov-24-2020 23:05:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Reissued:Opened	Clinical - Thank you. If subject was not admitted to Hospital, please uncheck 'YES' above for 'did this serious event require or prolong hospitalization'.
Nov-24-2020 09:53:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 2: Answered	subject was not admitted to the hospital, she was only seen at her PCP's office. We are

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				awaiting records
Nov-24-2020 09:41:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	SAE event number is not assigned by the site. The subject was not hospitalized for this condition.
Nov-24-2020 09:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	Clinical - Serious criteria reported as Hospitalized and Medically Important; however, SAE report only reports Medically Important. Please review if subject was admitted to Hosp Yes/No, and update in the appropriate location
Nov-24-2020 03:48:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ananta Gogoi (pfe.gogoia)	Query 1: Opened	For AE Atrial Fibrillation: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-23-2020 09:17:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES	Transcription Error

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			<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>NO</p> <p>Other medically important serious event</p> <p>YES</p>	
Nov-23-2020 09:11:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Atrial Fibrillation: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-23-2020 07:53:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Atrial Fibrillation with ventricular Response: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-23-2020 07:15:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Atrial Fibrillation: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-23-2020 07:15:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES Is this serious event associated with congenital anomaly or bir	Initial Entry

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			th defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO	
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8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Nov-23-2020 07:15:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-06-2021 14:35:08 (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:	New Information

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			OTHER <i>If Other, specify:</i> Idiopathic, no cause noted in medical records	
Dec-15-2020 08:58:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nicholas Roosa (pfe.roosan)	Query 1: Closed	Response satisfies query
Dec-08-2020 10:47:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	per PI, will not note as genetic predisposition. awaiting records from specialist before completing data. Subject is scheduled to see a Cardiologist early Jan 2021
Dec-03-2020 12:19:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nicholas Roosa (pfe.roosan)	Query 1: Opened	Should this be "Genetic Predisposition" ? Per medical records, patient states familiar history of a-fib
Nov-23-2020 07:15:53 (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> Unk at this time. will update once records received	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-23-2020 07:15:53 (UTC-05:00) Eastern	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NOT APPLICABLE	Initial Entry

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Time (US & Canada)

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-24-2020 23:06:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Nov-24-2020 09:50:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	aspirin has been added to the SAE FUP
Nov-24-2020 09:41:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL - Med Rx for the event A Fib is reported as YES; however, SAE report does not include information on any Con Med used for treatment of this event. Please submit a SAE safety update with information on treatment, as well as further evaluation.
Nov-23-2020 07:15:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-23-2020 07:15:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Dec-07-2020 11:24:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query

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Dec-07-2020 11:24:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: RECOVERED/RESOLVED	New Information
Dec-07-2020 11:23:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Atrial Fibrillation with Rapid Ventricular Response: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Nov-23-2020 07:15:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NOT RECOVERED/NOT RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Nov-23-2020 07:15:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Nov-25-2020 01:38:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Data Entry: 2020461222	Initial Entry

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1. Category:

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Nov-23-2020 09:14:54 (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-23-2020 09:14:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-01-2020 11:24:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jeffrey Signora TMSQUERY (pfe.signoj01_tmsquery)	Query 1: Closed	Response satisfies query
Nov-30-2020 09:13:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Per Query- Leave as 1 AE term
Nov-25-2020 20:54:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quot)	Query 1: Reissued: Opened	Please reupdate AE#1 term to 'Atrial Fibrillation, rapid ventricular response' to facilitate coding and inactivate AE#2.
Nov-23-2020	ACV0PFEINFP6000	Lora Morris	Query	Subject had A-Fib

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12:38:37 (UTC-05:00) Eastern Time (US & Canada)		(pfe.lmorris)	1: Answered	with rapid ventricular response. Site was asked to split the 2 terms. Please clarify if we can place the terms as 1 AE, as it was previously submitted this way
Nov-23-2020 11:04:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Opened	Clarify as follows..Please clarify Rapid Ventricular Response. Event is ambiguous, please provide diagnosis/disorder causing response.
Nov-23-2020 09:14:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Rapid Ventricular Response	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-23-2020 09:17:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Nov/17/2020 06:00	Transcription Error
Nov-23-2020 09:14:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Nov/17/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-23-2020 09:14:54 (UTC-05:00) Eastern	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

Header Text: c4591001

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Time (US & Canada)

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-23-2020 09:14:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: 2	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-25-2020 04:47:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	Response satisfies query
Nov-24-2020 09:39:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	SAE Event Number is not assigned by the site, this is an additional SAE that is combined with the A-Fib.
Nov-24-2020 03:49:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ananta Gogoi (pfe.gogoia)	Query 1: Opened	For AE Rapid Ventricular Response: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-23-2020 09:14:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Rapid Ventricular Response: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

*** THIS REPEATING FORM HAS BEEN DELETED ***

				Number" is blank.
Nov-23-2020 09:14:54 (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>NO</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>NO</p> <p>Other medically important serious event</p> <p>YES</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-23-2020 09:14:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<p>Data Entry: NO</p>	Initial Entry

9. Is this event related to study treatment:

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

*** THIS REPEATING FORM HAS BEEN DELETED ***

Date	Location	User	Value	Reason
Nov-23-2020 09:14:54 (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 at this time, will u pdate once records received	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-23-2020 09:14:54 (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
Nov-23-2020 09:14:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-23-2020 09:14:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Nov-23-2020 09:14:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NOT RECOVERED/NOT RESOL VED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

*** THIS REPEATING FORM HAS BEEN DELETED ***

Date	Location	User	Value	Reason
Nov-23-2020 09:14:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Jan-28-2021 15:48:42 (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
Jan-28-2021 15:48:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-28-2021 15:48:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Unspecified Sleep Apnea	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-28-2021 15:48:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Jan/5/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-28-2021 15:48:42 (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
Jan-29-2021 08:32:25 (UTC-05:00) Eastern	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: 2	Transcription Error

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Time (US & Canada)				
Jan-28-2021 15:48:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Jan-28-2021 15:48:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Jan-28-2021 15:48:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-28-2021 15:48:42 (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> Obesity	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (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

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Jan-28-2021 15:48:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NOT APPLICABLE	Initial Entry
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-28-2021 15:48:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-28-2021 15:48:42 (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
Jan-28-2021 15:48:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NOT RECOVERED/NOT RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Jan-28-2021 15:48:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811045

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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Date	Location	User	Value	Reason
Jan-05-2021 13:47:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811045

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Jan-05-2021 13:47:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jan-05-2021 13:47:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Jan-05-2021 13:47:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Jan-05-2021 13:47:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Flu Vaccination	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Jan-05-2021 13:47:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Nov/11/2020	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811045

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-05-2021 09:40:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Feb/4/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1081

Subject No: 10811045

Generated By: pfe.levissc

Form: FURTHER VACCINATION CONFIRMATION - 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

[Back to Form](#)

1. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Feb-05-2021 09:40:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at V accination 1/2	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

Generated By: pfe.lewissc

Form: TREATMENT UNBLINDED - 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 Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-24-2021 00:29:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Closed	Auto closed by Validation Check: VC_DS001_36
Feb-23-2021 13:13:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-23-2021 13:13:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry : Feb/4/ 2021	Transcription Error
Feb-22-2021 21:11:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW7350972;Date Treatment Unblinded should be equal to or after DOV in REVAX CONTACT visit when Reason is ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION.Please review and update as appropriate.
Feb-05-2021 09:39:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry : Feb/2/ 2021	Initial Entry

2. Primary Reason for Unblinding:

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

Form: TREATMENT UNBLINDED - 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

Date	Location	User	Value	Reason
Feb-05-2021 09:39:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

Generated By: pfe.lewissc

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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I. Subject Status

Date	Location	User	Value	Reason
Oct-07-2020 09:26:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-17-2020 16:36:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-17-2020 10:38:30 (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-25-2020 01:37:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.QUITOR)	Query 1: Closed	Response satisfies query
Nov-23-2020 07:53:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	AE CRF has been added
Nov-23-2020 05:39:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.QUITOR)	Query 1: Opened	SAE RECON:AER#2020461222 atrial fibrillation with rapid ventricular response(onset date:17Nov2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Oct-07-2020 09:26:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/7/2020	Initial Entry
Aug-17-2020 16:36:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/17/2020	Initial Entry

090177e196ae3f06\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811045

Generated By: pfe.levisse

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Aug-17-2020 10:38:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/17/2020	Initial Entry
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Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811045

Generated By: pfe.lewissc

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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1. Casebook Signature

Date	Location	User	Value	Reason
Oct-22-2020 13:49:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: Click Here to Enable	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1081

Subject No: 10811046

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: 10811046

Generated By: pfe.lewissc

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 Aug/17/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1081

Subject No: 10811046

Generated By: pfe.lewissc

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	[10811046]
2.	Birth Date:	(b) (6)/1965
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	BLACK OR AFRICAN AMERICAN
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811046

Generated By: pfe.lewissc

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	Aug/17/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1081

Subject No: 10811046

Generated By: pfe.lewissc

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 _____
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811046

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	Aug/17/2020
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: 10811046

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

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Presbyopia]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Chronic Bronchitis-Stable]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Pneumonia]
	Start Date:	UNK/UNK/2011
	Ongoing:	NO End Date: UNK/UNK/2014
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Pneumonia]
	Start Date:	UNK/UNK/2014
	Ongoing:	NO End Date: Dec/UNK/2014

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811046

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

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Sleep Apnea]
	Start Date:	UNK/UNK/2014
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	UNK/UNK/2008
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Dyslipidemia]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Diabetes Mellitus Type 2]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Obesity]
	Start Date:	UNK/UNK/2003
	Ongoing:	YES

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811046

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

1 j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Abdominal Hernia]
	Start Date:	UNK/UNK/2012
	Ongoing:	NO End Date: UNK/UNK/2012
1 k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Osteoarthritis of Left Knee]
	Start Date:	UNK/UNK/2014
	Ongoing:	YES
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Osteoarthritis of Low Back]
	Start Date:	UNK/UNK/2014
	Ongoing:	YES
1.m	Line/MH Number:	[13]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Chronic Back Pain]
	Start Date:	UNK/UNK/2014
	Ongoing:	YES
1 n	Line/MH Number:	[14]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Allergy-Dilaudid-itching]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811046

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

1.o	Line/MH Number:	[15]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Allergy-Sulfa]
	Start Date:	UNK/UNK/1989
	Ongoing:	YES
1.p	Line/MH Number:	[16]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Allergy-Shellfish-Hives]
	Start Date:	UNK/UNK/1989
	Ongoing:	YES
1.q	Line/MH Number:	[17]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Insomnia]
	Start Date:	UNK/UNK/2008
	Ongoing:	YES
1.r	Line/MH Number:	[18]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Anxiety]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.s	Line/MH Number:	[19]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Depression]
	Start Date:	UNK/UNK/2009
	Ongoing:	YES

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811046

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

1.t	Line/MH Number:	[20]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Blood Transfusion]
	Start Date:	UNK/UNK/1989
	Ongoing:	NO End Date: UNK/UNK/1999
1.u	Line/MH Number:	[21]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Abdominal Hernia Repair]
	Start Date:	UNK/UNK/2012
	Ongoing:	NO End Date: UNK/UNK/2012
1.v	Line/MH Number:	[22]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Abdominal Hernia Repair]
	Start Date:	UNK/UNK/2017
	Ongoing:	NO End Date: UNK/UNK/2017
1.w	Line/MH Number:	[23]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hysterectomy]
	Start Date:	UNK/UNK/1999
	Ongoing:	NO End Date: UNK/UNK/1999

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1081

Subject No: 10811046

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:	Aug/17/2020
2.	Weight:	[204.5]
3.	Unit:	LB
4.	Height:	[64.75]
5.	Unit:	in
6.	Body Mass Index:	[34.3]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.5]
	Unit:	F
	Temperature Location:	FOREHEAD

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1081

Subject No: 10811046

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:	Aug/17/2020
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

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811046

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 :	Aug/17/2020
2.	Randomization Number:	[52203]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811046

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: Aug/17/2020
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	[BP1J7P]
5.b	Sample ID	[BP1J7R]
5.c	Sample ID	[BP1J7S]
5.d	Sample ID	[BPHZGT]
5.e	Sample ID	[BPHZGV]

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811046

Generated By: pfe.lewissc

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: Aug/17/2020
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	[BP1J7Z]
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090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811046

Generated By: pfe.lewissc

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:	Aug/17/2020 11:32
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

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1081

Subject No: 10811046

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	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811046

Generated By: pfe.lewissc

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/9/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811046

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811046

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1081

Subject No: 10811046

Generated By: pfe.levissc

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/9/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.7]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1081

Subject No: 10811046

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/9/2020
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

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811046

Generated By: pfe.lewissc

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/9/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP97PC]
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090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811046

Generated By: pfe.lewissc

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/9/2020 10:49
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811046

Generated By: pfe.lewissc

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/7/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811046

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811046

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	RIGHT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811046

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: Oct/7/2020
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	[BRTXTS]
5.b	Sample ID	[BRTXTT]
5.c	Sample ID	[BP1HV1]

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811046

Generated By: pfe.lewissc

Form: DATE OF VISIT

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

Date of Visit

1.	Date of Visit	Mar/3/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811046

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Mar/3/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRM4M3]
5.b	Sample ID	[BRM4M4]
5.c	Sample ID	[BS64SB]
5.d	Sample ID	[BKZ4GL]

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811046

Generated By: pfe.levisc

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: 10811046

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	[]
----	-----------	-----

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811046

Generated By: pfe.levissc

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: 10811046

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	[]
----	-----------	-----

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811046

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_ILL - New Unscheduled Visit

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811046

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

Signs and Symptoms

1.	Date of Assessment:	//
2.	Date of First Symptom Started:	//
3.	Symptoms Ongoing?	

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

5.	Symptoms - Other Text:	[]
----	------------------------	-----

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811046

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: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811046

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	[]
----	-----------	-----

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811046

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

Health Care Utilization

1.	Physician or Healthcare Professional:	
	Occurrence of Visits or Contacts:	

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[]
----	-------------------------------------	-----

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	
----	--	--

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811046

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

Illness Details

1.	Category of Clinical Event:	
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	
3.	Toxicity Grade:	

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811046

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 Visit

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: 10811046

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: 10811046

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: 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: 10811046

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Unplanned Assessments

1.	Assessments	
----	-------------	--

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1081

Subject No: 10811046

Generated By: pfe.lewissc

Form: DISPOSITION - TREATMENT

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 - Treatment

1.	Date of Completion/Discontinuation/Death :	Oct/7/2020
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: 10811046

Generated By: pfe.levissc

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Disposition - Follow-Up

1.	Date of Completion/Discontinuation/Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[]

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
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: 10811046

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 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: 10811046

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	[]
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090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

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: 10811046

Subject Initials: ---

Generated By: pfe.leviscc

Generated Time (GMT): 29-Mar-2021 10:11

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Diabetic Ketoacidosis	Sep/17/2020 UNK:UNK	NO End Date Time: Sep/18/2020 UNK:UNK	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811046

Generated By: pfe.levisse

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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[eCRF Audit Trail History](#)
[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Diabetic Ketoacidosis]
4.	Start Date Time:	Sep/17/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/18/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO 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

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811046

Generated By: pfe.levisse

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

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: [self-induced due to watermelon diet]
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?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020371255]

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (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: 10811046

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1081

Subject No: 10811046

Generated By: pfe.levisse

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

[Back to Form](#)

Medication Error

1.	Category:	
2.	Medication Error (Type of Medication Error):	[]
3.	Start Date:	//
4.	Is the medication error still ongoing?	
5.	Latest Action Taken with Study Treatment:	
6.	Was a Concomitant Medication given?	
7.	Was a Non-Drug Treatment given?	
8.	Did the Medication Error cause the subject to be discontinued from the study?	
9.	Was this medication error associated with any adverse events?	
10.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (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: 10811046

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

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

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: 10811046

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Concomitant Medications

1.	What is the medication identifier?	[]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[]
5.	Date:	//

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (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: 10811046

Subject Initials: ---

Generated By: pfe.levisse

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

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811046

Generated By: pfe.levisse

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?	

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (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: 10811046

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

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811046

Generated By: pfe.levisse

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: 10811046

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811046

Generated By: pfe.levisse

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: 10811046

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: 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: 10811046

Subject Initials: ---

Generated By: pfe.lewissc

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: 10811046

Subject Initials: ---

Generated By: pfe.lewissc

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:	

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

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:** 10811046**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?	

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: 10811046

Subject Initials: ---

Generated By: pfe.levisse

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: 10811046

Subject Initials: ---

Generated By: pfe.lewissc

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: 10811046

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: 10811046

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Informed Consent - Asymptomatic Surveillance

1.	Consent Was:	
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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: 10811046

Subject Initials: ---

Generated By: pfe.lewissc

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 Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811046

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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	[]
----	-----------	-----

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811046

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Feb/4/2021
2.	Erroneous Visit	

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811046

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2
----	---	--

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811046

Generated By: pfe.lewissc

Form: TREATMENT UNBLINDED

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

Treatment Unblinded

1.	Date Treatment Unblinded :	Feb/4/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811046

Generated By: pfe.levisse

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 :	//
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Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811046

Generated By: pfe.levisse

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Death Details

1.	Date of Collection / Notification of Death:	//
----	---	----

Cause of Death

2.	Cause of Death Status:	
	Cause of Death:	[]

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811046

Generated By: pfe.lewissc

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	FOLLOW-UP
2.	Subject Status Date	Oct/7/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811046

Generated By: pfe.lewissc

Form: CASEBOOK SIGNATURE FORM

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](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
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Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811046

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
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1081

Subject No: 10811046

Generated By: pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-17-2020 10:53:28 (UTC-05:00) Eastern Time (US & Canada)	Tawnyn Ebner (pfe.tebner)	All inclusion and exclusion met <hr/> Not Done

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811046

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

This form requires signing by a member of each of the following signature groups:

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
Lora Morris	N/A	Feb-04-2021 17:01:02 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

James Fry	Approved	Jan-23-2021 11:57:46 (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	Jan-15-2021 07:46:58 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Michael Butcher	Approved	Oct-22-2020 15:21:54 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
-----------------	----------	---	------	--------

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.

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811046

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-17-2020 10:51:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn 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
Aug-17-2020 10:51:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811046

Generated By: pfe.lewissc

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

[Back to Form](#)

I. Consent Was:

Date	Location	User	Value	Reason
Aug-17-2020 10:52:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: OBTAINED Date Written Consent Obtained Aug/17/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1081

Subject No: 10811046

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

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Aug-17-2020 10:51:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10811046	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-17-2020 10:51:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1965	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-17-2020 10:52:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-17-2020 10:52:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Aug-17-2020 10:52:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BLACK OR AFRICAN AMERIC AN	Initial Entry

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811046

Generated By: pfe.lewissc

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Aug-17-2020 10:53:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Aug/17/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811046

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-17-2020 10:54:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Aug/17/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-17-2020 10:54:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-17-2020 10:54:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: COMPLETED	Initial Entry

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1081**Subject No:** 10811046**Generated By:** pfe.lewissc**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
Aug-17-2020 13:24:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: Presbyopia Start Date: UNK/UNK/2016 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 13:24:33 (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
Aug-17-2020 13:24:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Presbyopia	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 13:24:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2016	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 13:24:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

I.b

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811046

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Aug-17-2020 13:25:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 2 ber: Medical Histor Chronic Bronchit y Term: is-Stable Start Date: UNK/UNK/2005 Ongoing: YES	Initial Entry

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 13:25:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 13:25:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Chronic Bronchitis-Stable	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 13:25:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2005	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 13:25:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Aug-17-2020 13:25:31 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numbe 3	Initial Entry

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811046

Generated By: pfe.levisse

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

Time (US & Canada)			r: Medical History Term: Pneumonia Start Date: UNK/UNK/2011 Ongoing: NO End Date: UNK/UNK/2014
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I.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 13:25:31 (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
Aug-17-2020 13:25:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Pneumonia	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 13:25:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2011	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 13:25:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO End Date: UNK/UNK/2014	Initial Entry

I.d

Date	Location	User	Value	Reason
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090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811046

Generated By: pfe.levisse

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

Aug-17-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: Pneumonia Start Date: UNK/UNK/2014 Ongoing: NO End Date: Dec/UNK/2014	Initial Entry
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I.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

I.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Pneumonia	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2014	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO End Date: Dec/UNK/2014	Initial Entry

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811046

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Aug-17-2020 13:26:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Term: Sleep Apnea Start Date: UNK/UNK/2014 Ongoing: YES	Initial Entry

I.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 13:26:24 (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
Aug-17-2020 13:26:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Sleep Apnea	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 13:26:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2014	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 13:26:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
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090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811046

Generated By: pfe.levisse

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

Aug-17-2020 13:26:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 6 Medical History Term: Hypertension Start Date: UNK/UNK/2008 Ongoing: YES	Initial Entry
---	-----------------	-------------------------	---	---------------

If Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 13:26:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

If Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 13:26:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Hypertension	Initial Entry

If Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 13:26:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2008	Initial Entry

If Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 13:26:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

I.g

Date	Location	User	Value	Reason
Aug-17-2020 13:26:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 7	Initial Entry

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			Medical History Term: Dyslipidemia Start Date: UNK/UNK/2016 Ongoing: YES	
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I.g Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 13:26:59 (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
Aug-17-2020 13:26:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Dyslipidemia	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 13:26:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2016	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 13:26:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

I.h

Date	Location	User	Value	Reason
Aug-17-2020 13:27:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 8 Medical History Term: Diabetes Mellitus Type 2	Initial Entry

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			Start Date: UNK/UNK/2016	
			Ongoing: YES	

1.h Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 13:27:23 (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
Aug-17-2020 13:27:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Diabetes Mellitus Type 2	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 13:27:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2016	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 13:27:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

1.i

Date	Location	User	Value	Reason
Aug-17-2020 13:27:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 9 Medical History Term: Obesity Start Date: UNK/UNK/2003 Ongoing: YES	Initial Entry

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Header Text: c4591001

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1.i Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 13:27:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

1.i Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 13:27:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Obesity	Initial Entry

1.i Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 13:27:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2003	Initial Entry

1.i Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 13:27:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

1.j

Date	Location	User	Value	Reason
Aug-17-2020 13:28:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 10 Medical History Term: Abdominal Hernia Start Date: UNK/UNK/2012 Ongoing: NO End Date: UNK/UNK/2012	Initial Entry

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L.j Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 13:28:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10	Initial Entry

L.j Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 13:28:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Abdominal Hernia	Initial Entry

L.j Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 13:28:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2012	Initial Entry

L.j Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 13:28:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO End Date: UNK/UNK/2012	Initial Entry

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Header Text: c4591001

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1.k

Date	Location	User	Value	Reason
Aug-17-2020 13:28:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 11 ber: Medical Histor Osteoarthritis of y Term: Left Knee Start Date: UNK/UNK/2014 Ongoing: YES	Initial Entry

1.k Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 13:28:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11	Initial Entry

1.k Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 13:28:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Osteoarthritis of Left Knee	Initial Entry

1.k Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 13:28:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2014	Initial Entry

1.k Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 13:28:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

1.l

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Date	Location	User	Value	Reason
Aug-17-2020 13:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 12 ber: Medical Histor Osteoarthritis of y Term: Low Back Start Date: UNK/UNK/2014 Ongoing: YES	Initial Entry

1.1 Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 13:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12	Initial Entry

1.1 Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 13:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Osteoarthritis of Low Back	Initial Entry

1.1 Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 13:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2014	Initial Entry

1.1 Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 13:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

1.m

Date	Location	User	Value	Reason
Aug-17-2020 13:29:32 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

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Time (US & Canada)			Line/MH Number 13 : Medical History T Chronic Back erm: Pain Start Date: UNK/UNK/20 14 Ongoing: YES	
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1.m Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 13:29:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 13	Initial Entry

1.m Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 13:29:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> Chronic Back Pain	Initial Entry

1.m Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 13:29:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> UNK/UNK/2014	Initial Entry

1.m Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 13:29:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> YES	Initial Entry

1.n

Date	Location	User	Value	Reason
Aug-17-2020 13:30:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Line/MH Num 14 ber:	Initial Entry

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			Medical History Term: Allergy-Dilaudid-itching Start Date: UNK/UNK/2010 Ongoing: YES
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1.n Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 13:30:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 14	Initial Entry

1.n Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 13:30:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Allergy-Dilaudid-itching	Initial Entry

1.n Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 13:30:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2010	Initial Entry

1.n Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 13:30:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

1.o

Date	Location	User	Value	Reason
Aug-17-2020 13:30:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 15 : Medical History Term: Allergy-Sulfam	Initial Entry

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Subject No: 10811046

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Generated Time (GMT): 29-Mar-2021 10:11

			Start Date:	UNK/UNK/1989	
			Ongoing:	YES	

I.o Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 13:30:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 15	Initial Entry

I.o Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 13:30:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Allergy-Sulfa	Initial Entry

I.o Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 13:30:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/1989	Initial Entry

I.o Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 13:30:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

I.p

Date	Location	User	Value	Reason
Aug-17-2020 13:32:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 16 Medical History Term: Allergy-Shellfish-Hives Start Date: UNK/UNK/1989	Initial Entry

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			Ongoing:	YES	
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I.p Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 13:32:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 16	Initial Entry

I.p Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 13:32:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Allergy-Shellfish-Hives	Initial Entry

I.p Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 13:32:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/1989	Initial Entry

I.p Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 13:32:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

I.q

Date	Location	User	Value	Reason
Aug-17-2020 13:33:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 17 : Medical History T Insomnia erm: Start Date: UNK/UNK/2 008 Ongoing: YES	Initial Entry

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1.q Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 13:33:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: 17	Initial Entry

1.q Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 13:33:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Insomnia	Initial Entry

1.q Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 13:33:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2008	Initial Entry

1.q Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 13:33:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

1.r

Date	Location	User	Value	Reason
Aug-17-2020 13:33:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: Line/MH Number 18 : Medical History T Anxiety erm: Start Date: UNK/UNK/2 000 Ongoing: YES	Initial Entry

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I.r Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 13:33:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: 18	Initial Entry

I.r Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 13:33:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Anxiety	Initial Entry

I.r Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 13:33:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2000	Initial Entry

I.r Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 13:33:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

I.s

Date	Location	User	Value	Reason
Aug-17-2020 13:33:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: Line/MH Number 19 : Medical History T Depression erm: Start Date: UNK/UNK/2 009 Ongoing: YES	Initial Entry

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I.s Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 13:33:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: 19	Initial Entry

I.s Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 13:33:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Depression	Initial Entry

I.s Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 13:33:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2009	Initial Entry

I.s Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 13:33:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

I.t

Date	Location	User	Value	Reason
Aug-17-2020 13:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: Line/MH Numbe 20 r: Medical History Blood Transfusi Term: on Start Date: UNK/UNK/198 9 Ongoing: NO End Date: UNK/UNK/ 1999	Initial Entry

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Header Text: c4591001

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Site No: 1081

Subject No: 10811046

Generated By: pfe.levisse

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.t Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 13:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: 20	Initial Entry

1.t Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 13:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Blood Transfusion	Initial Entry

1.t Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 13:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/1989	Initial Entry

1.t Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 13:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO End Date: UNK/UNK/1999	Initial Entry

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811046

Generated By: pfe.levisse

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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<i>1.u</i>				
Date	Location	User	Value	Reason
Aug-17-2020 13:35:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 21 Medical History Term: Abdominal Hernia Repair Start Date: UNK/UNK/2012 Ongoing: NO End Date: UNK/UNK/2012	Initial Entry

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811046

Generated By: pfe.levisse

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.u Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 13:35:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: 21	Initial Entry

1.u Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 13:35:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Abdominal Hernia Repair	Initial Entry

1.u Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 13:35:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2012	Initial Entry

1.u Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 13:35:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO End Date: UNK/UNK/2012	Initial Entry

1.v

Date	Location	User	Value	Reason
Aug-17-2020 13:35:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: Line/MH Num 22 ber: Medical Histor Abdominal Herni y Term: a Repair Start Date: UNK/UNK/2017	Initial Entry

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811046

Generated By: pfe.levisse

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

			Ongoing:	NO End Date: UNK/UNK/2017
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1.v Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 13:35:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: 22	Initial Entry

1.v Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 13:35:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Abdominal Hernia Repair	Initial Entry

1.v Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 13:35:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2017	Initial Entry

1.v Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 13:35:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO End Date: UNK/UNK/2017	Initial Entry

1.w

Date	Location	User	Value	Reason
Aug-17-2020 13:36:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: Line/MH Number: 23	Initial Entry

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811046

Generated By: pfe.levisse

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: Hysterectomy Start Date: UNK/UNK/1999 Ongoing: NO End Date: UNK/UNK/1999	
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1.w Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 13:36:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: 23	Initial Entry

1.w Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 13:36:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Hysterectomy	Initial Entry

1.w Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 13:36:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/1999	Initial Entry

1.w Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 13:36:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO End Date: UNK/UNK/1999	Initial Entry

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1081

Subject No: 10811046

Generated By: pfe.lewissc

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
Aug-17-2020 13:36:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> Aug/17/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-17-2020 13:36:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> 204.5	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-17-2020 13:36:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-17-2020 13:36:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> 64.75	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-17-2020 13:36:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-17-2020 13:36:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 34.3	Initial Entry

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1081

Subject No: 10811046

Generated By: pfe.levisse

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

7.a

Date	Location	User	Value	Reason
Aug-17-2020 13:36:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Record Identifier:: 1 Temperature: 97.5 Temperature Unit: F Temperature Locatio n:: FOREHEA D	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-17-2020 13:36:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-17-2020 13:36:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: 97.5	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-17-2020 13:36:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-17-2020 13:36:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: FOREHEAD	Initial Entry

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811046**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Aug-17-2020 13:36:52 (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
Aug-17-2020 13:36:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-17-2020 13:36:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Aug/17/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Aug-17-2020 13:36:52 (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
Aug-17-2020 13:36:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-17-2020 13:36:52 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811046

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Time (US & Canada)			Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: Not Done:: NOT DONE
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-17-2020 13:36:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-17-2020 13:36:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Aug-17-2020 13:36:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NOT DONE	Initial Entry

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811046

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
Aug-17-2020 13:37:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Aug/17/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-17-2020 13:37:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: 52203	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: 10811046

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Data Origin

Date	Location	User	Value	Reason
Aug-17-2020 11:18:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-17-2020 11:18:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-17-2020 11:18:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-17-2020 11:18:15 (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.
Aug-17-2020 11:18:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Aug/17/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-17-2020 11:18:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BP1J7P	Initial Entry

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (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: 10811046

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.a Sample ID

Date	Location	User	Value	Reason
Aug-17-2020 11:18:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: BP1J7P	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-17-2020 11:18:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: Sample ID: BP1J7R	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-17-2020 11:18:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: BP1J7R	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-17-2020 11:18:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: Sample ID: BP1J7S	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-17-2020 11:18:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: BP1J7S	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-17-2020 11:18:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: Sample ID: BPHZGT	Initial Entry

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (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: 10811046

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.d Sample ID

Date	Location	User	Value	Reason
Aug-17-2020 11:18:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BPHZGT	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-17-2020 11:19:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BPHZGV	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-17-2020 11:19:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BPHZGV	Initial Entry

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (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:** 10811046**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-17-2020 11:04:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-17-2020 11:04:31 (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
Aug-17-2020 11:04:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-17-2020 11:04:31 (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.
Aug-17-2020 11:04:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Aug/17/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-17-2020 11:04:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BP1J7Z	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811046

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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

5.a Sample ID

Date	Location	User	Value	Reason
Aug-17-2020 11:04:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BP1J7Z	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811046

Generated By: pfe.lewissc

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
Aug-17-2020 13:37:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-17-2020 13:37:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-17-2020 13:37:22 (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
Aug-17-2020 13:37:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Aug/17/2020 11:32	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-17-2020 13:37:22 (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
Aug-17-2020 13:37:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: LEFT	Initial Entry

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811046

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

7. Route:

Date	Location	User	Value	Reason
Aug-17-2020 13:37:22 (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
Aug-17-2020 13:37:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Aug-17-2020 13:37:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1081

Subject No: 10811046

Generated By: pfe.lewissc

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-03-2020 00:14:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pramod Margaj (pfe.margap03)	Query 1: Closed	Closed by DM: PM.
Sep-02-2020 07:10:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Sep-02-2020 07:10:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES - REACTOGENICITY E -DIARY COLLECTED FOR T HIS SUBJECT	Changed Information
Sep-02-2020 04:13:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Premraj Bhoyar (pfe.bhoyap)	Query 1: Opened	eDiary: REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT is 'No' however VAX 1 eDiary records are available for the subject. Please verify and update. Else, confirm in query response appropriately.
Aug-17-2020 13:37:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO - REACTOGENICITY E- DIARY NOT COLLECTED F OR THIS SUBJECT	Initial Entry

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811046

Generated By: pfe.lewissc

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-09-2020 10:36:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sep/9/2020	Initial Entry

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:52**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811046**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Sep-09-2020 11:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-09-2020 11:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Symptom:: FE VE R Were fever or systemic symp toms present on the last day the Subject Diary was compl eted?: NO	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Sep-09-2020 11:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: FEVER	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-09-2020 11:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-09-2020 11:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Symptom:: FAT IG	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811046

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

			UE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	
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2.b Symptom:

Date	Location	User	Value	Reason
Sep-09-2020 11:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-09-2020 11:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-09-2020 11:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> Symptom:: HEA DA CHE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:52**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811046**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11**2.c Symptom:**

Date	Location	User	Value	Reason
Sep-09-2020 11:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-09-2020 11:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-09-2020 11:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Symptom:: CH IL LS Were fever or systemic symp NO toms present on the last day the Subject Diary was compl eted?:	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Sep-09-2020 11:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-09-2020 11:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811046

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Sep-09-2020 11:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Symptom:: VO MIT ING Were fever or systemic sym ptoms present on the last d ay the Subject Diary was c ompleted?:	Initial Entry
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2.e Symptom:

Date	Location	User	Value	Reason
Sep-09-2020 11:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-09-2020 11:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Sep-09-2020 11:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic sym ptoms present on the last d ay the Subject Diary was co mpleted?:	Initial Entry

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811046

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

2.f Symptom:

Date	Location	User	Value	Reason
Sep-09-2020 11:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-09-2020 11:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-09-2020 11:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Symptom:: NEW OR WORSE NED MUS CLE PAIN Were fever or systemi c symptoms present o n the last day the Sub ject Diary was comple ted?: NO	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Sep-09-2020 11:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NEW OR WORSE NED MUSCLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-09-2020 11:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811046

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

2.h

Date	Location	User	Value	Reason
Sep-09-2020 11:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Symptom:: NEW OR WORSE NED JOI NT PAIN Were fever or systemi NO c symptoms present o n the last day the Subj ect Diary was complet ed?:	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Sep-09-2020 11:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NEW OR WORSENERD JOINT PA IN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-09-2020 11:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-09-2020 11:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-09-2020 11:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: LEFT	Initial Entry

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811046

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.a

Date	Location	User	Value	Reason
Sep-09-2020 11:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reaction s present on the last day the Subject Diary was complete d?: NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-09-2020 11:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-09-2020 11:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-09-2020 11:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reaction s present on the last day th e Subject Diary was compl eted?: NO	Initial Entry

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811046

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-09-2020 11:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-09-2020 11:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-09-2020 11:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Injection Site Reaction: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-09-2020 11:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-09-2020 11:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO	Initial Entry

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1081

Subject No: 10811046

Generated By: pfe.lewissc

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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1. Date:

Date	Location	User	Value	Reason
Sep-09-2020 11:27:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Sep/9/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-09-2020 11:27:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Record Identifier:: 1 Temperature: 97.7 Temperature Unit: F Temperature Locat ORAL CAVI ion:: TY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-09-2020 11:27:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-09-2020 11:27:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: 97.7	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-09-2020 11:27:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: F	Initial Entry

2.a Temperature Location:

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1081

Subject No: 10811046

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Sep-09-2020 11:27:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811046**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
Sep-09-2020 11:27:39 (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-09-2020 11:27:39 (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-09-2020 11:27:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Sep/9/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-09-2020 11:27:39 (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-09-2020 11:27:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-09-2020 11:27:39 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811046

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Time (US & Canada)			Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: Not Done:: NOT DONE
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-09-2020 11:27:39 (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-09-2020 11:27:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-09-2020 11:27:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NOT DONE	Initial Entry

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (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:** 10811046**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
Sep-09-2020 10:37:14 (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-09-2020 10:37:14 (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-09-2020 10:37:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-09-2020 10:37:14 (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-09-2020 10:37:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Sep/9/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-09-2020 10:37:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: Sample ID: BP97PC	Initial Entry

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: 10811046

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.a Sample ID

Date	Location	User	Value	Reason
Sep-09-2020 10:37:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BP97PC	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811046

Generated By: pfe.lewissc

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-09-2020 11:28:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-09-2020 11:28:16 (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-09-2020 11:28:16 (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-09-2020 11:28:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Sep/9/2020 10:49	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-09-2020 11:28:16 (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-09-2020 11:28:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: RIGHT	Initial Entry

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811046

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

7. Route:

Date	Location	User	Value	Reason
Sep-09-2020 11:28:16 (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-09-2020 11:28:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION 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-09-2020 11:28:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811046

Generated By: pfe.lewissc

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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1. Date of Visit

Date	Location	User	Value	Reason
Oct-07-2020 09:37:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Oct/7/2020	Initial Entry

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:52**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811046**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Oct-07-2020 09:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-07-2020 09:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom:: FE VE R Were fever or systemic sym N ptoms present on the last da O y the Subject Diary was co mpleted?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Oct-07-2020 09:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: FEVER	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 09:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Oct-07-2020 09:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom:: FA TIG	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811046

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

			UE Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
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2.b Symptom:

Date	Location	User	Value	Reason
Oct-07-2020 09:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 09:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Oct-07-2020 09:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001
Visit: V3_MONTH1_POSTVAX2_L
Form Version: 21-Aug-2020 02:52
Site No: 1081
Subject No: 10811046
Generated By: pfe.levisse

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - 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

2.c Symptom:

Date	Location	User	Value	Reason
Oct-07-2020 09:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 09:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Oct-07-2020 09:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom:: CH IL LS Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Oct-07-2020 09:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 09:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811046

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Oct-07-2020 09:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom:: VO MIT ING Were fever or systemic sy mptoms present on the las t day the Subject Diary wa s completed?:	Initial Entry
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2.e Symptom:

Date	Location	User	Value	Reason
Oct-07-2020 09:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 09:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Oct-07-2020 09:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic sy mptoms present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:52**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811046**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11**2.f Symptom:**

Date	Location	User	Value	Reason
Oct-07-2020 09:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 09:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Oct-07-2020 09:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom:: NEW OR WORSE NED MUS CLE PAI N Were fever or system ic symptoms present on the last day the Su bject Diary was com pleted?: NO	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Oct-07-2020 09:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NEW OR WORSE NED MUSCLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 09:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811046

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

2.h

Date	Location	User	Value	Reason
Oct-07-2020 09:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom:: NEW OR WORSE NED JOINT PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Oct-07-2020 09:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NEW OR WORSE NED JOINT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 09:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Oct-07-2020 09:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Oct-07-2020 09:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: RIGHT	Initial Entry

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811046

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.a

Date	Location	User	Value	Reason
Oct-07-2020 09:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-07-2020 09:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 09:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-07-2020 09:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:52**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811046**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11**5.b Injection Site Reaction:**

Date	Location	User	Value	Reason
Oct-07-2020 09:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 09:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-07-2020 09:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Injection Site Reaction PAIN AT INJECTION SITE : Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-07-2020 09:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 09:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	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:** 10811046**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-07-2020 09:56:39 (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-07-2020 09:56:39 (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-07-2020 09:56:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-07-2020 09:56:39 (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-07-2020 09:56:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Oct/7/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-07-2020 09:56:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: Sample ID: BRTXTS	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: 10811046

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.a Sample ID

Date	Location	User	Value	Reason
Oct-07-2020 09:56:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BRTXTS	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-07-2020 09:57:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BRTXTT	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-07-2020 09:57:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BRTXTT	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-07-2020 09:57:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BP1HV1	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-07-2020 09:57:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BP1HV1	Initial Entry

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811046

Generated By: pfe.levissc

Form: DATE OF VISIT - 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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I. Date of Visit

Date	Location	User	Value	Reason
Mar-03-2021 08:04:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Mar/3/2021	Initial Entry

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001**Visit:** V4_MONTH6_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1081**Subject No:** 10811046**Generated By:** pfe.lewissc**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Mar-03-2021 08:04:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-03-2021 08:04:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-03-2021 08:04:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-03-2021 08:04:47 (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.
Mar-03-2021 08:04:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Mar/3/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-03-2021 08:04:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: Sample ID: BRM4M3	Initial Entry

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811046

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.a Sample ID

Date	Location	User	Value	Reason
Mar-03-2021 08:04:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: BRM4M3	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-03-2021 08:05:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: Sample ID: BRM4M4	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-03-2021 08:05:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: BRM4M4	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-03-2021 08:05:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: Sample ID: BS64SB	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-03-2021 08:05:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: BS64SB	Initial Entry

5.d

Date	Location	User	Value	Reason
Mar-03-2021 08:05:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: Sample ID: BKZ4GL	Initial Entry

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811046

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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

5.d Sample ID

Date	Location	User	Value	Reason
Mar-03-2021 08:05:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BKZ4GL	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811046

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-07-2020 09:38:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Oct/7/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-07-2020 09:38:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-07-2020 09:38:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: COMPLETED	Initial Entry

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811046

Generated By: pfe.lewissc

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
Sep-24-2020 15:28:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811046

Generated By: pfe.levisse

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
Sep-24-2020 15:28:40 (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
Sep-24-2020 15:28:40 (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
Jan-17-2021 05:55:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	Response satisfies query
Jan-15-2021 07:46:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Jan-15-2021 07:46:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Diabetic Ketoacidosis	Changed Information
Jan-13-2021 06:02:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON:AER#2020371255, the term in Safety DB was updated to 'Diabetic Ketoacidoses' while retained as Hyperglycemic episode in AE CRF. Please confirm correct term. If safety update is required, please submit a follow-up form.
Sep-24-2020 15:28:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Hyperglycemic episode	Initial Entry

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811046

Generated By: pfe.levisse

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

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-24-2020 15:28:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sep/17/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-24-2020 15:28:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO End Date Time: Sep/18/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-12-2020 12:04:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nicholas Roosa (pfe.roosan)	Query 1: Closed	Response satisfies query
Oct-07-2020 08:28:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-07-2020 08:28:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: 3	Transcription Error
Oct-07-2020 07:28:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Swetha Thangellapally (pfe.thangs22)	Query 1: Reissued:Opened	Page is unfreeze, you will be able to change the data now. Kindly update the data accordingly. Thanks.
Oct-06-2020 13:23:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	correct, this was a transcription error, unable to change data, only able to answer query. Please advise
Oct-06-2020 13:04:46 (UTC-05:00) Eastern	ACV0PFEINFP6000	Nicholas Roosa	Query 1: Opened	Per source AE log, toxicity grade of 3.

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811046

Generated By: pfe.levisse

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

Time (US & Canada)		(pfe.roosan)		Please confirm.
Sep-24-2020 15:28:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: 2	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-05-2020 14:36:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Query closed; will follow for SAE update with the requested COVID test info
Nov-04-2020 13:52:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 2: Answered	this has been noted in the most recent SAE update, as of 04Nov2020
Nov-04-2020 11:59:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Reissued:Opened	Clinical - Thank you. Please document in SAE report that you are awaiting medical records to determine if a COVID test was performed (DMC request)
Nov-04-2020 09:10:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 2: Answered	It is still unknown if COVID testing was performed. Still awaiting records. Data will be updated once records are received. Please clarify if 'unknown if COVID testing was performed at time of hospitalization'

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1081**Subject No:** 10811046**Generated By:** pfe.levisse**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

				needs to be added to SAE form
Oct-23-2020 17:07:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	Clinical COVID testing has not been reported in the SAE submitted to safety. Please submit a follow-up SAE form [#2020371255] to provide whether COVID testing was performed (yes/no) and if yes, the results.
Sep-25-2020 06:10:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-24-2020 15:28:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Hyperglycemic episode: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Sep-24-2020 15:28:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1081

Subject No: 10811046

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

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			<p>persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	
--	--	--	---	--

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
Sep-24-2020 15:28:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-24-2020 15:28:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> self-induced due to watermelon diet	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-24-2020 15:28:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NOT APPLICABLE	Initial Entry

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811046

Generated By: pfe.levisse

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

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-24-2020 15:28:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-24-2020 15:28:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Sep-24-2020 15:28:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Sep-24-2020 15:28:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Sep-25-2020 06:10:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Data Entry: 2020371255	Initial Entry

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811046

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-04-2021 17:01:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Feb/4/2021	Initial Entry

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1081

Subject No: 10811046

Generated By: pfe.levissc

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History

Form Status: Data Complete, Frozen

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 - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Feb-04-2021 17:01:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at V accination 1/2	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811046

Generated By: pfe.lewissc

Form: TREATMENT UNBLINDED - 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 Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-24-2021 00:29:48 (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_DS001_36
Feb-23-2021 13:14:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: An swere d	Transcription Error
Feb-23-2021 13:14:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry : Feb/4/ 2021	Transcription Error
Feb-22-2021 21:11:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Op ened	DMW7350973;Date Treatment Unblinded should be equal to or after DOV in REVAX CONTACT visit when Reason is ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION.Please review and update as appropriate.
Feb-04-2021 17:01:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry : Feb/2/ 2021	Initial Entry

2. Primary Reason for Unblinding:

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811046

Generated By: pfe.levisse

Form: TREATMENT UNBLINDED - 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

Date	Location	User	Value	Reason
Feb-04-2021 17:01:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811046

Generated By: pfe.levissc

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, 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 Status

Date	Location	User	Value	Reason
Oct-07-2020 09:38:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-17-2020 13:37:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-17-2020 10:54:00 (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
Oct-07-2020 09:38:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/7/2020	Initial Entry
Aug-17-2020 13:37:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/17/2020	Initial Entry
Aug-17-2020 10:54:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/17/2020	Initial Entry

090177e196ae3f0a\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811046

Generated By: pfe.lewissc

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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I. Casebook Signature

Date	Location	User	Value	Reason
Oct-22-2020 15:20:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: Click Here to Enable	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1081

Subject No: 10811048

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: 10811048

Generated By: pfe.levisse

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 Aug/17/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

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	[10811048]
2.	Birth Date:	(b) (6)/1935
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: 10811048

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	Aug/17/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

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 _____
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

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	Aug/17/2020
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: 10811048

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:	[Glaucoma-Bilateral]
	Start Date:	UNK/UNK/2013
	Ongoing:	NO End Date: UNK/UNK/2017
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Presbyopia]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Tonsillitis]
	Start Date:	UNK/UNK/1940
	Ongoing:	NO End Date: UNK/UNK/1940
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Dyslipidemia]
	Start Date:	UNK/UNK/1998
	Ongoing:	YES

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811048

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.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HYPOTHYROIDISM]
	Start Date:	Jun/UNK/2020
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Gastroesophageal reflux disease]
	Start Date:	UNK/UNK/1944
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Gallstones]
	Start Date:	UNK/UNK/1966
	Ongoing:	NO End Date: UNK/UNK/1966
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Irritable Bowel Syndrome]
	Start Date:	UNK/UNK/2014
	Ongoing:	YES
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Colon Polyps-Benign]
	Start Date:	UNK/UNK/2002
	Ongoing:	YES

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811048

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

1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Osteoarthritis-Right Hand]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Osteoarthritis-Bilateral Knees]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Osteoarthritis-Toes-All]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.m	Line/MH Number:	[13]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Osteoporosis]
	Start Date:	UNK/UNK/2004
	Ongoing:	YES
1.n	Line/MH Number:	[14]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Allergy-Codeine]
	Start Date:	UNK/UNK/2002
	Ongoing:	YES

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811048

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

1.o	Line/MH Number:	[15]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Tonsillectomy]
	Start Date:	Jul/UNK/1940
	Ongoing:	NO End Date: Jul/UNK/1940
1.p	Line/MH Number:	[16]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Cataract Repair Surgery]
	Start Date:	UNK/UNK/2017
	Ongoing:	NO End Date: UNK/UNK/2017
1.q	Line/MH Number:	[17]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Arthroscopic Surgery-Right Knee Cartilage Removal]
	Start Date:	UNK/UNK/2002
	Ongoing:	NO End Date: UNK/UNK/2002
1 r	Line/MH Number:	[18]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Ovarian Cystectomy]
	Start Date:	UNK/UNK/1960
	Ongoing:	NO End Date: UNK/UNK/1960

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811048

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

1.s	Line/MH Number:	[19]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Knee Replacement-Left Knee]
	Start Date:	UNK/UNK/2009
	Ongoing:	NO End Date: UNK/UNK/2009
1.t	Line/MH Number:	[20]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Cholecystectomy]
	Start Date:	UNK/UNK/1966
	Ongoing:	NO End Date: UNK/UNK/1966

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

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:	Aug/17/2020
2.	Weight:	[117.0]
3.	Unit:	LB
4.	Height:	[56.0]
5.	Unit:	in
6.	Body Mass Index:	[26.2]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.7]
	Unit:	F
	Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

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:	Aug/17/2020
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

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

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 :	Aug/17/2020
2.	Randomization Number:	[229863]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

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: Aug/17/2020
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	[BP1J8B]
5.b	Sample ID	[BP1J8C]
5.c	Sample ID	[BP1J8D]
5.d	Sample ID	[BPHZGY]
5.e	Sample ID	[BPHZGZ]

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

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: Aug/17/2020
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	[BP1J81]
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

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:	Aug/17/2020 12:18
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

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

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
----	--	--

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811048

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/9/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1081

Subject No: 10811048

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/9/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.0]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

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/9/2020
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

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

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/9/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP97PD]
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

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/9/2020 11:46
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

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811048

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/7/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

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: Oct/7/2020
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	[BP1HV5]
5.b	Sample ID	[BRTXV1]
5.c	Sample ID	[BRTXV2]

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811048

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:	
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Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811048

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Signs and Symptoms

1.	Date of Assessment:	//
2.	Date of First Symptom Started:	//
3.	Symptoms Ongoing?	

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

5.	Symptoms - Other Text:	[]
----	------------------------	-----

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811048

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	[]
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Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811048

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	[]
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Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811048

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Health Care Utilization

1.	Physician or Healthcare Professional:	
	Occurrence of Visits or Contacts:	

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[]
----	-------------------------------------	-----

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	
----	--	--

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811048

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Illness Details

1.	Category of Clinical Event:	
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	
3.	Toxicity Grade:	

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled **Form:** DATE OF VISIT - ILLNESS CONVALESCENT 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: 10811048

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:	
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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: 10811048

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	[]
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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: 10811048

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: 10811048

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Unplanned Assessments

1.	Assessments	
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090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

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: 10811048

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/7/2020
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: 10811048

Generated By: pfe.levisse

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Disposition - Follow-Up

1.	Date of Completion/Discontinuation /Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[]

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
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: 10811048

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 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: 10811048

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: 10811048

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Hip Fracture, right	Jan/12/2021 UNK:UNK	NO End Date Time: Jan/22/2021 UNK:UNK	Repeating Pages
2. DELETED	ADVERSE EVENT	2	Hip replacement	Jan/13/2021 UNK:UNK	NO End Date Time: Jan/13/2021 UNK:UNK	Repeating Pages
3.	ADVERSE EVENT	3	Fall on stairs at home	Jan/12/2021 UNK:UNK	NO End Date Time: Jan/12/2021 UNK:UNK	Repeating Pages

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

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)	[Hip Fracture, right]
4.	Start Date Time:	Jan/12/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/22/2021 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO 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: [fall at home]

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811048

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

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?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021030829]

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1081**Subject No:** 10811048**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Deleted**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:11

*** THIS REPEATING FORM HAS BEEN DELETED ***

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Hip replacement]
4.	Start Date Time:	Jan/13/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/13/2021 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? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? YES Is this serious event life threatening? NO 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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

***** THIS REPEATING FORM HAS BEEN DELETED *****

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: [hip fracture from fall at home]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Fall on stairs at home]
4.	Start Date Time:	Jan/12/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/12/2021 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO 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

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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: [fall at home-no underlying suspected medical cause]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021030829]

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (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: 10811048

Subject Initials: ---

Generated By: pfe.levisse

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: 10811048

Generated By: pfe.levisse

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	[]

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (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: 10811048

Subject Initials: ---

Generated By: pfe.levisse

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

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

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: 10811048

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:	//

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (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: 10811048

Subject Initials: ---

Generated By: pfe.levisse

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

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

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?	

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (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: 10811048

Subject Initials: ---

Generated By: pfe.levisse

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

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

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: 10811048

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

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: 10811048

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: 10811048

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: 10811048

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: 10811048

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?	

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (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: 10811048

Subject Initials: ---

Generated By: pfe.levisse

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: 10811048

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Contact Outcome

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[]

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811048

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	Jan/11/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811048

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	---

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

Form: TREATMENT UNBLINDED

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](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/11/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811048

Subject Initials: ---

Generated By: pfe.levisse

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: 10811048

Generated By: pfe.levisse

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Death Details

1.	Date of Collection / Notification of Death:	//
----	---	----

Cause of Death

2.	Cause of Death Status:	
	Cause of Death:	[]

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

Form: DATE OF VISIT

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](#)

Date of Visit

1.	Date of Visit	Jan/29/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

Form: INFORMED CONSENT - FURTHER VACCINATION

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](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/29/2021
----	--------------	--

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811048

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable _____
----	---	-------------------------

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable _____
----	---	-------------------------

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

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 - Screening for Further Vaccination

1.	Date of Completion/Discontinuation /Death :	Jan/29/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST

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](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Jan/29/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	
	Not Done:	NOT DONE

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/29/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BS64V9]
5.b	Sample ID	[BS64VB]
5.c	Sample ID	[BP1J0M]
5.d	Sample ID	[BP1J0N]

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/29/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BKN9RJ]
-----	-----------	----------

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

Form: VACCINATION

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](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/29/2021 12:14
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

Form: DATE OF VISIT

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](#)

Date of Visit

1.	Date of Visit	Feb/22/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST

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](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Feb/22/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	
	Not Done:	NOT DONE

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/22/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRN2V9]
-----	-----------	----------

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

Form: VACCINATION

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](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/22/2021 13:02
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811048

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: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Contact Outcome

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[]

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811048

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: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Contact Outcome

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[]

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811048

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: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Contact Outcome

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[]

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811048

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[]

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811048

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	FOLLOW-UP
2.	Subject Status Date	Oct/7/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811048

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
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Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811048

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
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-17-2020 11:57:11 (UTC-05:00) Eastern Time (US & Canada)	Tawny Ebner (pfe.tebner)	All inclusion and exclusion met Not Done

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER
VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811048

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-29-2021 12:11:13 (UTC-05:00) Eastern Time (US & Canada)	Jenni Steinbrunner (pfe.jsteinbrunner)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811048

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

This form requires signing by a member of each of the following signature groups:

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
Ricell Ann Piojo	N/A	Jan-25-2021 04:32:24 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

James Fry	Approved	Jan-23-2021 11:58:16 (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.

James Fry	N/A	Jan-15-2021 08:39:44 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:
N/A

Michael Butcher	Approved	Oct-22-2020 15:06:28 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
-----------------	----------	---	------	--------

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.

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

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
Aug-17-2020 11:56:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn 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
Aug-17-2020 11:56:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn 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: 10811048

Generated By: pfe.levisse

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
Aug-17-2020 11:56:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: OBTAINED Date Written Consent Obtained Aug/17/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

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

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Aug-17-2020 11:56:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10811048	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-17-2020 11:55:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1935	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-17-2020 11:56:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-17-2020 11:56:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын 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
Aug-17-2020 11:56:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: WHITE	Initial Entry

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811048

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
Aug-17-2020 11:57:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Aug/17/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

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
Aug-17-2020 11:57:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Aug/17/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-17-2020 11:57:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-17-2020 11:57:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: COMPLETED	Initial Entry

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1081**Subject No:** 10811048**Generated By:** pfe.levisse**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
Aug-17-2020 16:45:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Line/MH Number: 1 Medical History Term: Glaucoma-Bilateral Start Date: UNK/UNK/2013 Ongoing: NO End Date: UNK/UNK/2017	Transcription Error
Aug-17-2020 16:45:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: Glaucoma-Bilateral Start Date: UNK/UNK/2013 Ongoing: NO End Date: UNK/UNK/2007	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 16:45:03 (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
Aug-17-2020 16:45:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Glaucoma-Bilateral	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

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.a Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 16:45:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2013	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 16:45:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-17-2020 16:45:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO End Date: UNK/UNK/2017	Transcription Error
Aug-17-2020 16:45:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For Term Glaucoma- Bilateral End Date is prior to Start Date.
Aug-17-2020 16:45:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO End Date: UNK/UNK/2007	Initial Entry

1.b

Date	Location	User	Value	Reason
Aug-17-2020 16:46:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Te Presbyopia rm: Start Date: UNK/UNK/20 00 Ongoing: YES	Initial Entry

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811048

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
Aug-17-2020 16:46:28 (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
Aug-17-2020 16:46:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Presbyopia	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 16:46:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2000	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 16:46:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

I.c

Date	Location	User	Value	Reason
Aug-17-2020 16:46:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 3 : Medical History T Tonsillitis erm: Start Date: UNK/UNK/194 0 Ongoing: NO End Date: UNK/UNK/1 940	Initial Entry

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

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I.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 16:46:56 (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
Aug-17-2020 16:46:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Tonsillitis	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 16:46:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/1940	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 16:46:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO End Date: UNK/UNK/1940	Initial Entry

I.d

Date	Location	User	Value	Reason
Aug-17-2020 16:47:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: Dyslipidemia Start Date: UNK/UNK/1998 Ongoing: YES	Initial Entry

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I.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 16:47:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

I.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 16:47:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Dyslipidemia	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 16:47:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/1998	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 16:47:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

I.e

Date	Location	User	Value	Reason
Aug-19-2020 10:46:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: Line/MH Number: Medical History Term: HYPOTHYROIDISM Start Date: Jun/UNK/2020 Ongoing: YES	Transcription Error
Aug-18-2020 08:10:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Line/MH Number: Medical History Term: HYPOTHYROIDISM	Changed Information

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			Start Date: Jun/UNK/2020 Ongoing: YES	
Aug-17-2020 17:20:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Line/MH Number: 5 Medical History Term: hypothyroidism Start Date: Jun/UNK/2020 Ongoing: YES	Changed Information
Aug-17-2020 16:47:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Term: hypothyroidism Start Date: UNK/UNK/2020 Ongoing: YES	Initial Entry

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I.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 16:47:51 (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
Aug-24-2020 12:07:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jeffrey Signora TMSQUERY (pfe.signoj01_tmsquery)	Query 2: Clo sed	Response satisfies query
Aug-19-2020 10:46:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Ans wered	Transcription Error
Aug-19-2020 10:46:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry : HYP OTH YROI DISM	Transcription Error
Aug-19-2020 00:00:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 2: Op ened	Spacing: Verbatim Term contains leading, trailing or more than one consecutive space.
Aug-18-2020 22:26:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Clo sed	Discrepancy has been closed.
Aug-18-2020 22:26:00 (UTC-05:00)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Clo sed	Discrepancy has been closed.

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Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1081**Subject No:** 10811048**Generated By:** pfe.levisse**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

Eastern Time (US & Canada)				
Aug-18-2020 08:10:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Aug-18-2020 08:10:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry : HYPOTHYROIDISM	Changed Information
Aug-17-2020 19:02:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Opened	Clarify HYPOTHROIDISM as follows...Should spelling be HYPOTHYROIDISM? If so, edit. Otherwise clarify. Thank you.
Aug-17-2020 16:47:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry : hypot hroidism	Initial Entry

1.e Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 17:20:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-17-2020 17:20:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Jun/UNK/2020	Changed Information
Aug-17-2020 16:57:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Start Date is after or equal to the first vaccination date 17/Aug/2020. Please

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				review and update as appropriate.
Aug-17-2020 16:47:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2020	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 16:47:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Aug-17-2020 16:48:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 6 ber: Medical Histo Gastroesophageal r ry Term: eflux disease Start Date: UNK/UNK/1944 Ongoing: YES	Initial Entry

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I.f Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 16:48:13 (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
Aug-17-2020 16:48:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Gastroesophageal reflux disease	Initial Entry

I.f Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 16:48:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/1944	Initial Entry

I.f Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 16:48:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

I.g

Date	Location	User	Value	Reason
Aug-17-2020 16:48:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 7 : Medical History T Gallstones erm: Start Date: UNK/UNK/196 6 Ongoing: NO End Date: UNK/UNK/1 966	Initial Entry

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I.g Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 16:48:51 (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
Aug-17-2020 16:48:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Gallstones	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 16:48:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/1966	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 16:48:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO End Date: UNK/UNK/1966	Initial Entry

I.h

Date	Location	User	Value	Reason
Aug-17-2020 16:49:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 8 Medical History Term: Irritable Bowel Syndrome Start Date: UNK/UNK/2014 Ongoing: YES	Initial Entry

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I.h Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 16:49:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

I.h Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 16:49:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Irritable Bowel Syndrome	Initial Entry

I.h Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 16:49:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2014	Initial Entry

I.h Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 16:49:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

I.i

Date	Location	User	Value	Reason
Aug-17-2020 16:49:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 9 r: Medical History Term: Colon Polyps-B enign Start Date: UNK/UNK/200 2 Ongoing: YES	Initial Entry

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I.i Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 16:49:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

I.i Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 16:49:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Colon Polyps-Benign	Initial Entry

I.i Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 16:49:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2002	Initial Entry

I.i Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 16:49:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

I.j

Date	Location	User	Value	Reason
Aug-17-2020 16:50:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 10 Medical History: Osteoarthritis-Rig Term: ht Hand Start Date: UNK/UNK/2000 Ongoing: YES	Initial Entry

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I.j Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 16:50:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10	Initial Entry

I.j Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 16:50:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Osteoarthritis-Right Hand	Initial Entry

I.j Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 16:50:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2000	Initial Entry

I.j Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 16:50:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

I.k

Date	Location	User	Value	Reason
Aug-17-2020 16:50:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 11 Medical History Term: Osteoarthritis-Bilateral Knees Start Date: UNK/UNK/2000 Ongoing: YES	Initial Entry

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I.k Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 16:50:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11	Initial Entry

I.k Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 16:50:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Osteoarthritis-Bilateral Knees	Initial Entry

I.k Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 16:50:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2000	Initial Entry

I.k Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 16:50:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

I.l

Date	Location	User	Value	Reason
Aug-17-2020 16:51:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numbe 12 r: Medical History Osteoarthritis-To Term: es-All Start Date: UNK/UNK/2000 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Subject No: 10811048

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1.1 Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 16:51:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12	Initial Entry

1.1 Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 16:51:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Osteoarthritis-Toes-All	Initial Entry

1.1 Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 16:51:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2000	Initial Entry

1.1 Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 16:51:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

1.m

Date	Location	User	Value	Reason
Aug-17-2020 16:51:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 13 Medical History Term: Osteoporosis Start Date: UNK/UNK/2004 Ongoing: YES	Initial Entry

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Subject No: 10811048

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I.m Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 16:51:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 13	Initial Entry

I.m Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 16:51:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Osteoporosis	Initial Entry

I.m Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 16:51:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2004	Initial Entry

I.m Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 16:51:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

I.n

Date	Location	User	Value	Reason
Aug-17-2020 16:52:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 14 Medical History Term: Allergy-Codeine Start Date: UNK/UNK/2002 Ongoing: YES	Initial Entry

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

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.n Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 16:52:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 14	Initial Entry

I.n Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 16:52:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Allergy-Codeine	Initial Entry

I.n Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 16:52:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2002	Initial Entry

I.n Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 16:52:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

I.o

Date	Location	User	Value	Reason
Aug-17-2020 16:52:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 15 Medical History Te Tonsillectomy rm: Start Date: Jul/UNK/1940 Ongoing: NO End Date: Jul/UNK/19 40	Initial Entry

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

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.o Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 16:52:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 15	Initial Entry

I.o Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 16:52:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Tonsillectomy	Initial Entry

I.o Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 16:52:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Jul/UNK/1940	Initial Entry

I.o Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 16:52:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO End Date: Jul/UNK/1940	Initial Entry

I.p

Date	Location	User	Value	Reason
Aug-17-2020 16:53:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 16 Medical History Term: Cataract Repair Surgery Start Date: UNK/UNK/2017 Ongoing: NO End Date: UNK/UNK/2017	Initial Entry

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

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.p Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 16:53:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 16	Initial Entry

I.p Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 16:53:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Cataract Repair Surgery	Initial Entry

I.p Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 16:53:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2017	Initial Entry

I.p Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 16:53:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO End Date: UNK/UNK/2017	Initial Entry

I.q

Date	Location	User	Value	Reason
Aug-17-2020 16:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 17 Number: Medical History Term: Arthroscopic Surgery-Right Knee Cartilage Removal Start Date: UNK/UNK/2002 :	Initial Entry

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

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

Ongoing: NO

End Date:

UNK/UNK/2002

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

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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I.q Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 16:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 17	Initial Entry

I.q Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 16:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Arthroscopic Surgery-Right Knee Ca artilage Removal	Initial Entry

I.q Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 16:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2002	Initial Entry

I.q Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 16:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO End Date: UNK/UNK/2002	Initial Entry

I.r

Date	Location	User	Value	Reason
Aug-20-2020 07:31:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Line/MH Number: 18 Medical History Term: Ovarian Cystectomy Start Date: UNK/UNK/1960	Changed Information

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

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: ---

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			Ongoing: NO End Date: UNK/UNK/ 1960	
Aug-19-2020 10:49:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawynn Ebner (pfe.tebner)	Data Entry: Line/MH Number: 18 Medical History Term: Ovarian Cystectomy Start Date: UNK/UNK/1960 Ongoing: NO End Date: Jan/1/1960	Transcription Error
Aug-17-2020 16:54:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 18 Medical History Term: Ovarian Cystectomy Start Date: UNK/UNK/1960 Ongoing: YES	Initial Entry

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

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.r Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 16:54:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 18	Initial Entry

I.r Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 16:54:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Ovarian Cystectomy	Initial Entry

I.r Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 16:54:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/1960	Initial Entry

I.r Ongoing:

Date	Location	User	Value	Reason
Aug-21-2020 06:26:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Closed	Response satisfies query
Aug-20-2020 07:31:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Aug-20-2020 07:31:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO End Date: UNK/UNK/1960	Changed Information
Aug-20-2020 05:21:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Reissued:Opened	GPD Clin: End date 01Jan1960 whilst start date unk/unk/1960. if date known please update start date to match; else review which parts of dates are unknown

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

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

Aug-19-2020 10:49:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Aug-19-2020 10:49:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: NO End Date: Jan/1/1960	Transcription Error
Aug-19-2020 09:08:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	GPD Clin: Please review the Ongoing status of this surgery/procedure and update as appropriate
Aug-17-2020 16:54:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

I.s

Date	Location	User	Value	Reason
Aug-17-2020 16:55:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 19 ber: Medical History Term: Knee Replacement- Left Knee Start Date: UNK/UNK/2009 Ongoing: NO End Date: UNK/UNK/200 9	Initial Entry

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

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.s Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 16:55:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 19	Initial Entry

I.s Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 16:55:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Knee Replacement-Left Knee	Initial Entry

I.s Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 16:55:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2009	Initial Entry

I.s Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 16:55:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO End Date: UNK/UNK/2009	Initial Entry

I.t

Date	Location	User	Value	Reason
Aug-17-2020 16:56:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 20 : Medical History T Cholecystectom erm: y Start Date: UNK/UNK/196 6	Initial Entry

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

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

			Ongoing:	NO End Date: UNK/UNK/1966
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I.t Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 16:56:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 20	Initial Entry

I.t Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 16:56:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Cholecystectomy	Initial Entry

I.t Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 16:56:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/1966	Initial Entry

I.t Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 16:56:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO End Date: UNK/UNK/1966	Initial Entry

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

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
Aug-17-2020 16:57:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> Aug/17/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-17-2020 16:57:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> 117.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-17-2020 16:57:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-17-2020 16:57:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> 56.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-17-2020 16:57:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-17-2020 16:57:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 26.2	Initial Entry

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1081

Subject No: 10811048

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

7.a

Date	Location	User	Value	Reason
Aug-17-2020 16:57:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Record Identifier:: 1 Temperature: 97.7 Temperature Unit: F Temperature Location: FOREHEAD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-17-2020 16:57:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-17-2020 16:57:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: 97.7	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-17-2020 16:57:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-17-2020 16:57:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: FOREHEAD	Initial Entry

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811048

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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1. Lab Panel:

Date	Location	User	Value	Reason
Aug-17-2020 16:57:28 (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
Aug-17-2020 16:57:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-17-2020 16:57:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Aug/17/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Aug-17-2020 16:57:28 (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
Aug-17-2020 16:57:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-17-2020 16:57:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Define 113 d Identifier:	Initial Entry

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811048

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
Aug-17-2020 16:57:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-17-2020 16:57:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Aug-17-2020 16:57:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NOT DONE	Initial Entry

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

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
Aug-17-2020 16:57:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Aug/17/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-17-2020 16:57:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: 229863	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: 10811048

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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1. Data Origin

Date	Location	User	Value	Reason
Aug-17-2020 12:59:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-17-2020 12:59:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-17-2020 12:59:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-17-2020 12:59:09 (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.
Aug-17-2020 12:59:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawynn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Aug/17/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-17-2020 12:59:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawynn Ebner (pfe.tebner)	Data Entry: Sample ID: BP1J8B	Initial Entry

5.a Sample ID

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (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: 10811048

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

Date	Location	User	Value	Reason
Aug-17-2020 12:59:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: BP1J8B	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-17-2020 12:59:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: Sample ID: BP1J8C	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-17-2020 12:59:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: BP1J8C	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-17-2020 12:59:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: Sample ID: BP1J8D	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-17-2020 12:59:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: BP1J8D	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-17-2020 12:59:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: Sample ID: BPHZGY	Initial Entry

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (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: 10811048

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.d Sample ID

Date	Location	User	Value	Reason
Aug-17-2020 12:59:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	<u>Data Entry:</u> BPHZGY	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-17-2020 12:59:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BPHZGZ	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-17-2020 12:59:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	<u>Data Entry:</u> BPHZGZ	Initial Entry

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (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:** 10811048**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-17-2020 11:57:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-17-2020 11:57:56 (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
Aug-17-2020 11:58:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-17-2020 11:57:56 (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.
Aug-17-2020 11:57:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Aug/17/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-17-2020 11:58:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BP1J81	Initial Entry

5.a Sample ID

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: 10811048

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Date	Location	User	Value	Reason
Aug-17-2020 11:58:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BP1J81	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811048

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
Aug-17-2020 16:57:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-17-2020 16:57:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-17-2020 16:57:53 (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
Aug-17-2020 16:57:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Aug/17/2020 12:18	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-17-2020 16:57:53 (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
Aug-17-2020 16:57:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: LEFT	Initial Entry

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811048

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

7. Route:

Date	Location	User	Value	Reason
Aug-17-2020 16:57:53 (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
Aug-17-2020 16:57:53 (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
Aug-17-2020 16:57:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

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
Aug-17-2020 16:58:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO - REACTOGENICITY E-DIAR Y NOT COLLECTED FOR THIS S UBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811048

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-09-2020 10:59:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sep/9/2020	Initial Entry

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 21-Aug-2020 02:51**Site No:** 1081**Subject No:** 10811048**Generated By:** pfe.levisse**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[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Sep-09-2020 12:54:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Sep/9/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-09-2020 12:54:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Record Identifier:: 1 Temperature: 98.0 Temperature Unit: F Temperature Location:: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-09-2020 12:54:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-09-2020 12:54:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: 98.0	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-09-2020 12:54:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

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-09-2020 12:54:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	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: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811048

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-09-2020 12:54:45 (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-09-2020 12:54:45 (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-09-2020 12:54:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Sep/9/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-09-2020 12:54:45 (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-09-2020 12:54:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-09-2020 12:54:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Define 113 d Identifier:	Initial Entry

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811048

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-09-2020 12:54:45 (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-09-2020 12:54:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-09-2020 12:54:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NOT DONE	Initial Entry

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (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:** 10811048**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-09-2020 11:00:17 (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-09-2020 11:00:17 (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-09-2020 11:00:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-09-2020 11:00:17 (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-09-2020 11:00:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Sep/9/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-09-2020 11:00:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BP97PD	Initial Entry

5.a Sample ID

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: 10811048

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Date	Location	User	Value	Reason
Sep-09-2020 11:00:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawyn Ebner (pfe.tebner)	Data Entry: BP97PD	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811048

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-09-2020 12:55:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-09-2020 12:55:09 (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-09-2020 12:55:09 (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-09-2020 12:55:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Sep/9/2020 11:46	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-09-2020 12:55:09 (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-09-2020 12:55:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: LEFT	Initial Entry

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811048

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

7. Route:

Date	Location	User	Value	Reason
Sep-09-2020 12:55:09 (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-09-2020 12:55:09 (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-09-2020 12:55:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811048

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-07-2020 11:15:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Oct/7/2020	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: 10811048

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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1. Data Origin

Date	Location	User	Value	Reason
Oct-07-2020 11:49:40 (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-07-2020 11:49:40 (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-07-2020 11:49:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-07-2020 11:49:40 (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-07-2020 11:49:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Oct/7/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-07-2020 11:49:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BP1HV5	Initial Entry

5.a Sample ID

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (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: 10811048

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Date	Location	User	Value	Reason
Oct-07-2020 11:49:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> BP1HV5	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-07-2020 11:50:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BRTXV1	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-07-2020 11:50:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> BRTXV1	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-07-2020 11:50:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BRTXV2	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-07-2020 11:50:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> BRTXV2	Initial Entry

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1081

Subject No: 10811048

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-07-2020 11:15:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Oct/7/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-07-2020 11:15:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-07-2020 11:15:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: COMPLETED	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811048

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
Jan-15-2021 08:39:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Form Created	

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

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*** THIS REPEATING FORM HAS BEEN DELETED ***

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Date	Location	User	Value	Reason
Jan-26-2021 13:59:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Form Deleted	Transcription Error
Jan-15-2021 08:41:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

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Date	Location	User	Value	Reason
Jan-20-2021 15:41:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Form Created	

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811048

Subject Initials: ---

Generated By: pfe.levisse

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1. Category:

Date	Location	User	Value	Reason
Jan-15-2021 08:39:44 (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
Jan-15-2021 08:39:44 (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
Feb-04-2021 11:23:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Closed	Response satisfies query
Feb-03-2021 11:08:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	New Information
Feb-03-2021 11:08:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Hip Fracture, right	New Information
Jan-27-2021 15:22:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Opened	Clinical Event term is 'Hip Fracture'; however, SAE report event term is 'Hip Fracture Side Unknown'. Please review, harmonize reporting, and update in the appropriate location.
Jan-27-2021 15:21:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Closed	rewording
Jan-27-2021 15:18:41	ACV0PFEINFP6000	Kathryn	Query 3: Opened	Clinical Please

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1081**Subject No:** 10811048**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:11

(UTC-05:00) Eastern Time (US & Canada)		Sewell (pfe.sewelk02)		specify side of hip fracture in both AE event term and SAE safety report term
Jan-25-2021 22:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Jan-22-2021 22:53:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Jan-21-2021 13:41:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Query 2: Answered	Update SAE form sent today
Jan-20-2021 15:43:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Query 1: Answered	done
Jan-18-2021 08:42:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	CLINICAL SAE med history does not include conditions for which the subject is receiving medication; please add to SAE Med Hx (dyslipidemia; hypothyroid, GERD) in a SAE update safety FAX
Jan-18-2021 08:40:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical - A traumatic accident of fall needs to be reported recorded as an AE as well, even if an injury did not result. Please see specific CRF completion guidelines (Sect 8.17.4.2/Falls).
Jan-15-2021 08:39:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Hip Fracture	Initial Entry

4. Start Date Time:

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Subject No: 10811048

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Date	Location	User	Value	Reason
Jan-15-2021 08:39:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> Jan/12/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-05-2021 10:53:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> NO End Date Time: Jan/22/2021 UNK:UNK	New Information
Jan-15-2021 08:39:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-22-2021 22:55:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Jan-20-2021 15:37:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Jan-20-2021 15:37:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> 3	Changed Information
Jan-18-2021 08:44:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical As per protocol section 10.3.3 Grade 4 toxicity grading = Life Threatening"; however, seriousness criteria do Not include life-threatening. Please review, harmonize reporting between Grade and +/- life threatening, and update as applicable

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Jan-15-2021 08:39:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: 4	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Feb-04-2021 11:23:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Query closed; will follow for requested COVID test information.
Feb-03-2021 11:09:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Query 2: Answered	Hospital records not received. Unknown if she had a COVID test at admission. SAE form has been updated to reflect the same information.
Jan-22-2021 22:55:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Closed	Response satisfies query
Jan-22-2021 22:52:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Reissued:Opened	Clinical COVID test status (yes/no) during Hosp was not reported in the SAE. Please submit a follow-up SAE form [#2021040829] to document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results.
Jan-20-2021 15:39:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Changed Information
Jan-20-2021 15:39:18	ACV0PFEINFP6000	auto query	Query 2: Answered	Changed Information

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1081**Subject No:** 10811048**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:11

(UTC-05:00) Eastern Time (US & Canada)		(autoquery)		
Jan-20-2021 15:39:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<p>Data Entry:</p> <p>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>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</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>NO</p> <p>Other medically important serious event</p> <p>NO</p>	Changed Information
Jan-18-2021 08:46:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Opened	Clinical SAE serious criteria are Hosp & Disability; however, SAE report serious criterion is Hosp. Please review, harmonize reporting and update in the appropriate location.
Jan-18-2021 08:38:34 (UTC-05:00) Eastern	ACV0PFEINFP6000	Kathryn Sewell	Query 2: Opened	Clinical COVID test status (yes/no) during

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1081**Subject No:** 10811048**Generated By:** pfe.levissc**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:11

Time (US & Canada)		(pfe.sewelk02)		Hosp was not reported in the SAE. Please submit a follow-up SAE form [#2021040829] to document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results.
Jan-18-2021 06:19:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Deleted	Query can be addressed internally
Jan-15-2021 08:39:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Hip Fracture: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-15-2021 08:39:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? YES Is this serious event life threaten	Initial Entry

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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			ing?	
			NO	
			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.

Date	Location	User	Value	Reason
Jan-15-2021 08:39:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-15-2021 08:39:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> fall at home	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-15-2021 08:39:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-15-2021 08:39:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1081**Subject No:** 10811048**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:11

Date	Location	User	Value	Reason
Jan-15-2021 08:39:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Mar-08-2021 02:11:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	Response satisfies query
Mar-05-2021 10:52:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Mar-05-2021 10:52:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: RECOVERED/RESOLV ED	New Information
Mar-03-2021 04:49:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON:AER#2021030829,outcome was reported as RECOVERED/RESOLVED to Safety DB however, recorded as RECOVERING/RESOLVINGon AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Jan-15-2021 08:39:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: RECOVERING/RESOL VING	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Jan-15-2021 08:39:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Jan-19-2021 06:20:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Data Entry: 2021030829	Initial Entry
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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

*** THIS REPEATING FORM HAS BEEN DELETED ***

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1. Category:

Date	Location	User	Value	Reason
Jan-15-2021 08:41:24 (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
Jan-15-2021 08:41:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-08-2021 09:27:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 2: Closed	Response satisfies query
Feb-10-2021 08:33:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sathenapalli Suguna Srujan (pfe.srujas)	Query 2: Reissued:Opened	deleting query on a deleted AE term
Jan-27-2021 15:23:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Reissued:Candidate	deleting query on a deleted AE term
Jan-26-2021 13:59:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Jan-22-2021 22:57:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Reissued:Opened	Clinical Thank you, however the AE for Hip Replacement is still present
Jan-22-2021 12:47:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gladys Noi (pfe.noig)	Query 1: Closed	Response satisfies query
Jan-21-2021 13:44:32	ACV0PFEINFP6000	auto query	Query 2: Answered	procedure removed

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1081**Subject No:** 10811048**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Deleted**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:11***** THIS REPEATING FORM HAS BEEN DELETED *****

(UTC-05:00) Eastern Time (US & Canada)		(autoquery)		
Jan-21-2021 13:44:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	procedure removed
Jan-21-2021 13:44:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Hip replacement	procedure removed
Jan-18-2021 08:37:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	CLINICAL Hip replacement surgery is the treatment for SAE 'HIP FRACTURE', not a separate SAE. Per CRF completion guidelines Sect 8.50.2, do not list a surgical procedure as an AE event term.
Jan-18-2021 06:17:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.QUITOR)	Query 1: Opened	SAE RECON: the term was reported as 'Hip replacement surgery'. Per CRF completion guidelines, please avoid use of a procedure for the AE event name; please review and enter the AE term for which the procedure was performed.
Jan-15-2021 08:41:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Hip replacement surgery	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-15-2021 08:41:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Jan/13/2021 UNK:UNK	Initial Entry

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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-15-2021 08:41:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> NO End Date Time: Jan/13/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-15-2021 08:41:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> 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
Jan-24-2021 21:52:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quoter)	Query 2: Deleted	Query can be addressed internally
Jan-21-2021 13:44:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	For AE Hip replacement: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-18-2021 06:18:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quoter)	Query 1: Deleted	Query can be addressed internally
Jan-15-2021 08:41:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Hip replacement surgery: Response to "Is the adverse event

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				serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-15-2021 08:41:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<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>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>YES</p> <p>Is this serious event life threatening?</p> <p>NO</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
Jan-15-2021 08:41:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<p>Data Entry: NO</p>	Initial Entry

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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-15-2021 08:41:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> hip fracture from fall at home	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-15-2021 08:41:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-15-2021 08:41:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-15-2021 08:41:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Jan-27-2021 05:01:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Malerato Moloi (pfe.moloim)	Query 1: Closed	Response satisfies query
Jan-26-2021 13:59:01 (UTC-05:00) Eastern	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	will delete

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Time (US & Canada)				
Jan-21-2021 13:44:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Hip replacement: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Jan-21-2021 00:42:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Astrud van der Merwe (pfe.vandea62)	Query 1: Reissued:Opened	As per your response 'The hip replacement surgery only took one day...', please update Outcome of this event accordingly.
Jan-20-2021 15:42:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Query 1: Answered	The hip replacement surgery only took one day but she will be recovering from the fall for several weeks.
Jan-15-2021 08:41:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Hip replacement surgery: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Jan-15-2021 08:41:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: RECOVERING/RESOLVING	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Jan-15-2021 08:41:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Jan-20-2021 15:41:07 (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
Jan-20-2021 15:41:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-20-2021 15:41:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Fall on stairs at home	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-20-2021 15:41:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Jan/12/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-19-2021 01:56:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Feb-08-2021 08:15:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	This will be submitted today
Feb-04-2021 11:24:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued:Opened	Clinical Thank you; Please submit the FALL SAE stop date

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				as a SAE safety update
Feb-03-2021 11:11:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-03-2021 11:11:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO End Date Time: Jan/12/2021 UNK:UNK	Transcription Error
Jan-25-2021 22:29:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical Event of Fall is ongoing; however, this event is a single occurrence in time. Please update AE and SAE report with stop date for event 'fall'.
Jan-20-2021 15:41:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-20-2021 15:41:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: 3	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
Jan-25-2021 04:32:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quotior)	Query 2: Closed	Event added in SDB
Jan-24-2021 21:50:16 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Ricell Ann Piojo	Query 2: Reissued:Opened	SAE RECON: Please confirm if SAE form

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(US & Canada)		(pfe.quitor)		was sent
Jan-21-2021 13:45:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Query 2: Answered	updated SAE form being submitted today
Jan-21-2021 06:06:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Opened	SAE RECON: Fall on stairs at home(Onset date:12Jan2021) is not reported to Safety database but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF
Jan-21-2021 06:06:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Deleted	Query can be addressed internally
Jan-20-2021 15:41:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Fall on stairs at home: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-20-2021 15:41:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolonged hospitalization? YES Did this serious event result in per	Initial Entry

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			sistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO	
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8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Jan-20-2021 15:41:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-01-2021 15:13:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 2: Closed	Response satisfies query
Mar-01-2021 11:03:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	per query response
Mar-01-2021 11:03:08 (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	per query response

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			<i>If Other, specify:</i>	
			fall at home- no underlying suspected medical cause	
Feb-17-2021 13:13:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 2: Reissued:Opened	CLINQUERY: Thanks for clarifying - please add this information to the "If other, specify" field
Feb-17-2021 10:52:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Query 2: Answered	The patient missed a step. There is no suspected underlying medical cause.
Feb-10-2021 18:34:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 2: Opened	CLINQUERY: Please capture in field if any suspected underlying (medical) cause for fall
Jan-27-2021 15:19:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Fall has been reported as AE
Jan-27-2021 03:33:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (pfe.PFESDQ_PROD)	Query 1: Opened	DM: As per CRF CR 8.50.2.2. When a fall results in an injury, both the injury and the fall should

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				be recorded as AEs. Please refer CRF CR document and update AE appropriately, Thank you. "[sudhip SDQ=112799]"
Jan-20-2021 15:41:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> fall at home	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-20-2021 15:41:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-20-2021 15:41:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-20-2021 15:41:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES	Initial Entry

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Date	Location	User	Value	Reason
Feb-08-2021 08:15:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Answer Auto Query
Feb-08-2021 08:15:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: RECOVERED/RESOLVED	New Information
Feb-03-2021 17:01:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mina Francisco (pfe.francm73)	Query 1: Reissued:Candidate	Due to the hip fracture reported on the same day as the fall, subject is still recovering from the fall. Please review this in the beginning of April to re-issue a query to site to confirm that the outcome of AE is correct.
Feb-03-2021 11:12:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Query 1: Answered	She is still recovering from the results of the fall.
Feb-03-2021 11:11:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Fall on stairs at home: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Jan-20-2021 15:41:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: RECOVERING/RESOLVING	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Jan-20-2021 15:41:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
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Jan-25-2021 04:32:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Data Entry: 2021030829	Initial Entry
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Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

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Subject Initials: ---

Generated By: pfe.levisse

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I. Date of Visit

Date	Location	User	Value	Reason
Jan-15-2021 08:44:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Jan/11/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail
History

Form Status: Data Complete, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

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I. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Jan-18-2021 10:37:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-18-2021 02:16:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sonal K (pfe.ks66)	Query 1: Opened	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-15-2021 08:43:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Participant is willing to return for V accination 3 Participant is: eligible per local/national recom mendations and confirmed to ha ve received only placebo at Vacc ination 1/2	Transcription Error
Jan-15-2021 08:42:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-15-2021 08:42:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Participant is willing to return for V accination 3	Initial Entry

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

Form: TREATMENT UNBLINDED - 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 Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-18-2021 10:37:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Jan/11/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-18-2021 10:37:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: ASSESS ELIGIBILITY FOR ADDI TIONAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

Form: DATE OF VISIT - 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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I. Date of Visit

Date	Location	User	Value	Reason
Jan-29-2021 12:10:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jenni Steinbrunner (pfe.jsteinbrunner)	Data Entry: Jan/29/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION - eCRF
Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811048

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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I. Consent Was:

Date	Location	User	Value	Reason
Jan-29-2021 12:11:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jenni Steinbrunner (pfe.jsteinbrunner)	Data Entry: OBTAINED Date Written Consent Obtained Jan/29/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811048

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Jan-29-2021 12:11:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jenni Steinbrunner (pfe.jsteinbrunner)	Data Entry: Jan/29/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-29-2021 12:11:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-29-2021 12:11:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jenni Steinbrunner (pfe.jsteinbrunner)	Data Entry: COMPLETED	Initial Entry

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811048

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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1. Lab Panel:

Date	Location	User	Value	Reason
Jan-29-2021 12:14:29 (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
Jan-29-2021 12:14:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-29-2021 12:14:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jenni Steinbrunner (pfe.jsteinbrunner)	Data Entry: Jan/29/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Jan-29-2021 12:14:29 (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
Jan-29-2021 12:14:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Jan-29-2021 12:14:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Define 113 d Identifier:	Initial Entry

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811048

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

			Test:: Choriogonadotropin Beta_PX113 Result:: Not Done:: NOT DONE
--	--	--	--

6.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-29-2021 12:14:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jan-29-2021 12:14:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jenni Steinbrunner (pfe.jsteinbrunner)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Jan-29-2021 12:14:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jenni Steinbrunner (pfe.jsteinbrunner)	Data Entry: NOT DONE	Initial Entry

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811048

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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1. Data Origin

Date	Location	User	Value	Reason
Jan-29-2021 15:49:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-29-2021 15:49:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-29-2021 15:49:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-29-2021 15:49:09 (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.
Jan-29-2021 15:49:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Jan/29/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-29-2021 15:49:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BS64V9	Initial Entry

5.a Sample ID

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811048

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Date	Location	User	Value	Reason
Jan-29-2021 15:49:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	<u>Data Entry:</u> BS64V9	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-29-2021 15:49:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BS64VB	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-29-2021 15:49:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	<u>Data Entry:</u> BS64VB	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-29-2021 15:50:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BP1J0M	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-29-2021 15:50:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	<u>Data Entry:</u> BP1J0M	Initial Entry

5.d

Date	Location	User	Value	Reason
Jan-29-2021 15:50:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BP1J0N	Initial Entry

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811048

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.d Sample ID

Date	Location	User	Value	Reason
Jan-29-2021 15:50:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BP1J0N	Initial Entry

Header Text: c4591001**Visit:** V101_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811048**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-29-2021 15:53:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-29-2021 15:53:56 (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
Jan-29-2021 15:54:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-29-2021 15:53:56 (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.
Jan-29-2021 15:53:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Jan/29/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-29-2021 15:54:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BKN9RJ	Initial Entry

5.a Sample ID

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811048

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Date	Location	User	Value	Reason
Jan-29-2021 15:54:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawyn Ebner (pfe.tebner)	<u>Data Entry:</u> BKN9RJ	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

Form: VACCINATION - 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. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-29-2021 12:14:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jenni Steinbrunner (pfe.jsteinbrunner)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-29-2021 12:14:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-29-2021 12:14:55 (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
Jan-29-2021 12:14:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jenni Steinbrunner (pfe.jsteinbrunner)	Data Entry: Jan/29/2021 12:14	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-29-2021 12:14:55 (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
Jan-29-2021 12:14:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jenni Steinbrunner (pfe.jsteinbrunner)	Data Entry: LEFT	Initial Entry

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811048

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

7. Route:

Date	Location	User	Value	Reason
Jan-29-2021 12:14:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-29-2021 12:14:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-29-2021 12:14:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-29-2021 12:14:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Jan-29-2021 12:14:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jenni Steinbrunner (pfe.jsteinbrunner)	Data Entry: YES	Initial Entry

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811048

Generated By: pfe.levissc

Form: DATE OF VISIT - 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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I. Date of Visit

Date	Location	User	Value	Reason
Mar-02-2021 02:54:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Swapna Varikuti (pfe.variks)	Query 1: Closed	As per site confirmation - updated PD tracker
Mar-01-2021 10:57:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	data is correct. deviation has been noted in subjects chart
Feb-26-2021 02:13:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (pfe.PFESDQ_PROD)	Query 1: Opened	PDQ: Date of visit V102_VAX4 is out of window for 1 days from V101_VAX3 Dose Date. Please verify and update. Else, confirm in query response appropriately. "[lv04 SDQ=137481]"
Feb-22-2021 15:52:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry : Feb/22/2021	Initial Entry

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811048

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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1. Lab Panel:

Date	Location	User	Value	Reason
Feb-22-2021 15:55:47 (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
Feb-22-2021 15:55:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Feb-22-2021 15:55:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: Feb/22/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Feb-22-2021 15:55:47 (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
Feb-22-2021 15:55:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Feb-22-2021 15:55:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Define 113 d Identifier:	Initial Entry

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811048

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

			Test:: Choriogonadotropin Beta_PX113 Result:: Not Done:: NOT DONE
--	--	--	--

6.a Sponsor ID:

Date	Location	User	Value	Reason
Feb-22-2021 15:55:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Feb-22-2021 15:55:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawyn Ebner (pfe.tebner)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Feb-22-2021 15:55:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawyn Ebner (pfe.tebner)	Data Entry: NOT DONE	Initial Entry

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811048

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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1. Data Origin

Date	Location	User	Value	Reason
Feb-22-2021 15:52:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-22-2021 15:52:34 (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
Feb-22-2021 15:53:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-22-2021 15:52:34 (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.
Feb-22-2021 15:52:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Feb/22/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-22-2021 15:53:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BRN2V9	Initial Entry

5.a Sample ID

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811048

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Date	Location	User	Value	Reason
Feb-22-2021 15:53:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawyn Ebner (pfe.tebner)	Data Entry: BRN2V9	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

Form: VACCINATION - 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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-22-2021 16:14:48 (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
Feb-22-2021 16:14:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-22-2021 16:14:48 (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
Feb-22-2021 16:14:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Feb/22/2021 13:02	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-22-2021 16:14:48 (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
Feb-22-2021 16:14:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: LEFT	Initial Entry

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811048

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

7. Route:

Date	Location	User	Value	Reason
Feb-22-2021 16:14:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-22-2021 16:14:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-22-2021 16:14:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-22-2021 16:14:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Feb-22-2021 16:14:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Oct-07-2020 11:15:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-17-2020 16:57:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-17-2020 11:57:33 (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
Oct-07-2020 11:15:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/7/2020	Initial Entry
Aug-17-2020 16:57:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/17/2020	Initial Entry
Aug-17-2020 11:57:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/17/2020	Initial Entry

090177e196ae3f08\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811048

Generated By: pfe.levisse

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

I. Casebook Signature

Date	Location	User	Value	Reason
Oct-22-2020 13:51:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: Click Here to Enable	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811061

Subject Initials: ---

Generated By: pfe.levissc

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: 10811061

Generated By: pfe.lewissc

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 Aug/18/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1081

Subject No: 10811061

Generated By: pfe.lewissc

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	[10811061]
2.	Birth Date:	(b) (6)/1954
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: 10811061

Generated By: pfe.lewissc

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	Aug/18/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1081

Subject No: 10811061

Generated By: pfe.lewissc

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 _____
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811061

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	Aug/18/2020
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: 10811061

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:	[bilateral cataract extraction]
	Start Date:	Jul/UNK/2017
	Ongoing:	NO End Date: Jul/UNK/2017
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[deviated septum]
	Start Date:	UNK/UNK/1996
	Ongoing:	NO End Date: UNK/UNK/1996
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[dyslipidemia]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[GERD]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES

090177e196ae3eff\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: 10811061

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

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[intermittent constipation]
	Start Date:	UNK/UNK/2011
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[small bowel obstruction]
	Start Date:	Jul/UNK/2011
	Ongoing:	NO End Date: Oct/UNK/2011
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[right ankle fracture]
	Start Date:	UNK/UNK/1979
	Ongoing:	NO End Date: UNK/UNK/1979
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[torn tendon left foot]
	Start Date:	UNK/UNK/1988
	Ongoing:	NO End Date: UNK/UNK/1989

090177e196ae3eff\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: 10811061

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

1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[redundant colon]
	Start Date:	Jan/UNK/2011
	Ongoing:	NO End Date: Jan/UNK/2011
1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[right foot bunion]
	Start Date:	UNK/UNK/1998
	Ongoing:	NO End Date: UNK/UNK/1998
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[left foot bunion]
	Start Date:	UNK/UNK/2000
	Ongoing:	NO End Date: UNK/UNK/2000
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[pelvic mass]
	Start Date:	Jun/UNK/2007
	Ongoing:	NO End Date: Jun/UNK/2007

090177e196ae3eff\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: 10811061

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

1.m	Line/MH Number:	[13]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[c-section]
	Start Date:	May/UNK/1983
	Ongoing:	NO End Date: May/UNK/1983
1.n	Line/MH Number:	[14]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[total abdominal hysterectomy with bilateral oophorectomy]
	Start Date:	Jul/UNK/1993
	Ongoing:	NO End Date: Jul/UNK/1993
1.o	Line/MH Number:	[15]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[EPITHELIAL INCLUSION CYST OF VAGINA]
	Start Date:	Jun/UNK/2007
	Ongoing:	NO End Date: UNK/UNK/2007

090177e196ae3eff\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1081

Subject No: 10811061

Generated By: pfe.levisse

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:	Aug/18/2020
2.	Weight:	[177.2]
3.	Unit:	LB
4.	Height:	[62.5]
5.	Unit:	in
6.	Body Mass Index:	[31.9]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.5]
	Unit:	F
	Temperature Location:	FOREHEAD

090177e196ae3eff\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1081

Subject No: 10811061

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:	Aug/18/2020
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

090177e196ae3eff\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: 10811061

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 :	Aug/18/2020
2.	Randomization Number:	[232421]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811061

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: Aug/18/2020
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	[BPHZHT]
5.b	Sample ID	[BPHZHV]
5.c	Sample ID	[BP1JB2]
5.d	Sample ID	[BP1JB1]
5.e	Sample ID	[BP1JB0]

090177e196ae3eff\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: 10811061

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: Aug/18/2020
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	[BP1J9D]
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090177e196ae3eff\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: 10811061

Generated By: pfe.lewissc

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:	Aug/18/2020 16:08
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

090177e196ae3eff\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: 10811061

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
----	---	--

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811061

Generated By: pfe.levissc

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/3/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1081

Subject No: 10811061

Generated By: pfe.lewissc

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/3/2020
----	-------	------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.8]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1081

Subject No: 10811061

Generated By: pfe.levisse

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/3/2020
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

090177e196ae3eff\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811061

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/3/2020
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	[BP97NF]
-----	-----------	----------

090177e196ae3eff\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: 10811061

Generated By: pfe.lewissc

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/3/2020 16:09
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811061

Generated By: pfe.lewissc

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/1/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811061

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: Oct/1/2020
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	[BRTXS1]
5.b	Sample ID	[BRTXS2]
5.c	Sample ID	[BP1HT5]

090177e196ae3eff\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: 10811061

Generated By: pfe.lewissc

Form: DATE OF VISIT

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

Date of Visit

1.	Date of Visit	Mar/11/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811061

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Mar/11/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BM8X9S]
5.b	Sample ID	[BM8X9T]
5.c	Sample ID	[BSFNYS]
5.d	Sample ID	[BSFNYS]

090177e196ae3eff\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811061

Generated By: pfe.lewissc

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: 10811061

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: 10811061

Generated By: pfe.lewissc

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: 10811061

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	[]
----	-----------	-----

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811061

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_ILL - New Unscheduled Visit

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811061

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

Signs and Symptoms

1.	Date of Assessment:	//
2.	Date of First Symptom Started:	//
3.	Symptoms Ongoing?	

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

5.	Symptoms - Other Text:	[]
----	------------------------	-----

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811061

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	[]
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Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811061

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	[]
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Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811061

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

Health Care Utilization

1.	Physician or Healthcare Professional:	
	Occurrence of Visits or Contacts:	

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[]
----	-------------------------------------	-----

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	
----	--	--

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811061

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

Illness Details

1.	Category of Clinical Event:	
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	
3.	Toxicity Grade:	

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811061

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 Visit

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: 10811061

Subject Initials: ---

Generated By: pfe.lewissc

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: 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: 10811061

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: 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: 10811061

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Unplanned Assessments

1.	Assessments	
----	-------------	--

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1081

Subject No: 10811061

Generated By: pfe.levissc

Form: DISPOSITION - TREATMENT

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 - Treatment

1.	Date of Completion/Discontinuation/Death :	Oct/1/2020
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: 10811061

Generated By: pfe.levissc

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Disposition - Follow-Up

1.	Date of Completion/Discontinuation/Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[]

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
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: 10811061

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 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: 10811061

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: 10811061

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Lymphadenopathy Under left ear	Sep/10/2020 08:01	NO End Date Time: Sep/23/2020 08:00	Repeating Pages
2.	ADVERSE EVENT	2	Contact Dermatitis on lower extremities	Sep/11/2020 UNK:UNK	NO End Date Time: Sep/22/2020 UNK:UNK	Repeating Pages

090177e196ae3eff\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: 10811061

Generated By: pfe.levisse

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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[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Lymphadenopathy Under left ear]
4.	Start Date Time:	Sep/10/2020 08:01
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/23/2020 08:00
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Bacterial Infection]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae3eff\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: 10811061

Generated By: pfe.levisse

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

11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae3eff\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: 10811061

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

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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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Contact Dermatitis on lower extremities]
4.	Start Date Time:	Sep/11/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/22/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [contact with allergen or irritant]

090177e196ae3eff\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: 10811061

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

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

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

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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: 10811061

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1081

Subject No: 10811061

Generated By: pfe.levisse

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	[]

090177e196ae3eff\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: 10811061

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.	1	VACCINATIONS	NO	Influenza vaccine	Sep/16/2020	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811061

Generated By: pfe.levisse

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

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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Concomitant Medications

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Influenza vaccine]
5.	Date:	Sep/16/2020

090177e196ae3eff\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: 10811061

Subject Initials: ---

Generated By: pfe.lewissc

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: 10811061

Generated By: pfe.levisse

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?	

090177e196ae3eff\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: 10811061

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: 10811061

Generated By: pfe.levisse

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

[Back to Form](#)

Radiation Treatment

1.	Category:	
2.	What is the treatment Identifier?	[]
3.	Concomitant Non-drug Treatment Pre-specified:	
4.	Treatment:	[]
5.	Start Date:	//
6.	Ongoing?	

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811061

Subject Initials: ---

Generated By: pfe.lewissc

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: 10811061

Generated By: pfe.levisse

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

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: 10811061

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: 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: 10811061

Subject Initials: ---

Generated By: pfe.lewissc

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: 10811061

Subject Initials: ---

Generated By: pfe.lewissc

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: 10811061

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?	

090177e196ae3eff\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: 10811061

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: 10811061

Subject Initials: ---

Generated By: pfe.lewissc

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: 10811061

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: 10811061

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Informed Consent - Asymptomatic Surveillance

1.	Consent Was:	
----	--------------	--

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811061

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: 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: 10811061

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: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

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: 10811061

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Feb/4/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811061

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2
----	---	--

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811061

Generated By: pfe.lewissc

Form: TREATMENT UNBLINDED

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

Treatment Unblinded

1.	Date Treatment Unblinded :	Feb/4/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811061

Generated By: pfe.levissc

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 :	//
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090177e196ae3eff\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811061

Generated By: pfe.levissc

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Death Details

1.	Date of Collection / Notification of Death:	//
----	---	----

Cause of Death

2.	Cause of Death Status:	
	Cause of Death:	[]

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811061

Generated By: pfe.lewissc

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	FOLLOW-UP
2.	Subject Status Date	Oct/1/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811061

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
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Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811061

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
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1081

Subject No: 10811061

Generated By: pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-18-2020 15:44:44 (UTC-05:00) Eastern Time (US & Canada)	Tawny Ebner (pfe.tebner)	All inclusion and exclusion met <hr/> Not Done

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811061

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

This form requires signing by a member of each of the following signature groups:

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
Lora Morris	N/A	Feb-04-2021 16:57:52 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

James Fry	Approved	Jan-23-2021 12:00:33 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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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 11:30:40 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Michael Butcher	Approved	Nov-16-2020 09:11:14 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
-----------------	----------	---	------	--------

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.

090177e196ae3eff\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, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811061

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

Lora Morris	N/A	Nov-10-2020 11:26:01 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

James Fry	Approved	Oct-12-2020 15:34:26 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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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.

090177e196ae3eff\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: 10811061

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

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-18-2020 15:43:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn 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
Aug-18-2020 15:43:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae3eff\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811061

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Aug-18-2020 15:43:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: OBTAINED Date Written Consent Obtained Aug/18/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1081

Subject No: 10811061

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Aug-18-2020 15:43:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10811061	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-18-2020 15:43:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1954	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-18-2020 15:43:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-18-2020 15:43:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Aug-18-2020 15:43:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: WHITE	Initial Entry

090177e196ae3eff\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: 10811061

Generated By: pfe.lewissc

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Aug-18-2020 15:44:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Aug/18/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811061

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-18-2020 15:45:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Aug/18/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-18-2020 15:45:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-18-2020 15:45:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: COMPLETED	Initial Entry

090177e196ae3eff\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: 10811061

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](#)

1.a

Date	Location	User	Value	Reason
Aug-18-2020 16:35:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 1 ber: Medical Histor bilateral cataract e y Term: xtraction Start Date: Jul/UNK/2017 Ongoing: NO End Date: Jul/UNK/2017	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-18-2020 16:35:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

1.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-18-2020 16:35:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: bilateral cataract extraction	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 16:35:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: Jul/UNK/2017	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-18-2020 16:35:54 (UTC-05:00) Eastern	ACV0PFEINFP6000	Marcel Lanton	Data Entry: NO	Initial Entry

090177e196ae3eff\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: 10811061

Generated By: pfe.levisse

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

Time (US & Canada)	(pfe mlanton)	End Date:	
		Jul/UNK/2017	

I.b

Date	Location	User	Value	Reason
Aug-18-2020 16:36:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History: deviated septum Term: m Start Date: UNK/UNK/1996 Ongoing: NO End Date: UNK/UNK/1996	Initial Entry

090177e196ae3eff\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: 10811061

Generated By: pfe.levisse

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.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-18-2020 16:36:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-18-2020 16:36:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: deviated septum	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 16:36:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: UNK/UNK/1996	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-18-2020 16:36:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: NO End Date: UNK/UNK/1996	Initial Entry

1.c

Date	Location	User	Value	Reason
Aug-18-2020 16:36:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Term: dyslipidemia Start Date: UNK/UNK/2015 Ongoing: YES	Initial Entry

090177e196ae3eff\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

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Site No: 1081

Subject No: 10811061

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I.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-18-2020 16:36:43 (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
Aug-18-2020 16:36:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: dyslipidemia	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 16:36:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: UNK/UNK/2015	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Aug-18-2020 16:36:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Aug-18-2020 16:37:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: GERD Start Date: UNK/UNK/2015 Ongoing: YES	Initial Entry

090177e196ae3eff\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Subject No: 10811061

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I.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-18-2020 16:37:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

I.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-18-2020 16:37:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: GERD	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 16:37:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: UNK/UNK/2015	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Aug-18-2020 16:37:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: YES	Initial Entry

I.e

Date	Location	User	Value	Reason
Aug-19-2020 11:12:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Line/MH Num 5 ber: Medical Histor intermittent con y Term: stipation Start Date: UNK/UNK/201 1 Ongoing: YES	Transcription Error
Aug-18-2020 16:37:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 5 ber:	Initial Entry

090177e196ae3eff\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

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Subject No: 10811061

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			Medical History Term: intermittent constipation	
			Start Date: UNK/UNK/2011	
			Ongoing: YES	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1081

Subject No: 10811061

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

1.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-18-2020 16:37:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

1.e Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-19-2020 16:45:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Closed	Discrepancy has been closed.
Aug-19-2020 11:12:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Aug-19-2020 11:12:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: intermittent constipation	Transcription Error
Aug-19-2020 04:25:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Opened	Spacing: Verbatim Term contains leading, trailing or more than one consecutive space.
Aug-18-2020 16:37:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: intermittent constipation	Initial Entry

1.e Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 16:37:42	ACV0PFEINFP6000	Marcel	Data Entry:	Initial Entry

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Header Text: c4591001

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(UTC-05:00) Eastern Time (US & Canada)		Lanton (pfe.mlanton)	UNK/UNK/2011	
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I.e Ongoing:

Date	Location	User	Value	Reason
Aug-18-2020 16:37:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Aug-19-2020 11:14:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawyn Ebner (pfe.tebner)	Data Entry: Line/MH Number: 6 Medical History Term: small bowel obstruction Start Date: Jul/UNK/2011 Ongoing: NO End Date: Oct/UNK/2011	Transcription Error
Aug-18-2020 16:39:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: Line/MH Number: 6 Medical History Term: small bowel obstruction due to adhesions Start Date: Jul/UNK/2011 Ongoing: NO End Date: Oct/UNK/2011	Transcription Error
Aug-18-2020 16:38:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 6 Medical History Term: small bowel obstruction due to adhesions Start Date: Oct/UNK/2011	Initial Entry

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Header Text: c4591001

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			Ongoing: NO	
			End Date:	
			Oct/UNK/2011	

Header Text: c4591001

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Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

I.f Line/MH Number:

Date	Location	User	Value	Reason
Aug-18-2020 16:38:36 (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
Aug-19-2020 16:45:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Closed	Discrepancy has been closed.
Aug-19-2020 11:14:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Aug-19-2020 11:14:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: small bowel obstruction	Transcription Error
Aug-19-2020 06:26:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Opened	Multiple concepts in the term SMALL BOWEL OBSTRUCTION DUE TO ADHESIONS. Please split the term into SMALL BOWEL OBSTRUCTION and SMALL BOWEL ADHESIONS and submit separately. Thank you.
Aug-18-2020 16:38:36 (UTC-05:00)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: small bowel obstruction due	Initial Entry

090177e196ae3eff\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

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Subject No: 10811061

Generated By: pfe.levisse

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Site Name: (1081) Sterling Research Group - Mt. Auburn

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Eastern Time (US & Canada)			to adhesions	
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I.f Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 16:39:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: Jul/UNK/2011	Transcription Error
Aug-18-2020 16:38:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: Oct/UNK/2011	Initial Entry

I.f Ongoing:

Date	Location	User	Value	Reason
Aug-18-2020 16:38:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: NO End Date: Oct/UNK/2011	Initial Entry

I.g

Date	Location	User	Value	Reason
Aug-18-2020 16:40:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 7 Medical History right ankle fracture Term: Start Date: UNK/UNK/1979 Ongoing: NO End Date: UNK/UNK/ 1979	Initial Entry

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Header Text: c4591001

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I.g Line/MH Number:

Date	Location	User	Value	Reason
Aug-18-2020 16:40:47 (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
Aug-18-2020 16:40:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: right ankle fracture	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 16:40:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: UNK/UNK/1979	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Aug-18-2020 16:40:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: NO End Date: UNK/UNK/1979	Initial Entry

I.h

Date	Location	User	Value	Reason
Aug-18-2020 16:42:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 8 Medical History: torn tendon left foot Term: Start Date: UNK/UNK/198 8	Initial Entry

090177e196ae3eff\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

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Subject No: 10811061

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			Ongoing:	NO	
				End Date:	
				UNK/UNK/	
				1989	

1.h Line/MH Number:

Date	Location	User	Value	Reason
Aug-18-2020 16:42:14 (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
Aug-18-2020 16:42:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: torn tendon left foot	Initial Entry

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Header Text: c4591001

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Subject No: 10811061

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1.h Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 16:42:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: UNK/UNK/1988	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Aug-18-2020 16:42:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: NO End Date: UNK/UNK/1989	Initial Entry

1.i

Date	Location	User	Value	Reason
Aug-19-2020 11:14:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawryn Ebner (pfe.tebner)	Data Entry: Line/MH Number: 9 Medical History Term: redundant colon Start Date: Jan/UNK/2011 Ongoing: NO End Date: Jan/UNK/2011	Transcription Error
Aug-18-2020 16:43:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 9 Medical History Term: redundant colon leading to colonic inertia Start Date: Jan/UNK/2011	Initial Entry

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			Ongoing: NO	
			End Date:	
			Jan/UNK/2011	

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1.i Line/MH Number:

Date	Location	User	Value	Reason
Aug-18-2020 16:43:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

1.i Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-24-2020 12:07:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jeffrey Signora TMSQUERY (pfe.signoj01_tmsquery)	Query 1: Closed	Response satisfies query
Aug-19-2020 16:45:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 2: Closed	Discrepancy has been closed.
Aug-19-2020 11:14:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Aug-19-2020 11:14:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Aug-19-2020 11:14:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawyn Ebner (pfe.tebner)	Data Entry: redundant colon	Transcription Error
Aug-19-2020 10:16:30	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 2: Opened	Multiple concepts in the

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090177e196ae3eff\Final\Final On: 01-Apr-2021 05:06 (GMT)

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(UTC-05:00) Eastern Time (US & Canada)				term REDUNDANT COLON LEADING TO COLONIC INERTIA. Split the term into REDUNDANT COLON and COLONIC INERTIA and submit separately. Thank you.
Aug-19-2020 10:16:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Opened	Multiple concepts in the term REDUNDANT COLON LEADING TO COLONIC INERTIA. Split the term into REDUNDANT COLON and COLONIC INERTIA and submit separately. Thank you.
Aug-18-2020 16:43:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: redundant colon le ading to colonic i nertia	Initial Entry

Li Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 16:43:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: Jan/UNK/2011	Initial Entry

Header Text: c4591001

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I.i Ongoing:

Date	Location	User	Value	Reason
Aug-18-2020 16:43:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: NO End Date: Jan/UNK/2011	Initial Entry

I.j

Date	Location	User	Value	Reason
Aug-18-2020 16:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 10 Medical History Term: right foot bunion Start Date: UNK/UNK/1998 Ongoing: NO End Date: UNK/UNK/ 1998	Initial Entry

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Header Text: c4591001

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1.j Line/MH Number:

Date	Location	User	Value	Reason
Aug-18-2020 16:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10	Initial Entry

1.j Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-18-2020 16:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: right foot bunion	Initial Entry

1.j Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 16:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: UNK/UNK/1998	Initial Entry

1.j Ongoing:

Date	Location	User	Value	Reason
Aug-18-2020 16:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: NO End Date: UNK/UNK/1998	Initial Entry

1.k

Date	Location	User	Value	Reason
Aug-18-2020 16:44:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 11 Medical History: left foot bunion Term: Start Date: UNK/UNK/2000	Initial Entry

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Header Text: c4591001

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Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

			Ongoing:	NO End Date: UNK/UNK/ 2000	
--	--	--	-----------------	---	--

1.k Line/MH Number:

Date	Location	User	Value	Reason
Aug-18-2020 16:44:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11	Initial Entry

1.k Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-18-2020 16:44:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: left foot bunion	Initial Entry

1.k Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 16:44:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: UNK/UNK/2000	Initial Entry

1.k Ongoing:

Date	Location	User	Value	Reason
Aug-18-2020 16:44:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: NO End Date: UNK/UNK/2000	Initial Entry

1.l

Date	Location	User	Value	Reason
Aug-19-2020 12:27:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Line/MH Number: 12	Changed Information

090177e196ae3eff\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: 10811061

Generated By: pfe.levisse

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: pelvic mass Start Date: Jun/UNK/2007 Ongoing: NO End Date: Jun/UNK/2007	
Aug-18-2020 16:45:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 12 Medical History Term: pelvic mass with epithelial inclusion cyst of vagina Start Date: Jun/UNK/2007 : Ongoing: NO End Date: Jun/UNK/2007	Initial Entry

090177e196ae3eff\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: 10811061

Generated By: pfe.levisse

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

1.1 Line/MH Number:

Date	Location	User	Value	Reason
Aug-18-2020 16:45:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12	Initial Entry

1.1 Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-19-2020 18:25:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Closed	Discrepancy has been closed.
Aug-19-2020 12:27:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Aug-19-2020 12:27:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: pelvic mass	Changed Information
Aug-19-2020 11:49:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Opened	Multiple concepts in the term PELVIC MASS WITH EPITHELIAL INCLUSION CYST OF VAGINA. Split the term into PELVIC MASS and EPITHELIAL INCLUSION CYST OF VAGINA and submit separately. Thank you.

090177e196ae3eff\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: 10811061

Generated By: pfe.levisse

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

Aug-18-2020 16:45:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: pelvic mass with epithelial inclusion cyst of vagina	Initial Entry
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1.1 Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 16:45:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: Jun/UNK/2007	Initial Entry

1.1 Ongoing:

Date	Location	User	Value	Reason
Aug-18-2020 16:45:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: NO End Date: Jun/UNK/2007	Initial Entry

1.m

Date	Location	User	Value	Reason
Aug-18-2020 16:45:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 13 Medical History: c-section Term: Start Date: May/UNK/1983 Ongoing: NO End Date: May/UNK/1983	Initial Entry

090177e196ae3eff\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: 10811061

Generated By: pfe.levisse

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.m Line/MH Number:

Date	Location	User	Value	Reason
Aug-18-2020 16:45:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 13	Initial Entry

I.m Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-18-2020 16:45:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: c-section	Initial Entry

I.m Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 16:45:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: May/UNK/1983	Initial Entry

I.m Ongoing:

Date	Location	User	Value	Reason
Aug-18-2020 16:45:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: NO End Date: May/UNK/1983	Initial Entry

I.n

Date	Location	User	Value	Reason
Aug-18-2020 16:54:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 14 Number: Medical total abdominal hystere History T ctomy with bilateral oop erm: horectomy Start Dat Jul/UNK/1993 e:	Initial Entry

090177e196ae3eff\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:** 10811061**Generated By:** pfe.levisse**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**Ongoing:** NO

End Date:

Jul/UNK/1993

I.n Line/MH Number:

Date	Location	User	Value	Reason
Aug-18-2020 16:54:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 14	Initial Entry

I.n Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-18-2020 16:54:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: total abdominal hysterectomy wit h bilateral oophorectomy	Initial Entry

I.n Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 16:54:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: Jul/UNK/1993	Initial Entry

I.n Ongoing:

Date	Location	User	Value	Reason
Aug-18-2020 16:54:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: NO End Date: Jul/UNK/1993	Initial Entry

I.o

Date	Location	User	Value	Reason
Aug-19-2020 12:28:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 15 Number:	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811061

Generated By: pfe.levisse

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: EPITHELIAL INCLUSION CYST OF VAGINA Start Date: Jun/UNK/2007 Ongoing: NO End Date: UNK/UNK/2007
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I.o Line/MH Number:

Date	Location	User	Value	Reason
Aug-19-2020 12:28:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 15	Initial Entry

I.o Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-19-2020 12:28:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: EPITHELIAL INCLUSION CYST OF VAGINA	Initial Entry

I.o Start Date:

Date	Location	User	Value	Reason
Aug-19-2020 12:28:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Jun/UNK/2007	Initial Entry

I.o Ongoing:

Date	Location	User	Value	Reason
Aug-19-2020 12:28:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO End Date: UNK/UNK/2007	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1081

Subject No: 10811061

Generated By: pfe.lewiss

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
Aug-18-2020 16:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: Aug/18/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-18-2020 16:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: 177.2	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-18-2020 16:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-18-2020 16:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: 62.5	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-18-2020 16:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-18-2020 16:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 31.9	Initial Entry

090177e196ae3eff\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1081

Subject No: 10811061

Generated By: pfe.levisse

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

7.a

Date	Location	User	Value	Reason
Aug-18-2020 16:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: Record Identifier:: 1 Temperature: 97.5 Temperature Unit: F Temperature Locati on:: FOREHE AD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-18-2020 16:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-18-2020 16:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: 97.5	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-18-2020 16:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-18-2020 16:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: FOREHEAD	Initial Entry

090177e196ae3eff\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:** 30-Jul-2020 21:27**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811061**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Aug-18-2020 16:53:04 (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
Aug-18-2020 16:53:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-18-2020 16:53:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: Aug/18/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Aug-18-2020 16:53:04 (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
Aug-18-2020 16:53:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-18-2020 16:53:04 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811061

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Time (US & Canada)			Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin in Beta_PX113 Result:: Not Done:: NOT DONE
--------------------	--	--	---

6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-18-2020 16:53:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-18-2020 16:53:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Aug-18-2020 16:53:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: NOT DONE	Initial Entry

090177e196ae3eff\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: 10811061

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
Aug-18-2020 16:53:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: Aug/18/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-18-2020 16:53:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: 232421	Initial Entry

090177e196ae3eff\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: 10811061

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Data Origin

Date	Location	User	Value	Reason
Aug-18-2020 15:45:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-18-2020 15:45:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-18-2020 15:45:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-18-2020 15:45:33 (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.
Aug-18-2020 15:45:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Aug/18/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-18-2020 15:45:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BPHZHT	Initial Entry

090177e196ae3eff\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: 10811061

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.a Sample ID

Date	Location	User	Value	Reason
Aug-18-2020 15:45:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> BPHZHT	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-18-2020 15:45:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BPHZHV	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-18-2020 15:45:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> BPHZHV	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-18-2020 15:46:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BP1JB2	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-18-2020 15:46:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> BP1JB2	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-18-2020 15:47:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BP1JB1	Initial Entry

090177e196ae3eff\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: 10811061

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.d Sample ID

Date	Location	User	Value	Reason
Aug-18-2020 15:47:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BP1JB1	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-18-2020 15:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BP1JB0	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-18-2020 15:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BP1JB0	Initial Entry

090177e196ae3eff\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: 10811061

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Data Origin

Date	Location	User	Value	Reason
Aug-18-2020 15:48:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-18-2020 15:48:25 (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
Aug-18-2020 15:48:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-18-2020 15:48:25 (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.
Aug-18-2020 15:48:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Aug/18/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-18-2020 15:48:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BP1J9D	Initial Entry

090177e196ae3eff\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: 10811061

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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

5.a Sample ID

Date	Location	User	Value	Reason
Aug-18-2020 15:48:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BP1J9D	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811061

Generated By: pfe.lewissc

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
Aug-18-2020 16:55:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-18-2020 16:55:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-18-2020 16:55:21 (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
Aug-18-2020 16:55:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: Aug/18/2020 16:08	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-18-2020 16:55:21 (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
Aug-18-2020 16:55:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: LEFT	Initial Entry

090177e196ae3eff\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: 10811061

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

7. Route:

Date	Location	User	Value	Reason
Aug-18-2020 16:55:21 (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
Aug-18-2020 16:55:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Aug-18-2020 16:55:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: YES	Initial Entry

090177e196ae3eff\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: 10811061

Generated By: pfe.lewissc

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
Aug-18-2020 16:55:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: NO - REACTOGENICITY E-DI ARY NOT COLLECTED FOR T HIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811061

Generated By: pfe.lewissc

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-07-2020 03:53:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Avinash Gawas (pfe.gawasa)	Query 1: Closed	closed per SITE response
Sep-04-2020 10:41:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Query 1: Answered	Subject was unable to have the study visit within window and so was scheduled to have the visit earlier.
Sep-04-2020 05:17:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Avinash Gawas (pfe.gawasa)	Query 1: Opened	PDQ: Date of visit at this visit is out of window (-3 day) from Date of visit (18/Aug/2020) at V1D1VX1L visit. Please reconcile and update accordingly, else confirm date is correct as is.
Sep-03-2020 15:35:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sep/3/2020	Initial Entry

090177e196ae3eff\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1081

Subject No: 10811061

Generated By: pfe.levisse

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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1. Date:

Date	Location	User	Value	Reason
Sep-03-2020 16:57:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Sep/3/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-03-2020 16:57:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Record Identifier:: 1 Temperature: 97.8 Temperature Unit: F Temperature Locat ion:: ORAL CAVI TY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-03-2020 16:57:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-03-2020 16:57:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: 97.8	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-03-2020 16:57:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: F	Initial Entry

2.a Temperature Location:

090177e196ae3eff\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1081

Subject No: 10811061

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Sep-03-2020 16:57:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3eff\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:** 30-Jul-2020 21:27**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811061**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-03-2020 16:58:06 (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-03-2020 16:58:06 (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-03-2020 16:58:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Sep/3/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-03-2020 16:58:06 (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-03-2020 16:58:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-03-2020 16:58:06 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811061

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Time (US & Canada)			Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: Not Done:: NOT DONE
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-03-2020 16:58:06 (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-03-2020 16:58:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-03-2020 16:58:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NOT DONE	Initial Entry

090177e196ae3eff\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: 10811061

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Data Origin

Date	Location	User	Value	Reason
Sep-03-2020 15:35:28 (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-03-2020 15:35:28 (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-03-2020 15:35:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-03-2020 15:35:28 (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-03-2020 15:35:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Sep/3/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-03-2020 15:35:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BP97NF	Initial Entry

090177e196ae3eff\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811061

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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

5.a Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 15:35:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BP97NF	Initial Entry

090177e196ae3eff\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: 10811061

Generated By: pfe.lewissc

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-03-2020 16:58:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-03-2020 16:58:37 (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-03-2020 16:58:37 (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-03-2020 16:58:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Sep/3/2020 16:09	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-03-2020 16:58:37 (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-03-2020 16:58:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: LEFT	Initial Entry

090177e196ae3eff\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: 10811061

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

7. Route:

Date	Location	User	Value	Reason
Sep-03-2020 16:58:37 (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-03-2020 16:58:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION 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-03-2020 16:58:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

090177e196ae3eff\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: 10811061

Generated By: pfe.lewissc

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-01-2020 11:32:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Oct/1/2020	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: 10811061

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Data Origin

Date	Location	User	Value	Reason
Oct-01-2020 11:34:45 (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-01-2020 11:34:45 (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-01-2020 11:34:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-01-2020 11:34:45 (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-01-2020 11:34:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Oct/1/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-01-2020 11:34:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: Sample ID: BRTXS1	Initial Entry

090177e196ae3eff\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: 10811061

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.a Sample ID

Date	Location	User	Value	Reason
Oct-01-2020 11:34:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: BRTXS1	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-01-2020 11:35:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: Sample ID: BRTXS2	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-01-2020 11:35:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: BRTXS2	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-01-2020 11:35:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: Sample ID: BP1HT5	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-01-2020 11:35:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: BP1HT5	Initial Entry

090177e196ae3eff\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: 10811061

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, 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
Mar-11-2021 15:21:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Mar/11/2021	Initial Entry

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811061

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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1. Data Origin

Date	Location	User	Value	Reason
Mar-11-2021 15:21:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-11-2021 15:21:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-11-2021 15:22:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-11-2021 15:21:45 (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.
Mar-11-2021 15:21:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Mar/11/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-11-2021 15:22:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: Sample ID: BM8X9S	Initial Entry

090177e196ae3eff\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811061

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.a Sample ID

Date	Location	User	Value	Reason
Mar-11-2021 15:22:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> BM8X9S	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-11-2021 15:22:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BM8X9T	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-11-2021 15:22:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> BM8X9T	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-11-2021 15:22:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BSFNYS	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-11-2021 15:22:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> BSFNYS	Initial Entry

5.d

Date	Location	User	Value	Reason
Mar-11-2021 15:22:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BSFNYS	Initial Entry

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Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811061

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

5.d Sample ID

Date	Location	User	Value	Reason
Mar-11-2021 15:22:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BSFNYS	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811061

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-01-2020 11:33:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Oct/1/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-01-2020 11:33:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-01-2020 11:33:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: COMPLETED	Initial Entry

090177e196ae3eff\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: 10811061

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

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Date	Location	User	Value	Reason
Oct-01-2020 11:38:34 (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: 10811061

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1081) Sterling Research Group - Mt. Auburn

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Date	Location	User	Value	Reason
Nov-11-2020 11:11:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1081

Subject No: 10811061

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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1. Category:

Date	Location	User	Value	Reason
Oct-01-2020 11:38:34 (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
Oct-01-2020 11:38:34 (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
Nov-10-2020 13:25:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (pfe.hassaa38)	Query 1: Closed	Response satisfies query
Nov-10-2020 11:26:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	No other information was avail from subject medical records
Nov-10-2020 11:26:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Lymphadenopathy Under left e ar	No other information was avail from subject medical records
Oct-23-2020 09:01:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (pfe.hassaa38)	Query 1: Reissued:Opened	please keep the query with you in open status until the records are received. thanks
Oct-23-2020 08:44:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	records were requested, none received as of today
Oct-21-2020 14:53:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (pfe.hassaa38)	Query 1: Opened	ClinQuery: Lymphadenopathy: please specify which

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1081**Subject No:** 10811061**Generated By:** pfe.levisse**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

				lymph nodes and whether bilateral, left or right
Oct-08-2020 11:26:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: Lymphadenopathy	Transcription Error
Oct-08-2020 11:25:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: Lymphadenopathy due to bacterial infection	New Information
Oct-01-2020 15:00:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Diane Broadnax (pfe.dbroadnax)	Data Entry: Lymphadenopathy	New Information
Oct-01-2020 12:19:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Swollen Lymph Nodes Lt side of neck	Subject did not know exact diagnosis, only gave symptoms
Oct-01-2020 11:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Lymphadenopathy Lt side of neck	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-01-2020 11:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sep/10/2020 08:01	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-24-2020 11:30:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO End Date Time: Sep/23/2020 08:00	Transcription Error
Oct-01-2020 11:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO End Date Time: Sep/24/2020 08:00	Initial Entry

6. Toxicity Grade:

Header Text: c4591001

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Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

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Date	Location	User	Value	Reason
Oct-01-2020 11:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-01-2020 11:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-01-2020 11:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-09-2020 09:59:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nicholas Roosa (pfe.roosan)	Query 1: Closed	Response satisfies query
Oct-08-2020 11:27:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Query 1: Answered	Updated source to provide origin of AE per subject report.
Oct-06-2020 12:15:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nicholas Roosa (pfe.roosan)	Query 1: Opened	Bacterial infection is not listed in progress note or AE log, please confirm where this information originates and

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

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				upload to patient source in Complion.
Oct-01-2020 11:38:34 (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> Bacterial Infection	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-01-2020 11:38:34 (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
Oct-01-2020 11:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-01-2020 11:38:34 (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
Oct-01-2020 11:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
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Generated By: pfe.levisse

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Form Status: Data Complete, Frozen, Verified

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Oct-01-2020 11:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry
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Header Text: c4591001

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Site No: 1081

Subject No: 10811061

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

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1. Category:

Date	Location	User	Value	Reason
Nov-11-2020 11:11:29 (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 11:11:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-11-2020 11:11:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Contact Dermatitis on lower extre mities	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-11-2020 11:11:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sep/11/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-11-2020 11:11:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO End Date Time: Sep/22/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1081

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Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

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Nov-11-2020 11:11:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: 2	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Nov-11-2020 11:11:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Nov-11-2020 11:11:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-11-2020 11:11:29 (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 If Other, specify: contact with allergen or irritant	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-11-2020 11:11:29	ACV0PFEINFP6000	Lora Morris	Data Entry:	Initial Entry

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Header Text: c4591001

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Subject No: 10811061

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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(UTC-05:00) Eastern Time (US & Canada)		(pfe.lmorris)	NOT APPLICABLE	
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-11-2020 11:11:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-11-2020 11:11:29 (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-11-2020 11:11:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Nov-11-2020 11:11:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811061

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

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Date	Location	User	Value	Reason
Oct-08-2020 12:25:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811061

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Oct-08-2020 12:25:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Oct-08-2020 12:25:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Oct-08-2020 12:25:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Oct-08-2020 12:25:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: Influenza vaccine	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Oct-08-2020 12:25:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: Sep/16/2020	Initial Entry

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Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811061

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-04-2021 16:58:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Feb/4/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1081

Subject No: 10811061

Generated By: pfe.levissc

Form: FURTHER VACCINATION CONFIRMATION - 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. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Feb-04-2021 16:58:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at V accination 1/2	Initial Entry

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Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811061

Generated By: pfe.lewissc

Form: TREATMENT UNBLINDED - 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 Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-24-2021 00:29:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Closed	Auto closed by Validation Check: VC_DS001_36
Feb-23-2021 13:17:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-23-2021 13:17:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry : Feb/4/ 2021	Transcription Error
Feb-22-2021 21:11:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW7350978;Date Treatment Unblinded should be equal to or after DOV in REVAX CONTACT visit when Reason is ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION.Please review and update as appropriate.
Feb-04-2021 16:57:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry : Feb/2/ 2021	Initial Entry

2. Primary Reason for Unblinding:

090177e196ae3eff\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811061

Generated By: pfe.levissc

Form: TREATMENT UNBLINDED - 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

Date	Location	User	Value	Reason
Feb-04-2021 16:57:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry

090177e196ae3eff\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811061

Generated By: pfe.lewissc

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Oct-01-2020 11:33:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-18-2020 16:53:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-18-2020 15:45:06 (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
Oct-01-2020 11:33:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/1/2020	Initial Entry
Aug-18-2020 16:53:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/18/2020	Initial Entry
Aug-18-2020 15:45:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/18/2020	Initial Entry

090177e196ae3eff\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811061

Generated By: pfe.lewissc

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Casebook Signature

Date	Location	User	Value	Reason
Oct-12-2020 15:31:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae3eff\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: 10811090

Generated By: pfe.levissc

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: 10811090

Generated By: pfe.lewissc

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 Aug/24/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1081

Subject No: 10811090

Generated By: pfe.lewissc

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	[10811090]
2.	Birth Date:	(b) (6)/1964
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811090

Generated By: pfe.lewissc

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	Aug/24/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1081

Subject No: 10811090

Generated By: pfe.lewissc

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: 10811090

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	Aug/24/2020
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: 10811090

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

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Transient Ischemic Attack]
	Start Date:	Dec/1/2019
	Ongoing:	NO End Date: Dec/UNK/2019
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Spastic Cerebral Palsy]
	Start Date:	(b) (6)/1964
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Blood Clot causing TIA]
	Start Date:	Dec/1/2009
	Ongoing:	NO End Date: Dec/1/2009

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1081

Subject No: 10811090

Generated By: pfe.lewissc

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:	Aug/24/2020
2.	Weight:	[200.0]
3.	Unit:	LB
4.	Height:	[72.0]
5.	Unit:	in
6.	Body Mass Index:	[27.1]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[98.0]
	Unit:	F
	Temperature Location:	FOREHEAD

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811090

Generated By: pfe.lewissc

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 :	Aug/24/2020
2.	Randomization Number:	[238100]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811090

Generated By: pfe.lewissc

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: Aug/24/2020
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	[BP97XF]
5.b	Sample ID	[BP97XH]
5.c	Sample ID	[BP97XG]
5.d	Sample ID	[BPHZKN]
5.e	Sample ID	[BPHZKP]

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:03
Site No: 1081
Subject No: 10811090
Generated By: pfe.lewissc

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: Aug/24/2020
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	[BP97J8]
-----	-----------	----------

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811090

Generated By: pfe.lewissc

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:	Aug/24/2020 14:55
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1081

Subject No: 10811090

Generated By: pfe.lewissc

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
----	---	--

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811090

Generated By: pfe.levissc

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/14/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1081

Subject No: 10811090

Generated By: pfe.lewissc

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/14/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.2]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811090

Generated By: pfe.lewissc

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/14/2020
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	[BP97RN]
-----	-----------	----------

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811090

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/14/2020 14:39
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

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811090

Generated By: pfe.lewissc

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/13/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811090

Generated By: pfe.lewissc

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: Oct/13/2020
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	[BRTXXC]
5.b	Sample ID	[BRTXXD]
5.c	Sample ID	[BP1HWC]

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811090

Generated By: pfe.levissc

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: 10811090

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	[]
----	-----------	-----

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811090

Generated By: pfe.levissc

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: 10811090

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	[]
----	-----------	-----

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811090

Generated By: pfe.levisc

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: 10811090

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	[]
----	-----------	-----

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811090

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_ILL - New Unscheduled Visit

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811090

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

Signs and Symptoms

1.	Date of Assessment:	//
2.	Date of First Symptom Started:	//
3.	Symptoms Ongoing?	

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

5.	Symptoms - Other Text:	[]
----	------------------------	-----

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811090

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: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811090

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	[]
----	-----------	-----

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811090

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

Health Care Utilization

1.	Physician or Healthcare Professional:	
	Occurrence of Visits or Contacts:	

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[]
----	-------------------------------------	-----

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	
----	--	--

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811090

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

Illness Details

1.	Category of Clinical Event:	
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	
3.	Toxicity Grade:	

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811090

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 Visit

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: 10811090

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	[]
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090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811090

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: 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: 10811090

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Unplanned Assessments

1.	Assessments	
----	-------------	--

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1081

Subject No: 10811090

Generated By: pfe.lewissc

Form: DISPOSITION - TREATMENT

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 - Treatment

1.	Date of Completion/Discontinuation/Death :	Oct/13/2020
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: 10811090

Generated By: pfe.levissc

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Disposition - Follow-Up

1.	Date of Completion/Discontinuation/Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[]

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
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: 10811090

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 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: 10811090

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: 10811090

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Myocardial Infarction	Nov/15/2020 UNK: UNK	NO End Date Time: Nov/18/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	Suicide attempt	Jan/15/2021 UNK: UNK	NO End Date Time: Jan/18/2021 UNK:UNK	Repeating Pages

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811090

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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[eCRF Audit Trail History](#)
[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/15/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/18/2020 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? NO Did this serious event require or prolong hospitalization? YES 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

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811090

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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: [Hypertension]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021116993]

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811090

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

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:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Suicide attempt]
4.	Start Date Time:	Jan/15/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/18/2021 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO 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

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811090

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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: [Anxiety and depression following cardiac event]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021156090]

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (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: 10811090

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1081

Subject No: 10811090

Generated By: pfe.levisse

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

[Back to Form](#)

Medication Error

1.	Category:	
2.	Medication Error (Type of Medication Error):	[]
3.	Start Date:	//
4.	Is the medication error still ongoing?	
5.	Latest Action Taken with Study Treatment:	
6.	Was a Concomitant Medication given?	
7.	Was a Non-Drug Treatment given?	
8.	Did the Medication Error cause the subject to be discontinued from the study?	
9.	Was this medication error associated with any adverse events?	
10.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (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: 10811090

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 Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811090

Generated By: pfe.levisse

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

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.	Date:	//

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (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: 10811090

Subject Initials: ---

Generated By: pfe.levisse

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

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811090

Generated By: pfe.levisse

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?	

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (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: 10811090

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

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811090

Generated By: pfe.levisse

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: 10811090

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811090

Generated By: pfe.levisse

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

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: 10811090

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: 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: 10811090

Subject Initials: ---

Generated By: pfe.lewissc

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: 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: 10811090

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?	

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (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: 10811090

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: 10811090

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: 10811090

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: 10811090

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

Informed Consent - Asymptomatic Surveillance

1.	Consent Was:	
----	--------------	--

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811090

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: 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: 10811090

Subject Initials: ---

Generated By: pfe.lewissc

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: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811090

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Feb/4/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811090

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2
----	---	--

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811090

Generated By: pfe.lewissc

Form: TREATMENT UNBLINDED

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

Treatment Unblinded

1.	Date Treatment Unblinded :	Feb/4/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811090

Generated By: pfe.levisse

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 :	//
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Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811090

Generated By: pfe.lewissc

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Death Details

1.	Date of Collection / Notification of Death:	//
----	---	----

Cause of Death

2.	Cause of Death Status:	
	Cause of Death:	[]

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811090

Generated By: pfe.lewissc

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	FOLLOW-UP
2.	Subject Status Date	Oct/13/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811090

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
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Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811090

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
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1081

Subject No: 10811090

Generated By: pfe.levisse

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	Aug-24-2020 15:40:19 (UTC-05:00) Eastern Time (US & Canada)	Phillip Ross (pfe.pross)	Not Done

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811090

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

This form requires signing by a member of each of the following signature groups:

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
Lora Morris	N/A	Feb-04-2021 15:18:50 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

James Fry	Approved	Oct-23-2020 14:20:48 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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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.

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1081

Subject No: 10811090

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
Aug-24-2020 14:32:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn 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
Aug-24-2020 14:32:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn 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: 10811090

Generated By: pfe.lewissc

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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1. Consent Was:

Date	Location	User	Value	Reason
Aug-24-2020 14:32:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: OBTAINED Date Written Consent Obtained Aug/24/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1081

Subject No: 10811090

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
Aug-24-2020 14:31:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10811090	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-24-2020 14:31:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1964	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-24-2020 14:32:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-24-2020 14:32:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Aug-24-2020 14:32:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: WHITE	Initial Entry

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811090

Generated By: pfe.lewissc

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
Aug-24-2020 15:40:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Aug/24/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811090

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
Aug-24-2020 15:40:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Aug/24/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-24-2020 15:40:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-24-2020 15:40:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: COMPLETED	Initial Entry

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811090

Generated By: pfe.lewissc

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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I.a

Date	Location	User	Value	Reason
Aug-24-2020 15:44:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: Line/MH Number: 1 Medical History Term: Hypertension Start Date: UNK/UNK/2015 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-24-2020 15:44:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: 1	Initial Entry

I.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-24-2020 15:44:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Hypertension	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Aug-24-2020 15:44:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2015	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Aug-24-2020 15:44:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

I.b

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811090

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Aug-25-2020 17:12:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Line/MH Num 2 ber: Medical Histor Transient Ischemi y Term: c Attack Start Date: Dec/1/2019 Ongoing: NO End Date: Dec/UNK/2019	Changed Information
Aug-25-2020 17:11:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Line/MH Num 2 ber: Medical Histor Transient Ischemi y Term: c Attack Start Date: Dec/1/2019 Ongoing: NO End Date: Dec/2/2009	Changed Information
Aug-25-2020 17:11:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Line/MH Num 2 ber: Medical Histor Transient Ischemi y Term: c Attack Start Date: Dec/1/2019 Ongoing: NO End Date: Dec/UNK/2009	Changed Information
Aug-25-2020 17:11:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Line/MH Num 2 ber: Medical Histor Transient Ischemi y Term: c Attack Start Date: Dec/UNK/2019	Changed Information

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811090

Generated By: pfe.levisse

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

			Ongoing: NO End Date: Dec/UNK/2009	
Aug-24-2020 15:44:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term: Transient Ischemic Attack Start Date: Dec/UNK/2019 Ongoing: YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811090

Generated By: pfe.levisse

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.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-24-2020 15:44:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-27-2020 17:10:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Closed	Response satisfies query
Aug-27-2020 06:58:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Query 1: Answered	Changed data per query
Aug-26-2020 13:12:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Reissued:Opened	GDP Clin: Thank you for the update. However, line entry added (blood clot) was not intended by the query and the dates do not match to TIA. If an underlying cause/risk is known (eg atherosclerosis) then add; otherwise remove line 4 and leave data as was
Aug-25-2020 17:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Query 1: Answered	Changed data per query
Aug-25-2020 16:26:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	GPD Clin: Please confirm the underlying cause of TIA and capture as a separate line entry in the MH listing
Aug-24-2020 15:44:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Transient Ischemic Attack	Initial Entry

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811090

Generated By: pfe.levisse

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 Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 17:11:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Dec/1/2019	Changed Information
Aug-24-2020 15:44:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Dec/UNK/2019	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Aug-26-2020 13:08:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Closed	Response satisfies query
Aug-25-2020 17:12:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Aug-25-2020 17:12:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO End Date: Dec/UNK/2019	Changed Information
Aug-25-2020 17:11:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO End Date: Dec/2/2009	Changed Information
Aug-25-2020 17:11:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For Term Transient Ischemic Attack End Date is prior to Start Date.
Aug-25-2020 17:11:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Aug-25-2020 17:11:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO End Date: Dec/UNK/2009	Changed Information

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811090

Generated By: pfe.levisse

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

Aug-25-2020 16:24:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	GPD Clin: TIA is an acute event. Please review ongoing status and update as appropriate
Aug-24-2020 15:44:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

I.c

Date	Location	User	Value	Reason
Aug-24-2020 15:45:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Term: Spastic Cerebral Palsy Start Date: (b) (6)/1964 Ongoing: YES	Initial Entry

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811090

Generated By: pfe.levisse

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.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-24-2020 15:45:22 (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
Aug-24-2020 15:45:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Spastic Cerebral Palsy	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Aug-24-2020 15:45:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: (b) (6) /1964	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Aug-24-2020 15:45:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Aug-27-2020 06:58:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Line/MH Num 4 ber: Medical Histor Blood Clot causi y Term: ng TIA Start Date: Dec/1/2009 Ongoing: NO End Date: Dec/1/2009	Changed Information (DELETED)
Aug-25-2020 17:13:15	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811090

Generated By: pfe.levisse

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

(UTC-05:00) Eastern
Time (US & Canada)

(autocalc)

Line/MH Number: 4

Medical History Term: Blood Clot causing TIA

Start Date: Dec/1/2009

Ongoing: NO

End Date:

Dec/1/2009

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811090

Generated By: pfe.levisse

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.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-27-2020 06:58:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: 4	Changed Information (DELETED)
Aug-25-2020 17:13:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

I.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-28-2020 09:03:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jeffrey Signora TMSQUERY (pfe.signoj01_tmsquery)	Query 1: Closed	Response satisfies query
Aug-27-2020 06:58:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Blood Clot causing TIA	Changed Information (DELETED)
Aug-27-2020 06:58:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Aug-26-2020 17:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Opened	Multiple concepts in the term BLOOD CLOT CAUSING TIA. Split the term into BLOOD CLOT and TIA and submit

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811090

Generated By: pfe.levisse

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

				separately. Thank you.
Aug-25-2020 17:13:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Blood Clot causing TIA	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Aug-27-2020 06:58:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Dec/1/2009	Changed Information (DELETED)
Aug-25-2020 17:13:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Dec/1/2009	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Aug-27-2020 06:58:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO End Date: Dec/1/2009	Changed Information (DELETED)
Aug-25-2020 17:13:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO End Date: Dec/1/2009	Initial Entry

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1081

Subject No: 10811090

Generated By: pfe.lewissc

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
Aug-24-2020 15:46:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> Aug/24/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-24-2020 15:46:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> 200.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-24-2020 15:46:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-24-2020 15:46:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> 72.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-24-2020 15:46:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-24-2020 15:46:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 27.1	Initial Entry

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1081

Subject No: 10811090

Generated By: pfe.levisse

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

7.a

Date	Location	User	Value	Reason
Aug-24-2020 15:46:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Record Identifier:: 1 Temperature: 98.0 Temperature Unit: F Temperature Locatio n:: FOREHEA D	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-24-2020 15:46:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-24-2020 15:46:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: 98.0	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-24-2020 15:46:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-24-2020 15:46:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: FOREHEAD	Initial Entry

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811090

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
Aug-24-2020 15:46:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Aug/24/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-24-2020 15:46:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: 238100	Initial Entry

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (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: 10811090

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Data Origin

Date	Location	User	Value	Reason
Aug-24-2020 16:02:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-24-2020 16:02:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-25-2020 10:18:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sonal K (pfe ks66)	Query 2 : Closed	Response satisfies query
Aug-25-2020 08:35:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2 : Answered	Changed Information
Aug-25-2020 08:35:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES Date of Collection: Aug/ 24/2 020	Changed Information

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (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:** 10811090**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11

Aug-24-2020 22:24:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 2 : Opened	DMW4341678;Date of Collection is earlier or more than 1 day after Date of Visit. Please clarify or correct.
Aug-24-2020 16:02:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1 : Deleted	Close Auto Query
Aug-24-2020 16:02:12 (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.
Aug-24-2020 16:02:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawyn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Aug/ 23/2 020	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Oct-22-2020 17:04:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laurie Hawes (pfe.hawesl01)	Query 1: Closed	No need to query as per SPA
Oct-22-2020 09:54:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Attempted to remove carriage from text box. Hit delete & backspace multiple times
Oct-22-2020 09:54:43 (UTC-05:00) Eastern	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Attempted to remove carriage

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:03
Site No: 1081
Subject No: 10811090
Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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

Time (US & Canada)				from text box. Hit delete & backspace multiple times
Oct-22-2020 04:37:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pratiksha Mahadik (pfe.mahadp07)	Query 1: Reissued:Opened	DM: Thank you for response. However a carriage return is still being identified for this field. Please click into the enterable field and press delete and backspace multiple times to remove the characters.
Oct-21-2020 15:54:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	Please specify where there is a carriage, none seen from our end
Oct-21-2020 12:57:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Steven Finegan Prod (pfe.finegansm)	Query 1: Opened	A carriage is identified. To avoid processing errors, please remove the identified character by deleting the entry and re-entering the data (without using copy and paste).
Aug-24-2020 16:02:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry:	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-24-2020 16:02:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BP97XF	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811090

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Aug-24-2020 16:02:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BP97XF	Initial Entry
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5.b

Date	Location	User	Value	Reason
Aug-24-2020 16:02:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BP97XH	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-24-2020 16:02:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BP97XH	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-24-2020 16:02:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BP97XG	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-24-2020 16:02:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BP97XG	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-24-2020 16:03:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BPHZKN	Initial Entry

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (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: 10811090

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.d Sample ID

Date	Location	User	Value	Reason
Aug-24-2020 16:03:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BPHZKN	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-24-2020 16:03:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BPHZKP	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-24-2020 16:03:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BPHZKP	Initial Entry

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (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:** 10811090**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-24-2020 16:03:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-24-2020 16:03:52 (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
Aug-24-2020 16:04:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-24-2020 16:03:52 (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.
Aug-24-2020 16:03:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Aug/24/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-24-2020 16:04:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BP97J8	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811090

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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

5.a Sample ID

Date	Location	User	Value	Reason
Aug-24-2020 16:04:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BP97J8	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811090

Generated By: pfe.lewissc

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
Aug-24-2020 15:46:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-24-2020 15:46:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-24-2020 15:46:34 (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
Aug-24-2020 15:46:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Aug/24/2020 14:55	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-24-2020 15:46:34 (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
Aug-24-2020 15:46:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: LEFT	Initial Entry

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811090

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

7. Route:

Date	Location	User	Value	Reason
Aug-24-2020 15:46:34 (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
Aug-24-2020 15:46:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Aug-24-2020 15:46:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1081

Subject No: 10811090

Generated By: pfe.lewissc

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
Aug-24-2020 15:46:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO - REACTOGENICITY E-DIA RY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811090

Generated By: pfe.lewissc

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-14-2020 14:14:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sep/14/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1081

Subject No: 10811090

Generated By: pfe.lewissc

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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1. Date:

Date	Location	User	Value	Reason
Sep-14-2020 14:48:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sep/14/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-14-2020 14:48:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Record Identifier:: 1 Temperature: 98.2 Temperature Unit: F Temperature Location:: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-14-2020 14:48:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-14-2020 14:48:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: 98.2	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-14-2020 14:48:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: F	Initial Entry

2.a Temperature Location:

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1081

Subject No: 10811090

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Sep-14-2020 14:48:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: ORAL CAVITY	Initial Entry

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: 10811090

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Data Origin

Date	Location	User	Value	Reason
Sep-14-2020 14:15:18 (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-14-2020 14:15:18 (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-14-2020 14:15:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-14-2020 14:15:18 (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-14-2020 14:15:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Sep/14/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-14-2020 14:15:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: Sample ID: BP97RN	Initial Entry

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811090

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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

5.a Sample ID

Date	Location	User	Value	Reason
Sep-14-2020 14:15:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BP97RN	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811090

Generated By: pfe.lewissc

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-14-2020 14:48:42 (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-14-2020 14:48:42 (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-14-2020 14:48:42 (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-14-2020 14:48:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sep/14/2020 14:39	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-14-2020 14:48:42 (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-14-2020 14:48:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: LEFT	Initial Entry

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811090

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

7. Route:

Date	Location	User	Value	Reason
Sep-14-2020 14:48:42 (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-14-2020 14:48:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION 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-14-2020 14:48:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811090

Generated By: pfe.lewissc

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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1. Date of Visit

Date	Location	User	Value	Reason
Oct-13-2020 14:24:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Oct/13/2020	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:** 10811090**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-13-2020 14:50:58 (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-13-2020 14:50:58 (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-13-2020 14:51:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-13-2020 14:50:58 (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-13-2020 14:50:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Oct/13/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-13-2020 14:51:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: Sample ID: BRTXXC	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: 10811090

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.a Sample ID

Date	Location	User	Value	Reason
Oct-13-2020 14:51:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: BRTXXC	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-13-2020 14:51:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: Sample ID: BRTXXD	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-13-2020 14:51:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: BRTXXD	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-13-2020 14:51:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: Sample ID: BP1HWC	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-13-2020 14:51:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: BP1HWC	Initial Entry

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1081

Subject No: 10811090

Generated By: pfe.levissc

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-13-2020 14:25:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Oct/13/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-13-2020 14:25:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-13-2020 14:25:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: COMPLETED	Initial Entry

090177e196ae3f07\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811090

Generated By: pfe.lewissc

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
Feb-04-2021 15:18:50 (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: 10811090

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

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Date	Location	User	Value	Reason
Feb-23-2021 13:45:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811090

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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
Feb-04-2021 15:18:50 (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
Feb-04-2021 15:18:50 (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-12-2021 15:24:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 6: Closed	Response satisfies query
Mar-10-2021 15:46:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Query 6: Answered	Zoloft was not on the 13 Feb update and not on the 8 Mar update for #2021116993. It was only on the initial report of 4 Feb. It was on the 13 Feb initial report for the suicide attempt (#2021156090).
Mar-08-2021 19:39:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 5: Closed	Response satisfies query
Mar-08-2021 16:11:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 6: Reissued:Opened	Clinical Please check Zoloft again; still included on the 13Feb21 MI SAE (#2021116993)

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1081

Subject No: 10811090

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1081) Sterling Research Group - Mt. Auburn

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Mar-08-2021 10:40:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Query 6: Answered	Zoloft was removed from #2021116993 MI on the last update of 13 Feb 2021. Zoloft is listed in the con med section for #2021156090 Suicide Attempt updated 23 Feb 2021.
Mar-05-2021 21:04:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 6: Opened	Clinical - followup, in the most recent SAE followup (23Feb21), Zoloft remains in the Con meds section of the SAE for MI 9#2021116993)
Mar-05-2021 14:18:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Query 5: Answered	That is US standard of care as a primary preventative for heart attack and stroke in patients with a history of cardiovascular disease.
Mar-03-2021 12:16:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 5: Opened	Medical monitor_ Per report, the subject was under treatment with acetylsalicylic acid. Pls advise if it was given as a preventative for cardiac disorders. Thanks
Mar-01-2021 11:45:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Closed	Response satisfies query
Mar-01-2021 11:45:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Closed	Response satisfies query

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1081**Subject No:** 10811090**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:11

Mar-01-2021 11:25:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Query closed; will follow for report of Zoloft removal from prior Meds.
Mar-01-2021 11:23:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Feb-23-2021 13:59:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Query 4: Answered	Anxiety diagnosis has resulted since the Suicide Attempt and will be included on the SAE report but not in eCRF.
Feb-23-2021 13:54:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Query 3: Answered	In reviewing the SAE for the Suicide Attempt it was noted that the date of the event was entered incorrectly. A FU SAE report will be submitted.
Feb-23-2021 13:53:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Query 1: Answered	This has been entered.
Feb-23-2021 13:52:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Query 2: Answered	On the followup report for #2021116993, Zoloft was removed. It was not prescribed until the suicide attempt in January 2021.
Feb-16-2021 14:21:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Opened	Clinical in SAE report 'Failed Suicide Attempt', a new diagnosis of Anxiety beginning 15Jan21 was reported. Please review event for serious status in view of Suicide Attempt; only report Anxiety event on AE

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1081**Subject No:** 10811090**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:11

				CRF if Serious (as after visit 3)
Feb-16-2021 14:13:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Opened	Clinical On review of the SAE report for Failed Suicide Attempt, a history of 'Recent Cardiac Surgery' was reported. Please submit this information to MI SAE report (#2021116993)
Feb-16-2021 14:09:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	Clinical - Con Meds section of SAE (#2021116993) states the subject receives Zolofit; however, it is not reported what condition the subject receives this medication for. Please report condition, & month in 2020 when drug was started, if available
Feb-16-2021 13:58:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical SAE for event of 'Failed Suicide Attempt' submitted; however, AE CRF does not record this adverse event. Please enter new SAE.
Feb-04-2021 15:18:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Myocardial Infarction	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1081**Subject No:** 10811090**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:11

Mar-09-2021 17:20:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (pfe.gayedj)	Query 2: Closed	Clin: Thank you that is appreciated
Mar-08-2021 16:05:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Query closed; will follow for requested hospital dates information.
Mar-08-2021 10:45:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Query 1: Answered	report will be updated today.
Mar-08-2021 10:44:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Query 2: Answered	I will submit an update for the hospitalization dates but the report stated the spinal fusion was out-patient. I will attempt to clarify better.
Mar-08-2021 07:57:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (pfe.gayedj)	Query 2: Reissued:Opened	Clin: Please update SAE report with this clarification, Thank you
Mar-05-2021 21:01:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued:Opened	Clinical- Please submit the hospital dates reported here in a SAE safety update
Mar-05-2021 14:27:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Query 1: Answered	He was discharged on 18 Nov 2020. 3 days in hospital 15-18 Nov 2020
Mar-05-2021 14:13:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Query 2: Answered	The spinal surgery was same day, out patient.
Mar-04-2021 16:21:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (pfe.gayedj)	Query 2: Opened	Clin: Please clarify as per SAE report subject underwent spinal fusion surgery on 13 Nov, then on 15 Nov was diagnosed with MI

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				and hospitalised. Was he d/c from hospital after surgery and then re-admitted with MI or did the MI prolong the hospitalisation?
Mar-03-2021 12:23:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 1: Opened	Medical Monitor_Pls advise discharge date from hospital. Thanks
Feb-04-2021 15:18:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Nov/15/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-11-2021 13:05:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Mar-11-2021 12:03:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Mar-11-2021 12:03:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO End Date Time: Nov/18/2020 UNK:UNK	New Information
Mar-10-2021 21:53:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	Clinical End date is NONE; however, SAE report had end date of 18Nov20. Please review, harmonize reporting and update where applicable
Mar-04-2021 17:26:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Mar-02-2021 07:49:02	ACV0PFEINFP6000	James Fry	Query 1: Answered	Not available at this

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811090

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1081) Sterling Research Group - Mt. Auburn

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Generated Time (GMT): 29-Mar-2021 10:11

(UTC-05:00) Eastern Time (US & Canada)		(pfe.jfry)		time
Mar-01-2021 11:41:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical - please review for MI end date; if available, please submit to SAE as well
Feb-04-2021 15:18:50 (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
Feb-04-2021 15:18:50 (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
Feb-08-2021 11:07:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-04-2021 15:18:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Myocardial Infarction: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-04-2021 15:18:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect?	Initial Entry

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1081**Subject No:** 10811090**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:11

			NO	
			Did this serious event result in death?	
			NO	
			Did this serious event require or prolong hospitalization?	
			YES	
			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.*

Date	Location	User	Value	Reason
Feb-04-2021 15:18:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-01-2021 11:18:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Feb-23-2021 14:00:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Query 1: Answered	correct as reported.

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Feb-05-2021 13:26:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical Other cause for event of MI is HTN; SAE report also specifies that symptoms for this event started post-op on 13Nov20 following spinal fusion surgery. Please review for addition Other cause, and update as appropriate
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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-04-2021 15:18:50 (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	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-04-2021 15:18:50 (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
Feb-04-2021 15:18:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-05-2021 20:56:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Mar-02-2021 07:49:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Query 2: Answered	Not available at this time
Mar-01-2021 11:26:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	Clinical - please submit a SAE (#2021116993) followup with this

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				information re stent placement (at least 1); also results of catheterization
Mar-01-2021 11:19:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Feb-23-2021 13:38:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Query 1: Answered	Patient had at least one stent placed.
Feb-05-2021 13:25:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical Non-drug treatment is YES; please specify what non-drug treatment was received for SAE of MI
Feb-04-2021 15:18:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Mar-11-2021 12:05:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-11-2021 12:05:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: RECOVERED/RESOLVED	New Information
Mar-11-2021 12:03:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Myocardial Infarction: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Feb-04-2021 15:18:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: RECOVERING/RESOLVING	Initial Entry

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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Feb-04-2021 15:18:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Feb-08-2021 11:07:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pamela Benne prod (pfe.bennep07)	<u>Data Entry:</u> 2021116993	Initial Entry

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Generated By: pfe.levisse

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1. Category:

Date	Location	User	Value	Reason
Feb-23-2021 13:45:56 (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
Feb-23-2021 13:45:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-01-2021 19:09:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sian Jones (pfe.jones111)	Query 1: Closed	Response satisfies query
Mar-01-2021 17:08:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Query 1: Answered	No prior history revealed by patient.
Feb-25-2021 09:37:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sian Jones (pfe.jones111)	Query 1: Opened	clinical: please confirm subject with no prior history of depression or suicide attempt. Thanks
Feb-23-2021 13:45:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Suicide attempt	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-23-2021 13:45:56 (UTC-05:00) Eastern	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Jan/15/2021 UNK:UNK	Initial Entry

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Form Status: Data Complete, Frozen

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Time (US & Canada)

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-04-2021 17:24:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Mar-01-2021 17:09:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Query 1: Answered	SAE FU has been submitted.
Mar-01-2021 11:48:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical Event end date is 18Jan21; however, SAE report (#2021156090) does not report a stop date. Please review, harmonize reporting, and update where appropriate
Feb-23-2021 13:46:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO End Date Time: Jan/18/2021 UNK:UNK	Transcription Error
Feb-23-2021 13:45:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-23-2021 13:45:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: 3	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).

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Date	Location	User	Value	Reason
Feb-24-2021 00:31:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-23-2021 13:47:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Suicide attempt: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-23-2021 13:47:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/in capacity? NO Is this serious event life threatening? NO Other medically important serious event NO	Initial Entry

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Subject No: 10811090

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Subject Initials: ---

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8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Feb-23-2021 13:45:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-23-2021 13:45:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NOT RELATED If Not Related to study treatment(s) , this event is due to: OTHER <i>If Other, specify:</i> Anxiety and depression follo wing cardiac event	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-23-2021 13:45:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-23-2021 13:45:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-23-2021 13:45:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES	Initial Entry

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Form Status: Data Complete, Frozen

Site Name: (1081) Sterling Research Group - Mt. Auburn

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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Mar-03-2021 08:50:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	Response satisfies query
Mar-02-2021 03:08:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Reissued:Cand idate	Pending SDB update
Mar-01-2021 17:08:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Query 1: Answered	SAE FU has been submitted.
Feb-26-2021 00:17:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON:AER#2021156090,outcome was reported as Recovering/Resolving to Safety DB however, recorded as RECOVERED/RESOLVED on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Feb-23-2021 13:45:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: RECOVERED/RESOL VED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Feb-23-2021 13:45:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Feb-24-2021 00:31:56 (UTC-05:00) Eastern	ACV0PFEINFP6000	Ricell Ann Piojo	Data Entry: 2021156090	Initial Entry

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(pfe.quisitor)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

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Subject Initials: ---

Generated By: pfe.levissc

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-04-2021 16:54:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Feb/4/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1081

Subject No: 10811090

Generated By: pfe.levissc

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History

Form Status: Data Complete, Frozen

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

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1. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Feb-04-2021 16:54:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at V accination 1/2	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811090

Generated By: pfe.lewissc

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-24-2021 00:38:01 (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_DS001_36
Feb-23-2021 13:26:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: An swere d	Transcription Error
Feb-23-2021 13:26:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry : Feb/4/ 2021	Transcription Error
Feb-22-2021 21:30:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Op ened	DMW7351020;Date Treatment Unblinded should be equal to or after DOV in REVAX CONTACT visit when Reason is ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION.Please review and update as appropriate.
Feb-04-2021 17:00:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry : Feb/2/ 2021	Transcription Error
Feb-04-2021 16:53:59	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry	Initial Entry

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Form: TREATMENT UNBLINDED - eCRF Audit Trail History

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(UTC-05:00)
Eastern Time
(US &
Canada)

Feb/4/
2021

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-04-2021 16:53:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

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Site No: 1081

Subject No: 10811090

Generated By: pfe.lewissc

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

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1. Subject Status

Date	Location	User	Value	Reason
Oct-13-2020 14:25:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-24-2020 15:46:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-24-2020 15:40:41 (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
Feb-24-2021 00:33:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	Response satisfies query
Feb-23-2021 14:01:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Query 1: Answered	FU report will be submitted.
Feb-18-2021 02:12:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON:AER#2021156090 Failed Suicide attempt(onset date:15Nov2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form
Oct-13-2020 14:25:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/13/2020	Initial Entry
Aug-24-2020 15:46:18 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/24/2020	Initial Entry

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Generated By: pfe.levisse

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

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Time (US & Canada)				
Aug-24-2020 15:40:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/24/2020	Initial Entry

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811090

Generated By: pfe.lewissc

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Casebook Signature

Date	Location	User	Value	Reason
Oct-23-2020 14:20:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Click Here to Enable	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811102

Subject Initials: ---

Generated By: pfe.levisse

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: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811102

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/25/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811102

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10811102]
2.	Birth Date:	(b) (6)/1961
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811102

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	Aug/25/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1081

Subject No: 10811102

Generated By: pfe.levisse

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: 10811102

Generated By: pfe.levisse

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	Aug/25/2020
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:** 10811102**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:	[ALLERGY TO LOBSTER]	
	Start Date:	UNK/UNK/2008	
	Ongoing:	YES	
1.b	Line/MH Number:	[2]	
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Allergy metaxalone - hives]	
	Start Date:	UNK/UNK/2001	
	Ongoing:	YES	
1.c	Line/MH Number:	[3]	
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[osteoarthritis generalized]	
	Start Date:	UNK/UNK/2000	
	Ongoing:	YES	
1.d	Line/MH Number:	[]	Comments
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[]	Comments
	Start Date:	//	Comments
	Ongoing:		Comments

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811102

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

1e	Line/MH Number:	[]	Comments
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[]	Comments
	Start Date:	//	Comments
	Ongoing:		Comments
1f	Line/MH Number:	[6]	
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Diarrhea]	
	Start Date:	UNK/UNK/2008	
	Ongoing:	YES	

090177e196ae3f04\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: 10811102

Generated By: pfe.levisse

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:	Aug/25/2020
2.	Weight:	[199.0]
3.	Unit:	LB
4.	Height:	[75.0]
5.	Unit:	in
6.	Body Mass Index:	[24.9]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.8]
	Unit:	F
	Temperature Location:	FOREHEAD

090177e196ae3f04\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: 10811102

Generated By: pfe.levisse

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 :	Aug/25/2020
2.	Randomization Number:	[240120]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811102

Generated By: pfe.levisse

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: Aug/25/2020
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	[BP97YS]
5.b	Sample ID	[BP97YR]
5.c	Sample ID	[BP97YP]
5.d	Sample ID	[BPHZLG]
5.e	Sample ID	[BPHZLH]

090177e196ae3f04\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: 10811102

Generated By: pfe.levisse

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: Aug/25/2020
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	[BP97JL]
-----	-----------	----------

090177e196ae3f04\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: 10811102

Generated By: pfe.levisse

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:	Aug/25/2020 16:03
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

090177e196ae3f04\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: 10811102

Generated By: pfe.levisse

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
----	---	--

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811102

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/15/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1081

Subject No: 10811102

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/15/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.9]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811102

Generated By: pfe.levisse

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/15/2020
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	[BP97S3]
-----	-----------	----------

090177e196ae3f04\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: 10811102

Generated By: pfe.levisse

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/15/2020 12:13
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

090177e196ae3f04\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: 10811102

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/20/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811102

Generated By: pfe.levisse

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: Oct/20/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP1HXY]
5.b	Sample ID	[BP1HXZ]
5.c	Sample ID	[BS64JX]
5.d	Sample ID	[BS64JY]

090177e196ae3f04\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: 10811102

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: 10811102

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	[]
----	-----------	-----

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811102

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: 10811102

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	[]
----	-----------	-----

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811102

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: 10811102

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	[]
----	-----------	-----

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811102

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_ILL - New Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811102

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Signs and Symptoms

1.	Date of Assessment:	//
2.	Date of First Symptom Started:	//
3.	Symptoms Ongoing?	

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

5.	Symptoms - Other Text:	[]
----	------------------------	-----

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF 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: 10811102

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	[]
----	-----------	-----

090177e196ae3f04\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811102

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: POT_COVID_ILL - New Unscheduled Visit **Form:** HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811102

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Health Care Utilization

1.	Physician or Healthcare Professional:	
	Occurrence of Visits or Contacts:	

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[]
----	-------------------------------------	-----

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	
----	--	--

090177e196ae3f04\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811102

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Illness Details

1.	Category of Clinical Event:	
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	
3.	Toxicity Grade:	

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811102

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 Visit

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: 10811102

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: 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: 10811102

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: 10811102

Subject Initials: ---

Generated By: pfe.levisse

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: 10811102

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/20/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811102

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Disposition - Follow-Up

1.	Date of Completion/Discontinuation /Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[]

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New **Form:** DATE OF VISIT - REPEAT SWAB
Unscheduled Visit

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811102

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 Repeat Swab

3.	COVID-19 Repeat Swab:	
----	-----------------------	--

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB
Unscheduled Visit

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811102

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: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811102

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Adverse Event Report

1.	Category:	
2.	AE ID:	[]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[]
4.	Start Date Time:	//
5.	Is the adverse event still ongoing?	
6.	Toxicity Grade:	
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).	
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.	
9.	Is this event related to study treatment:	
10.	Latest Action Taken with Study Treatment:	
11.	Was a Concomitant Medication given?	

090177e196ae3f04\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: 10811102

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

12.	Was a Non-Drug Treatment given?	
13.	What was the outcome of this adverse event?:	
14.	Did the adverse event cause the subject to be discontinued from the study?	
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811102

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

090177e196ae3f04\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1081

Subject No: 10811102

Generated By: pfe.levisse

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

[Back to Form](#)

Medication Error

1.	Category:	
2.	Medication Error (Type of Medication Error):	[]
3.	Start Date:	//
4.	Is the medication error still ongoing?	
5.	Latest Action Taken with Study Treatment:	
6.	Was a Concomitant Medication given?	
7.	Was a Non-Drug Treatment given?	
8.	Did the Medication Error cause the subject to be discontinued from the study?	
9.	Was this medication error associated with any adverse events?	
10.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae3f04\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: 10811102

Subject Initials: ---

Generated By: pfe.levisse

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

090177e196ae3f04\Final\Final On: 01-Apr-2021 05:06 (GMT)

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: 10811102

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Concomitant Medications

1.	What is the medication identifier?	[]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[]
5.	Date:	//

090177e196ae3f04\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: 10811102

Subject Initials: ---

Generated By: pfe.levisse

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

090177e196ae3f04\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811102

Generated By: pfe.levisse

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

[Back to Form](#)

Concomitant Medications

1.	What is the medication identifier?	[]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[]
5.	Dose:	[]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
10.	Ongoing?	

090177e196ae3f04\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: 10811102

Subject Initials: ---

Generated By: pfe.levisse

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

090177e196ae3f04\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: 10811102

Generated By: pfe.levisse

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

[Back to Form](#)

Radiation Treatment

1.	Category:	
2.	What is the treatment Identifier?	[]
3.	Concomitant Non-drug Treatment Pre-specified:	
4.	Treatment:	[]
5.	Start Date:	//
6.	Ongoing?	

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811102

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

090177e196ae3f04\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811102

Generated By: pfe.levisse

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

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: 10811102

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: 10811102

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: 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: 10811102

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?	

090177e196ae3f04\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: 10811102

Subject Initials: ---

Generated By: pfe.levisse

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: 10811102

Subject Initials: ---

Generated By: pfe.levisse

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: 10811102

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 Version: 14-Jan-2021 02:29

Site No: 1081

Subject No: 10811102

Generated By: pfe.levisse

Form: INFORMED CONSENT - ASYMPTOMATIC
SURVEILLANCE

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Informed Consent - Asymptomatic Surveillance

1.	Consent Was:	
----	--------------	--

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811102

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: 10811102

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	[]
----	-----------	-----

090177e196ae3f04\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811102

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	Feb/3/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811102

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2
----	---	--

090177e196ae3f04\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811102

Generated By: pfe.levisse

Form: TREATMENT UNBLINDED

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](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Feb/3/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811102

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	//
----	------------------------------	----

090177e196ae3f04\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811102

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Death Details

1.	Date of Collection / Notification of Death:	//
----	---	----

Cause of Death

2.	Cause of Death Status:	
	Cause of Death:	[]

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811102

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	FOLLOW-UP
2.	Subject Status Date	Oct/20/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811102

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, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811102

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
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
------	-------------------	------	------	--------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1081

Subject No: 10811102

Generated By: pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-25-2020 15:35:23 (UTC-05:00) Eastern Time (US & Canada)	Tawnyn Ebner (pfe.tebner)	All inclusion and exclusion met Not Done

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811102

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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

[Back to Form](#)

Item	Date	User	Comment
1.d	Aug-27-2020 17:35:19 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	The CRF guidelines do not correctly reflect how to delete a line.

090177e196ae3f04\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: 10811102

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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

[Back to Form](#)

Item	Date	User	Comment
1.d	Aug-27-2020 17:35:19 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	The CRF guidelines do not correctly reflect how to delete a line.

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811102

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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

[Back to Form](#)

Item	Date	User	Comment
1.d	Aug-27-2020 17:35:19 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	The CRF guidelines do not correctly reflect how to delete a line.

090177e196ae3f04\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: 10811102

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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

[Back to Form](#)

Item	Date	User	Comment
1.d	Aug-27-2020 17:35:19 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	The CRF guidelines do not correctly reflect how to delete a line.

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811102

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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

[Back to Form](#)

Item	Date	User	Comment
1.e	Aug-27-2020 17:35:53 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	The CRF guidelines do not reflect how to correctly delete a line.

090177e196ae3f04\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: 10811102

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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
1.e	Aug-27-2020 17:35:53 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	The CRF guidelines do not reflect how to correctly delete a line.

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811102

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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
1.e	Aug-27-2020 17:35:53 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	The CRF guidelines do not reflect how to correctly delete a line.

090177e196ae3f04\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: 10811102

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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
1.e	Aug-27-2020 17:35:53 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	The CRF guidelines do not reflect how to correctly delete a line.

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811102

Subject Initials: ---

Generated By: pfe.levisse

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This form requires signing by a member of each of the following signature groups:

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
Lora Morris	N/A	Feb-04-2021 07:36:58 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

James Fry	Approved	Oct-23-2020 14:27:32 (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.

090177e196ae3f04\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811102

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-25-2020 15:19:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: 24 JUL 2020	Initial Entry

2. Select appropriate response - What cohort does the subject belong to?

Date	Location	User	Value	Reason
Aug-25-2020 15:19:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	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: 10811102

Generated By: pfe.levisse

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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1. Consent Was:

Date	Location	User	Value	Reason
Aug-25-2020 15:19:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> OBTAINED Date Written Consent Obtained Aug/25/2020	Initial Entry

090177e196ae3f04\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1081

Subject No: 10811102

Generated By: pfe.levisse

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
Aug-25-2020 15:19:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10811102	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-25-2020 15:19:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1961	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-25-2020 15:19:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-25-2020 15:19:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Aug-25-2020 15:19:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: WHITE	Initial Entry

090177e196ae3f04\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: 10811102

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: ---

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1. Date of Visit

Date	Location	User	Value	Reason
Aug-25-2020 15:35:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawyn Ebner (pfe.tebner)	Data Entry: Aug/25/2020	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811102

Generated By: pfe.levisse

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-25-2020 15:37:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Aug/25/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-25-2020 15:37:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-25-2020 15:37:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: COMPLETED	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811102

Generated By: pfe.levisse

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: ---

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I.a

Date	Location	User	Value	Reason
Aug-31-2020 08:23:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Line/MH Nu 1 mber: Medical Histo ALLERGY TO ry Term: LOBSTER Start Date: UNK/UNK/200 8 Ongoing: YES	Changed Information
Aug-27-2020 17:26:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Line/MH Nu 1 mber: Medical Histo Allergy to Lobs ry Term: ter- nausea Start Date: UNK/UNK/200 8 Ongoing: YES	New Information
Aug-26-2020 08:36:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Line/MH Numb 1 er: Medical History Allergy to L Term: obster Start Date: UNK/UNK/2 008 Ongoing: YES	Changed Information
Aug-25-2020 16:52:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 1 umber: Medical Hi Allergy to Lobster story Term - nausea and diarrh : ea Start Date: UNK/UNK/2008 Ongoing: YES	Initial Entry

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Header Text: c4591001

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1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 16:52:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

1.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-31-2020 09:50:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 2: Closed	Discrepancy has been closed.
Aug-31-2020 08:23:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Aug-31-2020 08:23:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: ALLERGY TO L OBSTER	Changed Information
Aug-31-2020 08:18:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jeffrey Signora TMSQUERY (pfe.signoj01_tmsquery)	Query 2: Reissued: Opened	Please click on the term and update.
Aug-28-2020 12:52:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Query 2: Answered	Ability to update information not available. Only

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Header Text: c4591001

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Form Status: Data Complete, Locked, Frozen, Verified

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Canada)				"answer" option available
Aug-28-2020 06:58:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 2: Opened	Multiple concepts in the term ALLERGY TO LOBSTER-NAUSEA. Split the term into ALLERGY TO LOBSTER and NAUSEA and submit separately. Thank you.
Aug-27-2020 17:26:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Allergy to Lobster- nausea	New Information
Aug-26-2020 13:04:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Closed	Discrepancy has been closed.
Aug-26-2020 08:36:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Allergy to L obster	Changed Information
Aug-26-2020 08:35:52 (UTC-05:00)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Query 1: Answered	Changed data per query

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811102

Generated By: pfe.levisse

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

Eastern Time (US & Canada)				
Aug-26-2020 02:58:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Opened	Multiple concepts in the term ALLERGY TO LOBSTER - NAUSEA AND DIARRHEA. Split the term into ALLERGY TO LOBSTER and NAUSEA and DIARRHEA and submit separately as three separate entries. Thank you.
Aug-25-2020 16:52:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Allergy to Lobster - nausea and diarrhea	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 16:52:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: UNK/UNK/2008	Initial Entry

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Header Text: c4591001

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Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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1.a Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 16:52:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Aug-25-2020 16:59:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Line/MH Nu 2 mber: Medical Histo Allergy metaxal ry Term: one - hives Start Date: UNK/UNK/200 1 Ongoing: YES	Initial Entry
Aug-25-2020 16:54:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 2 mber: Medical Histo Allergy metaxal ry Term: one - hives Start Date: Ongoing: YES	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Subject No: 10811102

Generated By: pfe.levisse

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Form Status: Data Complete, Locked, Frozen, Verified

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Subject Initials: ---

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1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 16:54:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-25-2020 16:54:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Allergy metaxalone - hives	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 16:59:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: UNK/UNK/2001	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 16:54:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Aug-25-2020 17:06:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 3 ber: Medical Histo osteoarthritis ge ry Term: neralized Start Date: UNK/UNK/200 0 Ongoing: YES	Initial Entry

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Generated By: pfe.levisse

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1.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 17:06:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

1.c Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-25-2020 17:06:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: osteoarthritis generalized	Initial Entry

1.c Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 17:06:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: UNK/UNK/2000	Initial Entry

1.c Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 17:06:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES	Initial Entry

1.d

Date	Location	User	Value	Reason
Aug-27-2020 17:43:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: Line/MH Number: Medical History Term: Start Date: Ongoing:	Transcription Error (DELETED)
Aug-27-2020 17:29:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Line/MH Number: Medical History Term:	Changed Information

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Header Text: c4591001

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Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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			Start Date: Ongoing:	
Aug-27-2020 17:28:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History Term: Start Date: UNK/UNK /2008 Ongoing: YES	This is his reaction to eating lobster. Med Hx updated to reflect this better.
Aug-26-2020 13:42:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Line/MH Number: 4 Medical History Term: Nausea Start Date: UNK/UNK /2008 Ongoing: YES	Changed Information
Aug-26-2020 08:37:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: Nausea and Diarrhea Start Date: UNK/UNK/2 008 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

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1.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-27-2020 17:43:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry:	Transcription Error (DELETED)
Aug-27-2020 17:28:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	This is his reaction to eating lobster. Med Hx updated to reflect this better.
Aug-26-2020 08:37:19 (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
Aug-27-2020 17:56:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 2: Closed	Response satisfies query
Aug-27-2020 17:43:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry:	Transcription Error (DELETED)
Aug-27-2020 17:28:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	This is his reaction to eating lobster. Med Hx updated to reflect this better.
Aug-27-2020 17:28:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry:	This is his reaction to eating lobster. Med Hx updated to reflect this

090177e196ae3f04\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:** 10811102**Generated By:** pfe.levisse**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

				better.
Aug-27-2020 13:27:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 2: Opened	GPD Clin: Per IC3 and Criteria for Temporary Delay of Enrolment (Protocol 5.5), please confirm stability of symptoms within 6 weeks of enrolment and no acute event within 48h before study intervention administration
Aug-26-2020 19:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Closed	Discrepancy has been closed.
Aug-26-2020 13:42:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Aug-26-2020 13:42:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry : Nausea	Changed Information
Aug-26-2020 13:10:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Opened	Multiple concepts in the term NAUSEA AND DIARRHEA . Split the term into NAUSEA

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Subject No: 10811102

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				and DIARRHEA and submit separately. Thank you.
Aug-26-2020 08:37:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry : Nausea and Diarrhea	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Aug-27-2020 17:43:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry:	Transcription Error (DELETED)
Aug-27-2020 17:29:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry:	Changed Information

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1.d Start Date:

Date	Location	User	Value	Reason
Aug-26-2020 08:37:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> UNK/UNK/2008	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Aug-27-2020 17:43:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	<u>Data Entry:</u>	Transcription Error (DELETED)
Aug-27-2020 17:29:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u>	Changed Information
Aug-26-2020 08:37:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> YES	Initial Entry

1.e

Date	Location	User	Value	Reason
Aug-27-2020 17:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	<u>Data Entry:</u> Line/MH Number: Medical History Term: Start Date: Ongoing:	Transcription Error (DELETED)
Aug-27-2020 17:30:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> Line/MH Number: Medical History Term: Start Date: Ongoing:	Changed Information
Aug-27-2020 17:30:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> Line/MH Number: Medical History Term:	Changed Information

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Header Text: c4591001

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			Start Date: Ongoing: YES	
Aug-27-2020 17:28:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History Term: Start Date: UNK/UNK /2008 Ongoing: YES	This is his reaction to eating lobster. Med Hx updated to reflect this better.
Aug-26-2020 13:42:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Term: Diarrhea Start Date: UNK/UNK /2008 Ongoing: YES	Initial Entry

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I.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-27-2020 17:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry:	Transcription Error (DELETED)
Aug-27-2020 17:28:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	This is his reaction to eating lobster. Med Hx updated to reflect this better.
Aug-26-2020 13:42:42 (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
Aug-27-2020 17:56:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Closed	Response satisfies query
Aug-27-2020 17:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry:	Transcription Error (DELETED)
Aug-27-2020 17:28:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	This is his reaction to eating lobster. Med Hx updated to reflect this better.
Aug-27-2020 17:28:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry:	This is his reaction to eating lobster. Med Hx updated to reflect this better.
Aug-27-2020 13:01:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	GPD Clin: Per IC3 and Criteria for Temporary Delay of Enrolment (Protocol 5.5), please confirm stability of symptoms within 6

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				weeks of enrolment and no acute event within 48h before study intervention administration
Aug-26-2020 13:42:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Diarrhea	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Aug-27-2020 17:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry:	Transcription Error (DELETED)
Aug-27-2020 17:30:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry:	Changed Information
Aug-26-2020 13:42:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2008	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Aug-27-2020 17:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry:	Transcription Error (DELETED)
Aug-27-2020 17:30:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry:	Changed Information
Aug-26-2020 13:42:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
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Sep-02-2020 14:39:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Line/MH Number: 6 Medical History Term: Diarrhea Start Date: UNK/UNK/ 2008 Ongoing: YES	Not clinically significant. Deleted entry (DELETED)
Sep-01-2020 07:59:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Line/MH Number: 6 Medical History Term: Diarrhea Start Date: UNK/UNK/ 2008 Ongoing: YES	Transcription Error
Aug-31-2020 13:32:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Line/MH Number: 6 Medical History Term: Diarrhea due to allergy to lobster Start Date: UNK/UNK/2008 Ongoing: YES	Changed Information
Aug-31-2020 08:24:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Line/MH Number: 6 Medical History Term: Diarrhea due to allergy Start Date: UNK/UNK/20 08 Ongoing: YES	Changed Information
Aug-31-2020 08:23:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Line/MH Number: 6 Medical History Term: Diarrhea	Changed Information

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			Start Date: UNK/UNK/ 2008 Ongoing: YES	
Aug-27-2020 17:27:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 6 Medical History Term: Allergy to lobster - diarrhea Start Date: UNK/UNK/2008 Ongoing: YES	Initial Entry

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1.f Line/MH Number:

Date	Location	User	Value	Reason
Sep-02-2020 14:39:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> 6	Not clinically significant. Deleted entry (DELETED)
Aug-27-2020 17:27:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 6	Initial Entry

1.f Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-03-2020 07:42:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 4: Closed	Response satisfies query
Sep-02-2020 14:39:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	<u>Data Entry:</u> Diarrhea	Not clinically significant. Deleted entry (DELETED)
Sep-02-2020 14:39:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	Not clinically significant. Deleted entry
Sep-02-2020 10:16:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 4: Opened	CLINQUERY: (prior split term query). Data reports ongoing diarrhea at time of entry to study. Please review if this entry is

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				applicable; if to remain, please clarify stability of condition prior to enrolment per IC3 and stopping criteria
Sep-01-2020 10:45:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 3: Closed	Discrepancy has been closed.
Sep-01-2020 07:59:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Transcription Error
Sep-01-2020 07:59:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawyn Ebner (pfe.tebner)	<u>Data Entry</u> : Diarrhea	Transcription Error
Aug-31-2020 17:05:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 3: Opened	Multiple concepts in the term DIARRHEA DUE TO ALLERGY TO LOBSTER. Split the term into DIARRHEA and ALLERGY TO

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				LOBSTER and report as separate entries. Thank you.
Aug-31-2020 15:02:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 2: Closed	Discrepancy has been closed.
Aug-31-2020 13:32:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Aug-31-2020 13:32:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry : Diarrhea due to allergy to lobster	Changed Information
Aug-31-2020 12:08:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 2: Opened	Multiple concepts in the term DIARRHEA DUE TO ALLERGY. Split the term into DIARRHEA and ALLERGY and report as 2 separate entries. Thank you.

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Aug-31-2020 09:51:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Clo sed	Discrepancy has been closed.
Aug-31-2020 08:24:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry : Diarr hea d ue to allerg y	Changed Information
Aug-31-2020 08:23:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: An swere d	Changed Information
Aug-31-2020 08:23:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry : Diarr hea	Changed Information
Aug-31-2020 08:19:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jeffrey Signora TMSQUERY (pfe.signoj01_tmsquery)	Query 1: Rei ssued: Open ed	Please click on the term and update.
Aug-28-2020 12:51:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Query 1: An swere d	Ability to update information not available

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1.f Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-28-2020 06:58:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Opened	Multiple concepts in the term ALLERGY TO LOBSTER - DIARRHEA. Split the term into ALLERGY TO LOBSTER and DIARRHEA and submit separately. Thank you.
Aug-27-2020 17:27:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry : Allergy to lobster - diarrhea	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Sep-02-2020 14:39:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2008	Not clinically significant. Deleted entry (DELETED)
Aug-27-2020 17:27:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: UNK/UNK/2008	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Sep-02-2020 14:39:31 (UTC-05:00) Eastern	ACV0PFEINFP6000	Phillip Ross	Data Entry: YES	Not clinically significant. Deleted

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Time (US & Canada)		(pfe.pross)		entry (DELETED)
Aug-27-2020 17:27:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES	Initial Entry

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Header Text: c4591001

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Subject No: 10811102

Generated By: pfe.levisse

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Form Status: Data Complete, Locked, Frozen, Verified

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1. Date:

Date	Location	User	Value	Reason
Aug-25-2020 16:55:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Aug/25/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-25-2020 16:55:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: 199.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-25-2020 16:55:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-25-2020 16:55:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: 75.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-25-2020 16:55:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
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Aug-25-2020 16:55:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 24.9	Initial Entry
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7.a

Date	Location	User	Value	Reason
Aug-25-2020 16:55:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Record Identifier:: 1 Temperature: 97.8 Temperature Unit: F Temperature Locat ion:: FOREHE AD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-25-2020 16:55:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-25-2020 16:55:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: 97.8	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-25-2020 16:55:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-25-2020 16:55:00 (UTC-05:00) Eastern	ACV0PFEINFP6000	James Fry	Data Entry: FOREHEAD	Initial Entry

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(pfe.jfry)

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Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811102

Generated By: pfe.levisse

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
Aug-25-2020 16:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Aug/25/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-25-2020 16:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: 240120	Initial Entry

090177e196ae3f04\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:** 10811102**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-25-2020 15:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-25-2020 15:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-25-2020 15:38:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-25-2020 15:38:39 (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.
Aug-25-2020 15:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Aug/25/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-25-2020 15:38:53 (UTC-05:00) Eastern	ACV0PFEINFP6000	Tawnyn Ebner	Data Entry: Sample ID: BP97YS	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: 10811102
 Subject Initials: ---
 Generated By: pfe.levisse
 Generated Time (GMT): 29-Mar-2021 10:11

Time (US & Canada)		(pfe.tebner)	
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5.a Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 15:38:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: BP97YS	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-25-2020 15:39:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: Sample ID: BP97YR	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 15:39:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: BP97YR	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-25-2020 15:39:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: Sample ID: BP97YP	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 15:39:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: BP97YP	Initial Entry

5.d

Date	Location	User	Value	Reason
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090177e196ae3f04\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: 10811102
Subject Initials: ---
Generated By: pfe.levisse
Generated Time (GMT): 29-Mar-2021 10:11

Aug-25-2020 15:39:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawryn Ebner (pfe.tebner)	Data Entry: Sample ID: BPHZLG	Initial Entry
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5.d Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 15:39:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawryn Ebner (pfe.tebner)	Data Entry: BPHZLG	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-25-2020 15:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawryn Ebner (pfe.tebner)	Data Entry: Sample ID: BPHZLH	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 15:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawryn Ebner (pfe.tebner)	Data Entry: BPHZLH	Initial Entry

090177e196ae3f04\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:** 10811102**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-25-2020 15:37:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-25-2020 15:37:59 (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
Aug-25-2020 15:38:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-25-2020 15:37:59 (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.
Aug-25-2020 15:37:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Aug/25/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-25-2020 15:38:08 (UTC-05:00) Eastern	ACV0PFEINFP6000	Tawнын Ebner	Data Entry: Sample ID: BP97JL	Initial Entry

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: 10811102

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Time (US & Canada)

(pfe.tebner)

5.a Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 15:38:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawynn Ebner (pfe.tebner)	Data Entry: BP97JL	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811102

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
Aug-25-2020 17:00:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-25-2020 17:00:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-25-2020 17:00:01 (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
Aug-25-2020 17:04:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-25-2020 17:04:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Aug/25/2020 16:03	Transcription Error
Aug-25-2020 17:00:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Dose Date is before or more than 1 day after Date of Visit 25/Aug/2020 of the corresponding Visit. Please review and update as appropriate.

090177e196ae3f04\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: 10811102

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

Aug-25-2020 17:00:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Jul/25/2020 16:03	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-25-2020 17:00:01 (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
Aug-25-2020 17:00:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-25-2020 17:00:01 (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
Aug-25-2020 17:00:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Aug-25-2020 17:00:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES	Initial Entry

090177e196ae3f04\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: 10811102

Generated By: pfe.levisse

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
Aug-25-2020 16:59:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO - REACTOGENICITY E-DI ARY 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: 10811102

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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1. Date of Visit

Date	Location	User	Value	Reason
Sep-15-2020 12:01:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawyn Ebner (pfe.tebner)	Data Entry: Sep/15/2020	Initial Entry

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 21-Aug-2020 02:51**Site No:** 1081**Subject No:** 10811102**Generated By:** pfe.levisse**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[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Sep-15-2020 12:34:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sep/15/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-15-2020 12:34:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Record Identifier 1 :: Temperature: 97.9 Temperature Unit: Temperature Location: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-15-2020 12:34:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-15-2020 12:34:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: 97.9	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-15-2020 12:34:02 (UTC-05:00) Eastern	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: F	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1081

Subject No: 10811102

Generated By: pfe.levisse

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

Time (US & Canada)

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-15-2020 12:34:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: ORAL CAVITY	Initial Entry

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:** 10811102**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-15-2020 12:02:07 (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-15-2020 12:02:07 (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-15-2020 12:02:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-15-2020 12:02:07 (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-15-2020 12:02:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Sep/15/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-15-2020 12:02:18 (UTC-05:00) Eastern	ACV0PFEINFP6000	Tawнын Ebner	Data Entry: Sample ID: BP97S3	Initial Entry

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: 10811102

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Time (US & Canada)

(pfe.tebner)

5.a Sample ID

Date	Location	User	Value	Reason
Sep-15-2020 12:02:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawynn Ebner (pfe.tebner)	Data Entry: BP97S3	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811102

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-15-2020 12:33:33 (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-15-2020 12:33:33 (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-15-2020 12:33:33 (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-15-2020 12:33:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sep/15/2020 12:13	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-15-2020 12:33:33 (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
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090177e196ae3f04\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: 10811102

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

Sep-15-2020 12:33:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: LEFT	Initial Entry
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7. Route:

Date	Location	User	Value	Reason
Sep-15-2020 12:33:33 (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-15-2020 12:33:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-15-2020 12:33:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

090177e196ae3f04\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: 10811102

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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1. Date of Visit

Date	Location	User	Value	Reason
Oct-20-2020 13:14:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Oct/20/2020	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:** 10811102**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-20-2020 15:14:10 (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-20-2020 15:14:10 (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-20-2020 15:14:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-20-2020 15:14:10 (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-20-2020 15:14:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Oct/20/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-20-2020 15:14:17 (UTC-05:00) Eastern	ACV0PFEINFP6000	Tawнын Ebner	Data Entry: Sample ID: BP1HXY	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: 10811102

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Time (US & Canada)		(pfe.tebner)	
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5.a Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 15:14:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: BP1HXY	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-20-2020 15:14:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: Sample ID: BP1HXZ	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 15:14:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: BP1HXZ	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-20-2020 15:14:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: Sample ID: BS64JX	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 15:14:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: BS64JX	Initial Entry

5.d

Date	Location	User	Value	Reason
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090177e196ae3f04\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: 10811102

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Oct-20-2020 15:14:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawyn Ebner (pfe.tebner)	Data Entry: Sample ID: BS64JY	Initial Entry
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5.d Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 15:14:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawyn Ebner (pfe.tebner)	Data Entry: BS64JY	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811102

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-20-2020 13:15:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Oct/20/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-20-2020 13:15:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-20-2020 13:15:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: COMPLETED	Initial Entry

090177e196ae3f04\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811102

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Feb-04-2021 07:37:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Feb/3/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1081

Subject No: 10811102

Generated By: pfe.levisse

Form: FURTHER VACCINATION CONFIRMATION - 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

[Back to Form](#)

1. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Feb-04-2021 07:37:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Participant is willing to return f or Vaccination 3 Participant is: eligible and NOT confirmed to have received only placeb o at Vaccination 1/2	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811102

Generated By: pfe.levisse

Form: TREATMENT UNBLINDED - 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

[Back to Form](#)

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-04-2021 07:36:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Feb/3/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-04-2021 07:36:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: ASSESS ELIGIBILITY FOR A DDITIONAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811102

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Oct-20-2020 13:15:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-25-2020 16:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-25-2020 15:37:08 (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
Oct-20-2020 13:15:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/20/2020	Initial Entry
Aug-25-2020 16:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/25/2020	Initial Entry
Aug-25-2020 15:37:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/25/2020	Initial Entry

090177e196ae3f04\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811102

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Casebook Signature

Date	Location	User	Value	Reason
Oct-23-2020 14:27:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Click Here to Enable	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1081

Subject No: 10811110

Generated By: pfe.levissc

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: 10811110

Generated By: pfe.lewissc

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 Aug/26/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1081

Subject No: 10811110

Generated By: pfe.lewissc

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	[10811110]
2.	Birth Date:	(b) (6)/1939
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: 10811110

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	Aug/26/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1081

Subject No: 10811110

Generated By: pfe.lewissc

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: 10811110

Generated By: pfe.lewissc

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	Aug/26/2020
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: 10811110

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

eCRF Audit Trail History

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Osteoarthritis of bilateral hands]
	Start Date:	UNK/UNK/2013
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Skin Cancer-Right Leg]
	Start Date:	UNK/UNK/2014
	Ongoing:	NO End Date: Dec/UNK/2015
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Skin Cancer- Left Arm]
	Start Date:	UNK/UNK/2014
	Ongoing:	NO End Date: UNK/UNK/2014
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Chronic Urinary Tract Infections]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811110

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

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Gastroesophageal reflux disease]
	Start Date:	UNK/UNK/2014
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Migraine]
	Start Date:	UNK/UNK/1990
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Rosacea]
	Start Date:	UNK/UNK/2013
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Osteopenia-stable since 2016]
	Start Date:	UNK/UNK/1985
	Ongoing:	YES
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Raynaud's Disease- No associated autoimmune conditions]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811110

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

1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Sleep Apnea]
	Start Date:	Apr/UNK/2017
	Ongoing:	YES
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypothyroidism]
	Start Date:	Aug/UNK/2009
	Ongoing:	YES
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hysterectomy]
	Start Date:	UNK/UNK/1989
	Ongoing:	NO End Date: UNK/UNK/1989
1.m	Line/MH Number:	[13]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Seasonal Allergies]
	Start Date:	UNK/UNK/1957
	Ongoing:	YES

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1081

Subject No: 10811110

Generated By: pfe.lewissc

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:	Aug/26/2020
2.	Weight:	[144.4]
3.	Unit:	LB
4.	Height:	[67.5]
5.	Unit:	in
6.	Body Mass Index:	[22.3]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.8]
	Unit:	F
	Temperature Location:	FOREHEAD

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1081

Subject No: 10811110

Generated By: pfe.lewissc

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:	Aug/26/2020
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

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811110

Generated By: pfe.lewissc

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 :	Aug/26/2020
2.	Randomization Number:	[241313]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811110

Generated By: pfe.lewissc

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: Aug/26/2020
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	[BP97ZD]
5.b	Sample ID	[BP97ZF]
5.c	Sample ID	[BP97ZG]
5.d	Sample ID	[BPHZLY]
5.e	Sample ID	[BPHZLZ]

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811110

Generated By: pfe.lewissc

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: Aug/26/2020
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	[BP97JV]
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090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811110

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:	Aug/26/2020 12:34
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

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1081

Subject No: 10811110

Generated By: pfe.lewissc

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
----	---	--

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811110

Generated By: pfe.levissc

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/16/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1081

Subject No: 10811110

Generated By: pfe.lewissc

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/16/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.5]
	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: 10811110

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/16/2020
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

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811110

Generated By: pfe.lewissc

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/16/2020
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	[BP97SL]
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090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811110

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/16/2020 10:13
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

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811110

Generated By: pfe.levissc

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/14/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811110

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: Oct/14/2020
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	[BP1HWJ]
5.b	Sample ID	[BRTXXP]
5.c	Sample ID	[BRTXXR]

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811110

Generated By: pfe.lewissc

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: 10811110

Generated By: pfe.lewissc

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	[]
----	-----------	-----

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811110

Generated By: pfe.levissc

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: 10811110

Generated By: pfe.lewissc

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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090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811110

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: 10811110

Generated By: pfe.lewissc

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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090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET
on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Sep/28/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Sep/28/2020

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Sep/28/2020
2.	Date of First Symptom Started:	Sep/26/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Oct/2/2020

Symptoms

4.a	Symptoms:	FEVER
	Was symptom present?	NO
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	NO
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	NO
4.d	Symptoms:	CHILLS
	Was symptom present?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	NO
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

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
on Sep/28/2020

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811110

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

Symptoms - Other

5.	Symptoms - Other Text:	[]
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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: 10811110

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 **Form:** MICROBIOLOGY SPECIMEN
on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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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

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

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: Sep/28/2020
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	[CV22460]
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090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

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:	[Telehealth Visit]	Comments

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION
on Sep/28/2020**Form Version:** 15-Sep-2020 21:53**Form Status:** Data Complete, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811110**Subject Initials:** ---**Generated By:** pfe.lewissc**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:	YES Number of Visits or Contacts: [1]
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	NO
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	NO
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
----	--	----

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: 10811110

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 **Form:** RESPIRATORY TREATMENT
on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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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

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS
on Sep/28/2020

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: 10811110

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:	1

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: 10811110

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

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE
on Sep/28/2020

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: 10811110

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: 10811110

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	

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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[Form Comments](#)
[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

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levissc

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

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levissc

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 _____	Comments	
	Low [] High [] Unit		

5.e	Sponsor ID:	Not Applicable _____	Comments
		[]	
	Test:	Bilirubin_PX21	
	Result:	Not Applicable _____	Comments
		[]	
Not Done:	Not Applicable _____	Comments	
LNMT	Not Applicable _____	Comments	
	Low [] High [] Unit		

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levissc

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 _____	Comments	
	Low [] High [] Unit		

5.g	Sponsor ID:	Not Applicable _____	Comments
		[]	
	Test:	Creatinine_PX48	
	Result:	Not Applicable _____	Comments
		[]	
Not Done:	Not Applicable _____	Comments	
LNMT	Not Applicable _____	Comments	
	Low [] High [] Unit		

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (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: 10811110

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	

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING Hematology on Sep/28/2020

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: 10811110

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

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levissc

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

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levissc

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 _____	Comments	
	Low [] High [] Unit		

5.e	Sponsor ID:	Not Applicable _____	Comments
		[]	
	Test:	Leukocytes_PX7	
	Result:	Not Applicable _____	Comments
		[]	
Not Done:	Not Applicable _____	Comments	
LNMT	Not Applicable _____	Comments	
	Low [] High [] Unit		

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levissc

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

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levissc

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

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levissc

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

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (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: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

#	Date:	Vital Signs Details			Form Instance
1.	Not Done	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		Not Done	Not Done	Not Done	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Vital Signs

1.	Date:	Not Done _____ //	Comments
----	-------	-------------------------	--------------------------

Vital Signs Details

2.a	Record Identifier:	Not Done _____ 1	
	Systolic:	Not Done _____ []	Comments
	Diastolic:	Not Done _____ []	Comments
	Respiratory Rate in respirations/minute:	Not Done _____ []	Comments
	Heart Rate in beats/minute:	Not Done _____ []	Comments

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (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: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

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 **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Sep/28/2020

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: 10811110

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	
	SPO2 Pulse Oximetry %	Not Applicable _____ []	Comments

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

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: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

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

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS
on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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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: 10811110

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

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
on Sep/28/2020

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: 10811110

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?	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

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (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: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

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 **Form:** IMAGING
on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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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

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET
on Oct/19/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/19/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_B
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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Oct/19/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Oct/19/2020
2.	Date of First Symptom Started:	Oct/11/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Nov/2/2020

Symptoms

4.a	Symptoms:	FEVER
	Was symptom present?	YES
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	NO
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	NO
4.d	Symptoms:	CHILLS
	Was symptom present?	YES
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	YES
4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	NO
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	NO

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Oct/19/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Symptoms - Other

5.a	Symptoms - Other Text:	[Fatigue]
5.b	Symptoms - Other Text:	[Right lower rib chest pain]
5.c	Symptoms - Other Text:	[RLL pneumonia with pleural effusion]

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

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.	Oct/16/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN
on Oct/19/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Microbiology Specimen

1.	Actual Date of Collection:	Oct/16/2020
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	OTHER
7.	Test Result:	NEGATIVE
8.	Comments/Findings/Details:	[]
9.	Trade Name Other, Specify:	[NALT Unknown]

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Oct/19/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

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Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Oct/19/2020
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	[CV22425]
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090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
on Oct/19/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

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?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[telehealth visit]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION
on Oct/19/2020**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:** 10811110**Subject Initials:** ---**Generated By:** pfe.levisse**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:	YES Number of Visits or Contacts: [1]
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [1]
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	NO
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	NO
1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[]
----	-------------------------------------	-----

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	NO
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Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811110

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 2 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT
on Oct/19/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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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

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** ILLNESS DETAILS
on Oct/19/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

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?	YES Respiratory Illness Diagnosis: [Right lower lobe pneumonia] Date of Diagnosis: Oct/16/2020
3.	Toxicity Grade:	2

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811110

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

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE
on Oct/19/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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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 2

Form Version: 21-Aug-2020 02:49

Site No: 1081

Subject No: 10811110

Generated By: pfe.levissc

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Oct/19/2020

Form Version: 21-Aug-2020 02:49

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Lab Chemistry Details

1.	Lab Panel:	
2.	Laboratory Name and Address	[]
3.	Collection Date:	//
4.	Specimen Type:	

Lab Result

5.	Sponsor ID:	[]
	Test:	
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

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: 10811110

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

#	Category for Lab Test	Vendor Name (DE RIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
on Oct/19/2020

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Laboratory Data Hematology

1.	Lab Panel:	
2.	Laboratory Name and Address	[]
3.	Collection Date:	//
4.	Specimen Type:	

Lab Result

5.	Sponsor ID:	[]
	Test:	
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811110

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

#	Date:	Vital Signs Details			Form Instance
1.		Record Identifier:	Systolic:	Diastolic:	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Oct/19/2020

Form Version: 21-Aug-2020 02:50

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Vital Signs

1.	Date:	//
----	-------	----

Vital Signs Details

2.	Record Identifier:	
	Systolic:	[]
	Diastolic:	[]
	Respiratory Rate in respirations/minute:	[]
	Heart Rate in beats/minute:	[]

Header Text: c4591001

Visit: POT_COVID_ILL 2

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: 10811110

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

#	Date:	Vital Signs Details		Form Instance
1.		Record Identifier:	Oxygen Saturation	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Oct/19/2020

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Vital Signs

1.	Date:	//
----	-------	----

Vital Signs Details

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

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 2 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS
on Oct/19/2020

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: 10811110

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 2

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811110

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 2 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
on Oct/19/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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[Form Comments](#)

[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

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811110

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.	Oct/16/2020	CHEST	X-RAY	ABNORMAL <i>If abnormal, specify findings:</i> Right lower lobe pneumonia with pleural effusion	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** IMAGING
on Oct/19/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Imaging

1.	Date of Assessment:	Oct/16/2020
2.	Location of Assessment:	CHEST
3.	Type of Imaging Exam:	X-RAY
4.	Assessment:	ABNORMAL If abnormal, specify findings: [Right lower lobe pneumonia with pleural effusion]

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Nov/17/2020

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Nov/17/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_B1
----	-------------------------	----------

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Nov/17/2020

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

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: Nov/17/2020
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	[BKN9MD]
5.b	Sample ID	[BKN9MF]
5.c	Sample ID	[BS64R6]
5.d	Sample ID	[BS64R7]

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811110

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: 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: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

Unplanned Assessments

1.	Assessments	
----	-------------	--

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

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: 10811110

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

eCRF Audit Trail History

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Oct/14/2020
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: 10811110

Generated By: pfe.levissc

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Disposition - Follow-Up

1.	Date of Completion/Discontinuation/Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[]

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
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: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

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: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

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: 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: 10811110

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Right lower lobe pneumonia	Oct/11/2020 UNK:UNK	NO End Date Time: Nov/18/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	loculated empyema	Oct/11/2020 UNK:UNK	NO End Date Time: Nov/18/2020 UNK:UNK	Repeating Pages

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811110

Generated By: pfe.levisse

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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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Right lower lobe pneumonia]
4.	Start Date Time:	Oct/11/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/18/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO 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

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811110

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

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: [idiopathic]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020415413]

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811110

Generated By: pfe.levisse

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:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[loculated empyema]
4.	Start Date Time:	Oct/11/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/18/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO 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

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811110

Generated By: pfe.levisse

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

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: [idiopathic]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020415413]

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (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: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1081

Subject No: 10811110

Generated By: pfe.levisse

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	[]

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (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: 10811110

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Concomitant Medications

1.	What is the medication identifier?	[]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[]
5.	Date:	//

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (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: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

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

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811110

Generated By: pfe.levisse

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

[Back to Form](#)

Concomitant Medications

1.	What is the medication identifier?	[]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[]
5.	Dose:	[]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
10.	Ongoing?	

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (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: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

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: 10811110

Generated By: pfe.levisse

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: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811110

Generated By: pfe.levisse

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: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

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: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

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: 10811110

Subject Initials: ---

Generated By: pfe.levissc

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:	

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

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: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

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?	

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (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: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

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: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

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: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

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: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

Informed Consent - Asymptomatic Surveillance

1.	Consent Was:	
----	--------------	--

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

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: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

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: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/18/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2
----	---	--

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811110

Generated By: pfe.levissc

Form: TREATMENT UNBLINDED

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](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/18/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811110

Generated By: pfe.lewissc

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: 10811110

Generated By: pfe.lewissc

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Death Details

1.	Date of Collection / Notification of Death:	//
----	---	----

Cause of Death

2.	Cause of Death Status:	
	Cause of Death:	[]

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811110

Generated By: pfe.levissc

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	FOLLOW-UP
2.	Subject Status Date	Oct/14/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levissc

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: 10811110

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 12:07:22 (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: 10811110

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	Aug-26-2020 13:24:20 (UTC-05:00) Eastern Time (US & Canada)	Tawryn Ebner (pfe.tebner)	All inclusion and exclusion met <hr/> Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
Form	Oct-15-2020 07:22:29 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Done
Form	Sep-29-2020 14:15:03 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
1	Oct-15-2020 07:22:29 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Done
1	Sep-29-2020 14:15:03 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
2	Oct-15-2020 07:22:29 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Done
2	Sep-29-2020 14:15:03 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
3	Oct-15-2020 07:22:29 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Done
3	Sep-29-2020 14:15:03 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Sep/28/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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Subject No: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
4	Oct-15-2020 07:22:29 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Done
4	Sep-29-2020 14:15:03 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
5	Oct-15-2020 07:22:29 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Done
5	Sep-29-2020 14:15:03 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
6	Oct-15-2020 07:22:29 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Done
6	Sep-29-2020 14:15:03 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
7	Oct-15-2020 07:22:29 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Done
7	Sep-29-2020 14:15:03 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
8	Oct-15-2020 07:22:29 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Done
8	Sep-29-2020 14:15:03 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
9	Oct-15-2020 07:22:29 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Done
9	Sep-29-2020 14:15:03 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
Form	Oct-15-2020 07:24:09 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	
Form	Sep-29-2020 14:22:59 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
1	Oct-15-2020 07:24:09 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	
1	Sep-29-2020 14:22:59 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811110

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
2	Oct-15-2020 07:24:09 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	
2	Sep-29-2020 14:22:59 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
3	Oct-15-2020 07:24:09 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	
3	Sep-29-2020 14:22:59 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
4	Oct-15-2020 07:24:09 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	
4	Sep-29-2020 14:22:59 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
Form	Sep-29-2020 14:24:22 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
1	Sep-29-2020 14:24:22 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
2	Sep-29-2020 14:24:22 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
3	Sep-29-2020 14:24:22 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
4	Sep-29-2020 14:24:22 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
5	Sep-29-2020 14:24:22 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
6	Sep-29-2020 14:24:22 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
Form	Sep-29-2020 14:26:33 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
1	Sep-29-2020 14:26:33 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
on Sep/28/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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Subject No: 10811110

Subject Initials: ---

Generated By: pfe.levissc

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Item	Date	User	Comment
2	Sep-29-2020 14:26:33 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
on Sep/28/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

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Item	Date	User	Comment
3	Sep-29-2020 14:26:33 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020 **Form:** ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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Generated By: pfe.levissc

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Item	Date	User	Comment
4	Sep-29-2020 14:26:33 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
Form	Sep-29-2020 14:26:57 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

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: 10811110

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Generated By: pfe.levissc

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Item	Date	User	Comment
1	Sep-29-2020 14:26:57 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

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Item	Date	User	Comment
2	Sep-29-2020 14:26:57 (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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Header Text: c4591001

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Item	Date	User	Comment
5.a	Sep-29-2020 14:26:57 (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
5.a	Sep-29-2020 14:26:57 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

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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: 10811110

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
5.b	Sep-29-2020 14:26:57 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

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: 10811110

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Generated By: pfe.levisse

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Item	Date	User	Comment
5.b	Sep-29-2020 14:26:57 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

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Item	Date	User	Comment
5.b	Sep-29-2020 14:26:57 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

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Item	Date	User	Comment
5.b	Sep-29-2020 14:26:57 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

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Item	Date	User	Comment
5.c	Sep-29-2020 14:26:57 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

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Item	Date	User	Comment
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Item	Date	User	Comment
5.c	Sep-29-2020 14:26:57 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

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Item	Date	User	Comment
5.d	Sep-29-2020 14:26:57 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

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Subject No: 10811110

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Item	Date	User	Comment
5.d	Sep-29-2020 14:26:57 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

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Item	Date	User	Comment
5.d	Sep-29-2020 14:26:57 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

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Item	Date	User	Comment
5.d	Sep-29-2020 14:26:57 (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 Sep/28/2020

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Site No: 1081

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Item	Date	User	Comment
5.e	Sep-29-2020 14:26:57 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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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
5.e	Sep-29-2020 14:26:57 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

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Item	Date	User	Comment
5.e	Sep-29-2020 14:26:57 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

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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 Sep/28/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1081

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Subject No: 10811110

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Item	Date	User	Comment
Form	Sep-29-2020 14:27:17 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

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Header Text: c4591001

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2	Sep-29-2020 14:27:17 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

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3	Sep-29-2020 14:27:17 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

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4	Sep-29-2020 14:27:17 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

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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.j	Sep-29-2020 14:27:17 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
5.j	Sep-29-2020 14:27:17 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

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
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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

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Item	Date	User	Comment
5.j	Sep-29-2020 14:27:17 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Comments
on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
Form	Sep-29-2020 14:28:01 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Televisit ----- Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Comments
on Sep/28/2020

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: 10811110

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Item	Date	User	Comment
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Comments
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Form Version: 21-Aug-2020 02:50

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Item	Date	User	Comment
2.a	Sep-29-2020 14:28:01 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Televisit <hr/> Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Comments
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Item	Date	User	Comment
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

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Item	Date	User	Comment
Form	Sep-29-2020 14:28:22 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments on Sep/28/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

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Item	Date	User	Comment
1	Sep-29-2020 14:28:22 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments on Sep/28/2020

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Item	Date	User	Comment
2.a	Sep-29-2020 14:28:22 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments
on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levissc

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Item	Date	User	Comment
Form	Sep-29-2020 14:28:45 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020 **Form:** OXYGENATION PARAMETERS - Comments

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: 10811110

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Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
1	Sep-29-2020 14:28:45 (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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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

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Item	Date	User	Comment
Form	Sep-29-2020 14:29:09 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
1	Sep-29-2020 14:29:09 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

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Subject No: 10811110

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Item	Date	User	Comment
4	Sep-29-2020 14:29:09 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

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Subject No: 10811110

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Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
5	Sep-29-2020 14:29:09 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

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Subject No: 10811110

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Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
6	Sep-29-2020 14:29:09 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Sep/28/2020

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: 10811110

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Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
Form	Sep-29-2020 14:29:30 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Sep/28/2020

Form Version: 06-Jul-2020 21:53

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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
4	Sep-29-2020 14:29:30 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Oct/19/2020

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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Subject Initials: ---

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Item	Date	User	Comment
Form	Oct-19-2020 10:48:52 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Oct/19/2020

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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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
on Oct/19/2020

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: 10811110

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Generated By: pfe.levisse

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Item	Date	User	Comment
Form	Oct-19-2020 10:49:43 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
on Oct/19/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

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Item	Date	User	Comment
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Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811110

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
Form	Oct-19-2020 10:50:09 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020 **Form:** OXYGENATION PARAMETERS - Comments

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
1	Oct-19-2020 10:50:09 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020 **Form:** OXYGENATION PARAMETERS - Comments

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
2	Oct-19-2020 10:50:09 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020 **Form:** OXYGENATION PARAMETERS - Comments

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
3	Oct-19-2020 10:50:09 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
Form	Oct-19-2020 10:50:27 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
1	Oct-19-2020 10:50:27 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
2	Oct-19-2020 10:50:27 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
3	Oct-19-2020 10:50:27 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
4	Oct-19-2020 10:50:27 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
5	Oct-19-2020 10:50:27 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
6	Oct-19-2020 10:50:27 (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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

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 12:07:22 (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-20-2020 08:27:04 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

James Fry	Approved	Nov-17-2020 20:45:16 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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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.

Tawyn Ebner	N/A	Nov-17-2020 14:49:49 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Michael Butcher	Approved	Nov-16-2020 09:11:52 (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.

James Fry	N/A	Oct-27-2020 14:52:00 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

James Fry	Approved	Oct-23-2020 14:30:55 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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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.

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1081

Subject No: 10811110

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
Aug-26-2020 13:22:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn 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
Aug-26-2020 13:22:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811110

Generated By: pfe.lewissc

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
Aug-26-2020 13:22:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: OBTAINED Date Written Consent Obtained Aug/26/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1081

Subject No: 10811110

Generated By: pfe.lewissc

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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I. Subject ID

Date	Location	User	Value	Reason
Oct-27-2020 15:54:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 2: Closed	Response satisfies query
Oct-27-2020 15:54:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 1: Closed	Response satisfies query
Oct-27-2020 14:33:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Query 2: Answered	This is part of a COVID illness visit already reported.
Oct-27-2020 14:33:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Query 1: Answered	This is part of a COVID illness already reported.
Oct-27-2020 07:00:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Opened	SAE RECON:AER#2020415413 pleural effusion(onset date:23Oct2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Oct-27-2020 06:59:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON:AER#2020415413 Right lower lobe pneumonia (onset date:23Oct2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Aug-26-2020 13:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10811110	Item copied from previous form

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

2. Birth Date:

Date	Location	User	Value	Reason
Aug-26-2020 13:22:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1939	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-26-2020 13:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-26-2020 13:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Aug-26-2020 13:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: WHITE	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811110

Generated By: pfe.levissc

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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1. Date of Visit

Date	Location	User	Value	Reason
Aug-26-2020 13:23:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Aug/26/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811110

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
Aug-26-2020 13:25:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Aug/26/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-26-2020 13:25:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-26-2020 13:25:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: COMPLETED	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811110

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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I.a

Date	Location	User	Value	Reason
Aug-26-2020 16:57:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 1 mber: Medical History Term: Osteoarthritis of bi lateral hands Start Date: UNK/UNK/2013 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-26-2020 16:57:20 (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
Aug-26-2020 16:57:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Osteoarthritis of bilateral hands	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Aug-26-2020 16:57:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2013	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Aug-26-2020 16:57:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

I.b

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811110

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Aug-26-2020 16:58:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numb 2 er: Medical History Skin Cancer-Rig Term: ht Leg Start Date: UNK/UNK/2014 Ongoing: NO End Date: Dec/UNK/20 15	Initial Entry

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-26-2020 16:58:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-26-2020 16:58:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Skin Cancer-Right Leg	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-26-2020 16:58:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2014	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-26-2020 16:58:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO End Date: Dec/UNK/2015	Initial Entry

090177e196ae3efa\Final\On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811110

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.c

Date	Location	User	Value	Reason
Aug-26-2020 17:02:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Term: Skin Cancer- Left Arm Start Date: UNK/UNK/2014 Ongoing: NO End Date: UNK/UNK/2014	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811110

Generated By: pfe.levisse

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.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-26-2020 17:02:06 (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
Aug-26-2020 17:02:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Skin Cancer- Left Arm	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Aug-26-2020 17:02:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2014	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Aug-26-2020 17:02:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO End Date: UNK/UNK/2014	Initial Entry

I.d

Date	Location	User	Value	Reason
Aug-26-2020 17:02:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 4 mber: Medical Histo Chronic Urinary Tr ry Term: act Infections Start Date: UNK/UNK/2000 Ongoing: YES	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1081**Subject No:** 10811110**Generated By:** pfe.levisse**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.d Line/MH Number:***

Date	Location	User	Value	Reason
Aug-26-2020 17:02:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

I.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-27-2020 17:51:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Closed	Response satisfies query
Aug-27-2020 17:37:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Query 1: Answered	Patient has not had a UTI for nearly 1 year. She did not meet Criteria for Temporary Delay.
Aug-27-2020 13:06:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	GPD Clin: Per IC3 and Criteria for Temporary Delay of Enrolment (Protocol 5.5), please confirm stability of symptoms within 6 weeks of enrolment and no acute event within 48h before study intervention administration
Aug-26-2020 17:02:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Chronic Urinary Tract Infections	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Aug-26-2020 17:02:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2000	Initial Entry

I.d Ongoing:

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811110

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Aug-26-2020 17:02:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

1.e

Date	Location	User	Value	Reason
Aug-26-2020 17:03:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 5 mber: Medical Histo Gastroesophageal r ry Term: eflux disease Start Date: UNK/UNK/2014 Ongoing: YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811110

Generated By: pfe.levisse

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
Aug-26-2020 17:03:21 (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
Aug-26-2020 17:03:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Gastroesophageal reflux disease	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Aug-26-2020 17:03:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2014	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Aug-26-2020 17:03:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Aug-26-2020 17:03:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 6 Medical History T Migraine erm: Start Date: UNK/UNK/1 990 Ongoing: YES	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811110

Generated By: pfe.levisse

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.f Line/MH Number:

Date	Location	User	Value	Reason
Aug-26-2020 17:03:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

1.f Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-26-2020 17:03:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Migraine	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Aug-26-2020 17:03:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/1990	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Aug-26-2020 17:03:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

1.g

Date	Location	User	Value	Reason
Aug-26-2020 17:04:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 7 Medical History Term: Rosacea Start Date: UNK/UNK/2013 Ongoing: YES	Initial Entry

090177e196ae3efa\Final\On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811110

Generated By: pfe.levisse

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.g Line/MH Number:

Date	Location	User	Value	Reason
Aug-26-2020 17:04:04 (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
Aug-26-2020 17:04:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Rosacea	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Aug-26-2020 17:04:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2013	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Aug-26-2020 17:04:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

I.h

Date	Location	User	Value	Reason
Aug-26-2020 17:04:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 8 ber: Medical History Term: Osteopenia-stable since 2016 Start Date: UNK/UNK/1985 Ongoing: YES	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811110

Generated By: pfe.levisse

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.h Line/MH Number:

Date	Location	User	Value	Reason
Aug-26-2020 17:04:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

I.h Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-26-2020 17:04:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Osteopenia-stable since 2016	Initial Entry

I.h Start Date:

Date	Location	User	Value	Reason
Aug-26-2020 17:04:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/1985	Initial Entry

I.h Ongoing:

Date	Location	User	Value	Reason
Aug-26-2020 17:04:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

I.i

Date	Location	User	Value	Reason
Aug-26-2020 17:05:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 9 Number: Medical History Term: Raynaud's Disease- No associated autoimmune conditions Start Date: UNK/UNK/2016 Ongoing: YES	Initial Entry

090177e196ae3efa\Final\On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811110

Generated By: pfe.levisse

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.i Line/MH Number:

Date	Location	User	Value	Reason
Aug-26-2020 17:05:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

1.i Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-26-2020 17:05:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Raynaud's Disease- No associated a utoimmune conditions	Initial Entry

1.i Start Date:

Date	Location	User	Value	Reason
Aug-26-2020 17:05:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2016	Initial Entry

1.i Ongoing:

Date	Location	User	Value	Reason
Aug-26-2020 17:05:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

1.j

Date	Location	User	Value	Reason
Aug-26-2020 17:05:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 10 Medical History Te Sleep Apnea rm: Start Date: Apr/UNK/20 17 Ongoing: YES	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811110

Generated By: pfe.levisse

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.j Line/MH Number:

Date	Location	User	Value	Reason
Aug-26-2020 17:05:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10	Initial Entry

1.j Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-26-2020 17:05:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Sleep Apnea	Initial Entry

1.j Start Date:

Date	Location	User	Value	Reason
Aug-26-2020 17:05:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Apr/UNK/2017	Initial Entry

1.j Ongoing:

Date	Location	User	Value	Reason
Aug-26-2020 17:05:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

1.k

Date	Location	User	Value	Reason
Aug-26-2020 17:06:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 11 Medical History Te Hypothyroidi rm: sm Start Date: Aug/UNK/20 09 Ongoing: YES	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1081**Subject No:** 10811110**Generated By:** pfe.levisse**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.k Line/MH Number:***

Date	Location	User	Value	Reason
Aug-26-2020 17:06:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11	Initial Entry

1.k Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-26-2020 17:06:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Hypothyroidism	Initial Entry

1.k Start Date:

Date	Location	User	Value	Reason
Aug-26-2020 17:06:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Aug/UNK/2009	Initial Entry

1.k Ongoing:

Date	Location	User	Value	Reason
Aug-26-2020 17:06:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

1.l

Date	Location	User	Value	Reason
Aug-26-2020 17:08:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 12 Medical History Term: Hysterectomy Start Date: UNK/UNK/1989 Ongoing: NO End Date: UNK/UNK/ 1989	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811110

Generated By: pfe.levisse

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

1.1 Line/MH Number:

Date	Location	User	Value	Reason
Aug-26-2020 17:08:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12	Initial Entry

1.1 Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-26-2020 17:08:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Hysterectomy	Initial Entry

1.1 Start Date:

Date	Location	User	Value	Reason
Aug-26-2020 17:08:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/1989	Initial Entry

1.1 Ongoing:

Date	Location	User	Value	Reason
Aug-26-2020 17:08:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO End Date: UNK/UNK/1989	Initial Entry

1.m

Date	Location	User	Value	Reason
Oct-14-2020 10:16:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 13 : Medical History T Seasonal Aller erm: gies Start Date: UNK/UNK/19 57 Ongoing: YES	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811110

Generated By: pfe.levisse

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.m Line/MH Number:

Date	Location	User	Value	Reason
Oct-14-2020 10:16:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 13	Initial Entry

I.m Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Oct-14-2020 10:16:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Seasonal Allergies	Initial Entry

I.m Start Date:

Date	Location	User	Value	Reason
Oct-14-2020 10:16:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: UNK/UNK/1957	Initial Entry

I.m Ongoing:

Date	Location	User	Value	Reason
Oct-14-2020 10:16:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1081

Subject No: 10811110

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
Aug-26-2020 17:07:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Aug/26/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-26-2020 17:07:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: 144.4	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-26-2020 17:07:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-26-2020 17:07:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: 67.5	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-26-2020 17:07:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-26-2020 17:07:12 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: 22.3	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1081

Subject No: 10811110

Generated By: pfe.levisse

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

Time (US & Canada)

7.a

Date	Location	User	Value	Reason
Aug-26-2020 17:07:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Record Identifier:: 1 Temperature: 97.8 Temperature Unit: F Temperature Locatio n:: FOREHEA D	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-26-2020 17:07:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-26-2020 17:07:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: 97.8	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-26-2020 17:07:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-26-2020 17:07:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: FOREHEAD	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 21-Aug-2020 02:49**Site No:** 1081**Subject No:** 10811110**Generated By:** pfe.lewissc**Form:** LAB URINALYSIS - PREGNANCY TEST - 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](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Aug-26-2020 16:22:43 (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
Aug-26-2020 16:22:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-26-2020 16:22:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: Aug/26/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Aug-26-2020 16:22:43 (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
Aug-26-2020 16:22:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-26-2020 16:22:27	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

(UTC-05:00) Eastern Time (US & Canada)		(autocalc)	Sponsor-Defined Identifier: 113	
			Test:: Choriogonadotropin Beta_PX113	
			Result::	
			Not Done:: NOT DONE	

6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-26-2020 16:22:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-26-2020 16:22:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Aug-26-2020 16:22:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: NOT DONE	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811110

Generated By: pfe.lewissc

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
Aug-26-2020 17:08:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Aug/26/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-26-2020 17:08:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: 241313	Initial Entry

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1081**Subject No:** 10811110**Generated By:** pfe.lewissc**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-26-2020 16:09:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-26-2020 16:09:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-26-2020 16:10:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-26-2020 16:09:32 (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.
Aug-26-2020 16:09:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Aug/26/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-26-2020 16:10:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BP97ZD	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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.a Sample ID

Date	Location	User	Value	Reason
Aug-26-2020 16:10:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> BP97ZD	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-26-2020 16:10:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BP97ZF	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-26-2020 16:10:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> BP97ZF	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-26-2020 16:10:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BP97ZG	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-26-2020 16:10:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> BP97ZG	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-26-2020 16:10:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BPHZLY	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.d Sample ID

Date	Location	User	Value	Reason
Aug-26-2020 16:10:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BPHZLY	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-26-2020 16:10:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BPHZLZ	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-26-2020 16:10:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BPHZLZ	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1081**Subject No:** 10811110**Generated By:** pfe.lewissc**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-26-2020 16:11:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-26-2020 16:11:19 (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
Aug-26-2020 16:11:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-26-2020 16:11:19 (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.
Aug-26-2020 16:11:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Aug/26/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-26-2020 16:11:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BP97JV	Initial Entry

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.a Sample ID

Date	Location	User	Value	Reason
Aug-26-2020 16:11:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	<u>Data Entry:</u> BP97JV	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811110

Generated By: pfe.lewissc

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
Aug-26-2020 17:08:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-26-2020 17:08:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-26-2020 17:08:50 (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
Aug-26-2020 17:08:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Aug/26/2020 12:34	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-26-2020 17:08:50 (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
Aug-26-2020 17:08:50 (UTC-05:00) Eastern	ACV0PFEINFP6000	Phillip Ross	Data Entry: LEFT	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811110

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

Time (US & Canada)

(pfe.pross)

7. Route:

Date	Location	User	Value	Reason
Aug-26-2020 17:08:50 (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
Aug-26-2020 17:08:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Aug-26-2020 17:08:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1081

Subject No: 10811110

Generated By: pfe.lewissc

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
Aug-26-2020 17:08:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO - REACTOGENICITY E-DIA RY 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: 10811110

Generated By: pfe.levissc

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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1. Date of Visit

Date	Location	User	Value	Reason
Sep-16-2020 09:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sep/16/2020	Initial Entry

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 15-Sep-2020 21:54**Site No:** 1081**Subject No:** 10811110**Generated By:** pfe.lewissc**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[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Sep-16-2020 11:04:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sep/16/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-16-2020 11:04:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Record Identifier:: 1 Temperature: 97.5 Temperature Unit: F Temperature Location:: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-16-2020 11:04:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-16-2020 11:04:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: 97.5	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-16-2020 11:04:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: F	Initial Entry

2.a Temperature Location:

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1081

Subject No: 10811110

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Sep-16-2020 11:04:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: ORAL CAVITY	Initial Entry

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:49**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811110**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-16-2020 11:04:54 (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-16-2020 11:04:54 (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-16-2020 11:04:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sep/16/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-16-2020 11:04:54 (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-16-2020 11:04:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-16-2020 11:04:54	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

(UTC-05:00) Eastern Time (US & Canada)		(autocalc)	Sponsor-Defined Identifier: 113	
			Test:: Choriogonadotropin Beta_PX113	
			Result::	
			Not Done:: NOT DONE	

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-16-2020 11:04:54 (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-16-2020 11:04:54 (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-16-2020 11:04:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NOT DONE	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (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:** 10811110**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-16-2020 09:53:33 (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-16-2020 09:53:33 (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-16-2020 09:53:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-16-2020 09:53:33 (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-16-2020 09:53:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Sep/16/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-16-2020 09:53:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BP97SL	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811110

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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

5.a Sample ID

Date	Location	User	Value	Reason
Sep-16-2020 09:53:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	<u>Data Entry:</u> BP97SL	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811110

Generated By: pfe.lewissc

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-16-2020 11:04:09 (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-16-2020 11:04:09 (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-16-2020 11:04:09 (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-16-2020 11:04:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sep/16/2020 10:13	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-16-2020 11:04:09 (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-16-2020 11:04:09 (UTC-05:00) Eastern	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: LEFT	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811110

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

Time (US & Canada)

7. Route:

Date	Location	User	Value	Reason
Sep-16-2020 11:04:09 (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-16-2020 11:04:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION 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-16-2020 11:04:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811110

Generated By: pfe.levissc

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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1. Date of Visit

Date	Location	User	Value	Reason
Oct-14-2020 09:19:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Oct/14/2020	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:** 10811110**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-14-2020 09:35:04 (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-14-2020 09:35:04 (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-14-2020 09:35:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-14-2020 09:35:04 (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-14-2020 09:35:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Oct/14/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-14-2020 09:35:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BP1HWJ	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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.a Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 09:35:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BP1HWJ	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-14-2020 09:35:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BRTXXP	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 09:35:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BRTXXP	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-14-2020 09:35:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BRTXXR	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 09:35:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BRTXXR	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811110

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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I. Date of Visit

Date	Location	User	Value	Reason
Oct-09-2020 11:54:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nicholas Roosa (pfe.roosan)	Query 3: Closed	Response satisfies query
Oct-07-2020 07:14:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sep/28/2020	Transcription Error
Oct-06-2020 13:39:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 3: Answered	source document is correct, this will need to be corrected in EDC. Please open pages in order to correct data
Oct-06-2020 13:29:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nicholas Roosa (pfe.roosan)	Query 3: Opened	Per source, visit occurred on 28Sep2020. Please confirm.
Sep-29-2020 14:21:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-29-2020 14:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Sep-29-2020 14:10:34 (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.
Sep-29-2020 14:10:34 (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

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

				Nasal Swab are missing. Please review and update as appropriate.
Sep-29-2020 14:10:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sep/26/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Sep-29-2020 14:10:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: COVID_A	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020**Form Version:** 15-Sep-2020 21:55**Site No:** 1081**Subject No:** 10811110**Generated By:** pfe.levissc**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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[Back to Form](#)**I. Date of Assessment:**

Date	Location	User	Value	Reason
Oct-09-2020 11:54:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nicholas Roosa (pfe.roosan)	Query 2: Closed	Response satisfies query
Oct-08-2020 12:59:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Behnaz Yousefzadeh-Khiabani (pfe.youseb01)	Query 3: Closed	Response satisfies query
Oct-07-2020 07:14:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Answer Auto Query
Oct-07-2020 01:13:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 3: Reissued:Opened	DM : Form is unfrozen now. Please review and update data as per previous query.
Oct-06-2020 14:22:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 3: Answered	Need to change DOV to 28Sep2020 once page unlocked. Data on this page is correct
Oct-06-2020 13:40:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	Date of assessment is not same as Date Visit. Please check and correct.
Oct-06-2020 13:40:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Oct-06-2020 13:40:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sep/28/2020	Transcription Error
Oct-06-2020 13:29:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nicholas Roosa (pfe.roosan)	Query 2: Opened	Per source, visit occurred on 28Sep2020. Please confirm.

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020**Form Version:** 15-Sep-2020 21:55**Site No:** 1081**Subject No:** 10811110**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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

Sep-29-2020 14:22:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-29-2020 14:22:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sep/26/2020	Transcription Error
Sep-29-2020 14:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of assessment is not same as Date Visit. Please check and correct.
Sep-29-2020 14:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sep/28/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Oct-09-2020 11:55:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nicholas Roosa (pfe.roosan)	Query 1: Closed	Response satisfies query
Oct-06-2020 14:23:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	26Sep2020 has now been noted on source document as of 06Oct2020
Oct-06-2020 13:31:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nicholas Roosa (pfe.roosan)	Query 1: Opened	Per source, patient "called over the weekend". Please confirm actual date in source and update as applicable.
Sep-29-2020 14:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sep/26/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Nov-05-2020 20:09:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Amita Sushant Surve (pfe.survea03)	Query 2: Closed	raised in error

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020**Form Version:** 15-Sep-2020 21:55**Site No:** 1081**Subject No:** 10811110**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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

Nov-05-2020 19:58:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Amita Sushant Surve (pfe.survea03)	Query 2: Opened	DM: Subject has completed illness Visit and symptoms are resolved, however corresponding Convalescent Visit not yet initiated. Please review and update as appropriate. Thank you.
Nov-04-2020 13:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gbenga Akinkunmi (pfe.akinkg)	Query 1: Closed	Response satisfies query
Nov-04-2020 11:10:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Nov-04-2020 11:10:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO Date of Last Symptom Resolved: Oct/2/2020	New Information
Oct-28-2020 11:27:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Divya M (pfe.md09)	Query 1: Opened	DM: COVID_B visit is conducted while symptoms from 1st visit is ongoing. Please clarify whether the reported symptoms are still ongoing? If symptoms have ended, please update 'Symptoms Ongoing' on to 'NO' and add Date of Last Symptom Resolved on the CRF.
Sep-29-2020 14:14:38 (UTC-05:00) Eastern	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811110

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

Time (US & Canada)				
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4.a

Date	Location	User	Value	Reason
Sep-29-2020 14:14:38 (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
Sep-29-2020 14:14:38 (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
Sep-29-2020 14:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Sep-29-2020 14:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Present: NO	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020**Form Version:** 15-Sep-2020 21:55**Site No:** 1081**Subject No:** 10811110**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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**4.b Symptoms:**

Date	Location	User	Value	Reason
Sep-29-2020 14:14:38 (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
Sep-29-2020 14:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Sep-29-2020 14:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptom: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: NO	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Sep-29-2020 14:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Sep-29-2020 14:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020**Form Version:** 15-Sep-2020 21:55**Site No:** 1081**Subject No:** 10811110**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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

Sep-29-2020 14:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry
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4.d Symptoms:

Date	Location	User	Value	Reason
Sep-29-2020 14:14:38 (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
Sep-29-2020 14:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Sep-29-2020 14:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptoms NEW OR INCREASE : D MUSCLE PAIN Symptom NO Present:	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Sep-29-2020 14:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Sep-29-2020 14:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

4.f

Date	Location	User	Value	Reason
Sep-29-2020 14:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptoms: NEW LOSS OF TASTE OR SMELL Symptom Present: NO	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Sep-29-2020 14:14:38 (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
Sep-29-2020 14:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Sep-29-2020 14:14:38 (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

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020**Form Version:** 15-Sep-2020 21:55**Site No:** 1081**Subject No:** 10811110**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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**4.g Symptoms:**

Date	Location	User	Value	Reason
Sep-29-2020 14:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NEW OR INCREASED SORE TH ROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Sep-29-2020 14:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES	Initial Entry

4.h

Date	Location	User	Value	Reason
Sep-29-2020 14:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptoms: DIARRHEA Symptom Present: NO	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Sep-29-2020 14:14:38 (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
Sep-29-2020 14:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Sep-29-2020 14:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptoms: VOMITING Symptom Present: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811110

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

4.i Symptoms:

Date	Location	User	Value	Reason
Sep-29-2020 14:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Sep-29-2020 14:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> NO	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Sep/28/2020**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:** 10811110**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Oct-15-2020 08:53:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Stephen Paolini (pfe.paolis01)	Query 1: Closed	Response satisfies query
Oct-15-2020 07:23:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	Not done has been marked to satisfy query
Oct-15-2020 07:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Done	Initial Entry
Oct-15-2020 04:12:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Swetha Thangellapally (pfe.thangs22)	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-13-2020 15:24:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Stephen Paolini (pfe.paolis01)	Query 1: Candidate	CLIQUEY: Per CCG's 'Not Done' needs to be applied to the CRF if local test was not completed. Please update.
Sep-29-2020 14:15:03 (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-15-2020 07:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Done	Initial Entry
Sep-29-2020 14:15:03 (UTC-05:00) Eastern	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Time (US & Canada)				
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3. Specimen Collection Location:

Date	Location	User	Value	Reason
Oct-15-2020 07:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Done	Initial Entry
Sep-29-2020 14:15:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Oct-15-2020 07:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Done	Initial Entry
Sep-29-2020 14:15:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Oct-15-2020 07:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Done	Initial Entry
Sep-29-2020 14:15:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Oct-15-2020 07:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Done	Initial Entry
Sep-29-2020 14:15:03 (UTC-05:00) Eastern	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Time (US & Canada)

7. Test Result:

Date	Location	User	Value	Reason
Oct-15-2020 07:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Done	Initial Entry
Sep-29-2020 14:15:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Oct-15-2020 07:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Done	Initial Entry
Sep-29-2020 14:15:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Oct-15-2020 07:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Done	Initial Entry
Sep-29-2020 14:15:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1081**Subject No:** 10811110**Generated By:** pfe.lewissc**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - 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[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-29-2020 14:21:31 (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 14:21:31 (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
Sep-29-2020 14:21:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-29-2020 14:21:31 (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 14:21:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES Date of Collection: Sep/28/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-29-2020 14:21:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sample ID: CV22460	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

5.a Sample ID

Date	Location	User	Value	Reason
Sep-29-2020 14:21:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> CV22460	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1081**Subject No:** 10811110**Generated By:** pfe.lewissc**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-15-2020 07:24:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry
Oct-15-2020 07:24:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry
Sep-29-2020 14:22:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-15-2020 07:24:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry
Oct-15-2020 07:24:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry
Sep-29-2020 14:22:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-15-2020 07:24:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry : NO	Initial Entry
Oct-15-2020 07:24:09 (UTC-05:00)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry :	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1081**Subject No:** 10811110**Generated By:** pfe.levisse**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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

Eastern Time (US & Canada)				
Oct-02-2020 02:06:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kirti Bhangale (pfe.bhank01)	Query 1: Closed	Response satisfies query
Oct-01-2020 14:07:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Query 1: Answered	unable to update. Should have been No as this was a televisit.
Oct-01-2020 03:26:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW4849356; Sample Collected is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Sep-29-2020 14:22:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry : Not Applicable	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Oct-15-2020 08:54:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Stephen Paolini (pfe.paolis01)	Query 1: Closed	Response satisfies query
Oct-15-2020 07:24:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Oct-15-2020 07:24:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Telehealth Visit	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811110

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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

Oct-15-2020 07:24:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry
Oct-15-2020 04:17:00 (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 15:28:06 (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.
Sep-29-2020 14:22:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Sep/28/2020

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

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I.a

Date	Location	User	Value	Reason
Sep-29-2020 14:24:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or NO Contacts:	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Sep-29-2020 14:24:08 (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
Sep-29-2020 14:24:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Sep-29-2020 14:24:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or NO Contacts:	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Sep/28/2020**Form Version:** 15-Sep-2020 21:53**Form Status:** Data Complete, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811110**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11***1.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Sep-29-2020 14:24:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: EMERGENCY ROOM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Sep-29-2020 14:24:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

1.c

Date	Location	User	Value	Reason
Sep-29-2020 14:24:08 (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: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Sep-29-2020 14:24:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Sep-29-2020 14:24:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Sep/28/2020

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

I.d

Date	Location	User	Value	Reason
Sep-29-2020 14:24:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: NO	Initial Entry

I.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Sep-29-2020 14:24:08 (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
Sep-29-2020 14:24:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

I.e

Date	Location	User	Value	Reason
Sep-29-2020 14:24:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Type of Practitioner: TELEPHONE C ONSULTATIO N Occurrence of V isits or Contacts : NO	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Sep/28/2020**Form Version:** 15-Sep-2020 21:53**Form Status:** Data Complete, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811110**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 10:11***1.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Sep-29-2020 14:24:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Sep-29-2020 14:24:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

1.f

Date	Location	User	Value	Reason
Sep-29-2020 14:24:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Type of Practitioner: OTH R Occurrence of Visits or C NO ontacts:	Initial Entry

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Sep-29-2020 14:24:08 (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
Sep-29-2020 14:24:08 (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
Sep-29-2020 14:24:08 (UTC-05:00) Eastern	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Sep/28/2020

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Time (US & Canada)				
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090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: RESPIRATORY TREATMENT - eCRF Audit Trail History on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. What is the treatment Identifier?

Date	Location	User	Value	Reason
Sep-29-2020 14:24:22 (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
Sep-29-2020 14:24:22 (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
Sep-29-2020 14:24:22 (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
Sep-29-2020 14:24:22 (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
Sep-29-2020 14:24:22 (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
Sep-29-2020 14:24:22	ACV0PFEINFP6000	James Fry	Data Entry:	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History
on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

(UTC-05:00) Eastern
Time (US & Canada)

(pfe.jfry)

Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: ILLNESS DETAILS - eCRF Audit Trail History on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Sep-29-2020 14:26:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNES S	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Sep-29-2020 14:26:07 (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-15-2020 11:12:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nicholas Roosa (pfe.roosan)	Query 1: Closed	Response satisfies query
Oct-13-2020 14:40:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	Updated SD will be uploaded into Complion by EOD. Toxicity grade was updated as of today.
Oct-13-2020 13:59:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nicholas Roosa (pfe.roosan)	Query 1: Opened	Where is this toxicity grade recorded in source?
Sep-29-2020 14:26:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: 1	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: ILLNESS DETAILS - SEVERE - eCRF Audit Trail History on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Sep-29-2020 14:26:33 (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
Sep-29-2020 14:26:33 (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
Sep-29-2020 14:26:33 (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
Sep-29-2020 14:26:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Sep-29-2020 14:26:57 (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
Sep-29-2020 14:26:57 (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
Sep-29-2020 14:26:57 (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
Sep-29-2020 14:26:57 (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
Sep-29-2020 14:26:57 (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	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

			Not Done:: Not Applicable	
			Lab Normal Range: Not Applicable	

5.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 14:26:57 (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
Sep-29-2020 14:26:57 (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
Sep-29-2020 14:26:57 (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
Sep-29-2020 14:26:57 (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
Sep-29-2020 14:26:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.b

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

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Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811110

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Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Date	Location	User	Value	Reason
Sep-29-2020 14:26:57 (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

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020**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:** 10811110**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11**5.b Sponsor ID:**

Date	Location	User	Value	Reason
Sep-29-2020 14:26:57 (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
Sep-29-2020 14:26:57 (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
Sep-29-2020 14:26:57 (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
Sep-29-2020 14:26:57 (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
Sep-29-2020 14:26:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-29-2020 14:26:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sponsor-Defined Identifier: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

Form Version: 21-Aug-2020 02:49

Site No: 1081

Subject No: 10811110

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Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - 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

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range:	Not Applicable	

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020**Form Version:** 21-Aug-2020 02:49**Site No:** 1081**Subject No:** 10811110**Generated By:** pfe.levisse**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - 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**5.c Sponsor ID:**

Date	Location	User	Value	Reason
Sep-29-2020 14:26:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Sep-29-2020 14:26:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Sep-29-2020 14:26:57 (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
Sep-29-2020 14:26:57 (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
Sep-29-2020 14:26:57 (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
Sep-29-2020 14:26:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sponsor-Defined Identifier: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

Form Version: 21-Aug-2020 02:49

Site No: 1081

Subject No: 10811110

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Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - 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

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range:	Not Applicable	

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020**Form Version:** 21-Aug-2020 02:49**Site No:** 1081**Subject No:** 10811110**Generated By:** pfe.levisse**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - 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**5.d Sponsor ID:**

Date	Location	User	Value	Reason
Sep-29-2020 14:26:57 (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
Sep-29-2020 14:26:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Sep-29-2020 14:26:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Sep-29-2020 14:26:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Sep-29-2020 14:26:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
Sep-29-2020 14:26:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sponsor-Defined Identifier: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

Form Version: 21-Aug-2020 02:49

Site No: 1081

Subject No: 10811110

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Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - 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

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range:	Not Applicable	

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020**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:** 10811110**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11**5.e Sponsor ID:**

Date	Location	User	Value	Reason
Sep-29-2020 14:26:57 (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
Sep-29-2020 14:26:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

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Sep-29-2020 14:26:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

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Sep-29-2020 14:26:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Sep-29-2020 14:26:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.f

Date	Location	User	Value	Reason
Sep-29-2020 14:26:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sponsor-Defined Identifier: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

Form Version: 21-Aug-2020 02:49

Site No: 1081

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Form Status: Data Complete, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range:	Not Applicable	

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020**Form Version:** 21-Aug-2020 02:49**Site No:** 1081**Subject No:** 10811110**Generated By:** pfe.levisse**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - 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**5.f Sponsor ID:**

Date	Location	User	Value	Reason
Sep-29-2020 14:26:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Sep-29-2020 14:26:57 (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
Sep-29-2020 14:26:57 (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
Sep-29-2020 14:26:57 (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
Sep-29-2020 14:26:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.g

Date	Location	User	Value	Reason
Sep-29-2020 14:26:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sponsor-Defined Identifier: Not Applicable	Initial Entry

Header Text: c4591001

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Form Version: 21-Aug-2020 02:49

Site No: 1081

Subject No: 10811110

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - 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

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range:	Not Applicable	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

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5.g Sponsor ID:

Date	Location	User	Value	Reason
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Sep-29-2020 14:26:57 (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
Sep-29-2020 14:26:57 (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
Sep-29-2020 14:26:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020**Form Version:** 21-Aug-2020 02:51**Site No:** 1081**Subject No:** 10811110**Generated By:** pfe.lewissc**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - 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[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-29-2020 14:27:17 (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
Sep-29-2020 14:27:17 (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
Sep-29-2020 14:27:17 (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
Sep-29-2020 14:27:17 (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
Sep-29-2020 14:27:17 (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	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

			Not Done::	Not Applicable
			Lab Normal Range:	Not Applicable

5.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 14:27:17 (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
Sep-29-2020 14:27:17 (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
Sep-29-2020 14:27:17 (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
Sep-29-2020 14:27:17 (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
Sep-29-2020 14:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.b

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

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Generated Time (GMT): 29-Mar-2021 10:11

Date	Location	User	Value	Reason
Sep-29-2020 14:27:17 (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

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **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:** 10811110**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11**5.b Sponsor ID:**

Date	Location	User	Value	Reason
Sep-29-2020 14:27:17 (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
Sep-29-2020 14:27:17 (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
Sep-29-2020 14:27:17 (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
Sep-29-2020 14:27:17 (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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5.c

Date	Location	User	Value	Reason
Sep-29-2020 14:27:17 (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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Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Generated Time (GMT): 29-Mar-2021 10:11

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range:	Not Applicable	

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **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:** 10811110**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11**5.c Sponsor ID:**

Date	Location	User	Value	Reason
Sep-29-2020 14:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Sep-29-2020 14:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Sep-29-2020 14:27:17 (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
Sep-29-2020 14:27:17 (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
Sep-29-2020 14:27:17 (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
Sep-29-2020 14:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sponsor-Defined Identifier: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

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: 10811110

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	

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020**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:** 10811110**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11**5.d Sponsor ID:**

Date	Location	User	Value	Reason
Sep-29-2020 14:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Sep-29-2020 14:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Sep-29-2020 14:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Sep-29-2020 14:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Sep-29-2020 14:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
Sep-29-2020 14:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sponsor-Defined Identifier: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

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: 10811110

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	

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020**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:** 10811110**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11**5.e Sponsor ID:**

Date	Location	User	Value	Reason
Sep-29-2020 14:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Sep-29-2020 14:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Sep-29-2020 14:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Sep-29-2020 14:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Sep-29-2020 14:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.f

Date	Location	User	Value	Reason
Sep-29-2020 14:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sponsor-Defined Identifier: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

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: 10811110

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	

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **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:** 10811110**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11**5.f Sponsor ID:**

Date	Location	User	Value	Reason
Sep-29-2020 14:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Sep-29-2020 14:27:17 (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
Sep-29-2020 14:27:17 (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
Sep-29-2020 14:27:17 (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
Sep-29-2020 14:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.g

Date	Location	User	Value	Reason
Sep-29-2020 14:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sponsor-Defined Identifier: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

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: 10811110

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	

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020**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:** 10811110**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11**5.g Sponsor ID:**

Date	Location	User	Value	Reason
Sep-29-2020 14:27:17 (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
Sep-29-2020 14:27:17 (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
Sep-29-2020 14:27:17 (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
Sep-29-2020 14:27:17 (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
Sep-29-2020 14:27:17 (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
Sep-29-2020 14:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sponsor-Defined Identifier: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

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: 10811110

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	

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020**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:** 10811110**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11**5.h Sponsor ID:**

Date	Location	User	Value	Reason
Sep-29-2020 14:27:17 (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
Sep-29-2020 14:27:17 (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
Sep-29-2020 14:27:17 (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
Sep-29-2020 14:27:17 (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
Sep-29-2020 14:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

5.i

Date	Location	User	Value	Reason
Sep-29-2020 14:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sponsor-Defined Identifier: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

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: 10811110

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	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

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: 10811110

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
Sep-29-2020 14:27:17 (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
Sep-29-2020 14:27:17 (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
Sep-29-2020 14:27:17 (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
Sep-29-2020 14:27:17 (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
Sep-29-2020 14:27:17 (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
Sep-29-2020 14:27:17 (UTC-05:00) Eastern	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sponsor-Defined Ide Not Applic	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

Time (US & Canada)			ntifier:	able	
			Test::	Not Applic able	
			Result::	Not Applic able	
			Not Done::	Not Applic able	
			Lab Normal Range:	Not Applic able	

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.j Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 14:27:17 (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
Sep-29-2020 14:27:17 (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
Sep-29-2020 14:27:17 (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
Sep-29-2020 14:27:17 (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
Sep-29-2020 14:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Sep-29-2020 14:28:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Done	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-29-2020 14:28:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Record Identifier:: Not Done Systolic:: Not Done Diastolic:: Not Done Respiratory Rate in respirations/minute: Not Done Heart Rate in beats/minute: Not Done	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-29-2020 14:28:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Done	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Sep-29-2020 14:28:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Done	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History
on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Sep-29-2020 14:28:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Done	Initial Entry
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2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Sep-29-2020 14:28:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Done	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Sep-29-2020 14:28:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Done	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Sep-29-2020 14:28:22 (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
Sep-29-2020 14:28:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Record Identifier: Not Applicabl : e Oxygen Saturatio Not Applicabl n: e	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-29-2020 14:28:22 (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
Sep-29-2020 14:28:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

090177e196ae3efa\Final\On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: OXYGENATION PARAMETERS - eCRF Audit Trail History on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Date Time of Assessment:

Date	Location	User	Value	Reason
Sep-29-2020 14:28:45 (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
Sep-29-2020 14:28:45 (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
Sep-29-2020 14:28:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit
on Sep/28/2020**Form Version:** 06-Jul-2020 21:55**Site No:** 1081**Subject No:** 10811110**Generated By:** pfe.levissc**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - 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[Back to Form](#)**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Sep-29-2020 14:29:09 (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
Sep-29-2020 14:29:09 (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
Sep-29-2020 14:29:09 (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
Sep-29-2020 14:29:09 (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
Sep-29-2020 14:29:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/28/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Date	Location	User	Value	Reason
Sep-29-2020 14:29:09 (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 **Form:** IMAGING - eCRF Audit Trail History
on Sep/28/2020

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: 10811110

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
Sep-29-2020 14:29:30 (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
Sep-29-2020 14:29:30 (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
Sep-29-2020 14:29:30 (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
Sep-29-2020 14:29:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Oct/19/2020**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:** 10811110**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Date of Visit**

Date	Location	User	Value	Reason
Oct-19-2020 15:22:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-19-2020 10:46:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Oct-19-2020 10:45:12 (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-19-2020 10:45:12 (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 missing. Please review and update as appropriate.
Oct-19-2020 10:45:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Oct/19/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Oct-19-2020 10:45:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_B	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Date of Assessment:

Date	Location	User	Value	Reason
Oct-19-2020 10:46:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Oct/19/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Oct-19-2020 10:46:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Oct/11/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Dec-15-2020 09:00:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nicholas Roosa (pfe.roosan)	Query 1: Closed	Response satisfies query
Dec-09-2020 12:15:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	Per Sub-I, Jim Fry, the mentioned fatigue from 09Nov2020 progress note was not affecting the subjects ADL's therefore no change needed for end date. Will keep date as the date of discharge from hospital, 02Nov2020. This has been noted on Conv Visit B1 SD
Dec-08-2020 10:29:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nicholas Roosa (pfe.roosan)	Query 1: Opened	Per source, patient still feeling "very fatigued" after 02Nov2020 hospital admission.

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020**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:** 10811110**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11

				Convalescent visit occurred on 17Nov2020
Nov-17-2020 14:52:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO Date of Last Symptom Resolved: Nov/2/2020	New Information
Oct-19-2020 10:46:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Oct-19-2020 10:46:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptoms: FEVER Symptom Present: YES	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Oct-19-2020 10:46:11 (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-19-2020 10:46:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES	Initial Entry

4.b

Date	Location	User	Value	Reason
Oct-19-2020 10:46:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptoms: NEW OR INCREASED COUGH	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1081**Subject No:** 10811110**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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

			Symptom P NO resent:	
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4.b Symptoms:

Date	Location	User	Value	Reason
Oct-19-2020 10:46:11 (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-19-2020 10:46:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Oct-19-2020 10:46:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Sympto NEW OR INCREASED ms: SHORTNESS OF BRE ATH Sympto NO m Prese nt:	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Oct-19-2020 10:46:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NEW OR INCREASED SHORTN ESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Oct-19-2020 10:46:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

4.d

Date	Location	User	Value	Reason
Oct-19-2020 10:46:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptoms: CHILLS Symptom Present: YES	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Oct-19-2020 10:46:11 (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-19-2020 10:46:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES	Initial Entry

4.e

Date	Location	User	Value	Reason
Oct-19-2020 10:46:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptoms NEW OR INCREASE : D MUSCLE PAIN Symptom YES Present:	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1081**Subject No:** 10811110**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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**4.e Symptoms:**

Date	Location	User	Value	Reason
Oct-19-2020 10:46:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Oct-19-2020 10:46:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES	Initial Entry

4.f

Date	Location	User	Value	Reason
Oct-19-2020 10:46:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptoms: NEW LOSS OF TAS TE OR SMELL Symptom NO Present:	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Oct-19-2020 10:46:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NEW LOSS OF TASTE OR SMEL L	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Oct-19-2020 10:46:11 (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-19-2020 10:46:11 (UTC-05:00) Eastern	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Time (US & Canada)			Symptoms NEW OR INCREASE : D SORE THROAT Symptom NO Present:
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4.g Symptoms:

Date	Location	User	Value	Reason
Oct-19-2020 10:46:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NEW OR INCREASED SORE TH ROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Oct-19-2020 10:46:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Oct-19-2020 10:46:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptoms: DIARRHEA Symptom Present: NO	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Oct-19-2020 10:46:11 (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-19-2020 10:46:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

4.i

090177e196ae3efa\Final\On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020**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:** 10811110**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11

Date	Location	User	Value	Reason
Oct-19-2020 10:46:11 (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-19-2020 10:46:11 (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-19-2020 10:46:11 (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-19-2020 10:46:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptoms - Other: Fatigue	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Oct-23-2020 09:51:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nicholas Roosa (pfe.roosan)	Query 1: Closed	Response satisfies query
Oct-23-2020 08:38:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	RLL pneumonia with pleural effusion has been added
Oct-22-2020 16:05:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lisa Metschuleit (pfe.metscl)	Query 1: Opened	Per source, please add Right Lower Lobe Pneumonia with a pleural effusion to other

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

				symptoms section
Oct-19-2020 10:46:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Fatigue	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-19-2020 10:46:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Symptoms - Other: Right lower rib chest pain	Initial Entry

5.b Symptoms - Other Text:

Date	Location	User	Value	Reason
Oct-19-2020 10:46:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Right lower rib chest pain	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-23-2020 08:37:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms - Other: RLL pneumonia with pleural effusion	Initial Entry

5.c Symptoms - Other Text:

Date	Location	User	Value	Reason
Oct-23-2020 08:37:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: RLL pneumonia with pleural effusion	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020 **Form:** MICROBIOLOGY SPECIMEN - Audit Trail

Form Version: 06-Jul-2020 21:54

Form Status:

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811110

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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Date	Location	User	Value	Reason
Oct-19-2020 10:47:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Oct/19/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Oct-19-2020 10:47:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Oct/16/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Oct-19-2020 10:47:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: SWABBED MATERIAL	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Oct-19-2020 10:47:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NASOPHARYNX	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Oct-19-2020 10:47:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYNDRO ME CORONAVIRUS 2	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Oct-19-2020 10:47:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC TES T	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Nov-04-2020 13:05:47 (UTC-05:00) Eastern	ACV0PFEINFP6000	Gbenga Akinkunmi	Query 3: Closed	Response satisfies query

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
on Oct/19/2020**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:** 10811110**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11

Time (US & Canada)		(pfe.akinkg)		
Nov-04-2020 10:14:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Initial Entry
Nov-04-2020 10:14:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: OTHER	Initial Entry
Nov-01-2020 17:10:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Campbell (pfe.campbm25)	Query 2: Closed	moving query to correct item
Nov-01-2020 17:09:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Campbell (pfe.campbm25)	Query 3: Opened	select OTHER if Trade name is currently Unavailable and update Trade Name Other, Specify field below per CCG 8.31.4
Nov-01-2020 17:07:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Campbell (pfe.campbm25)	Query 2: Opened	Per CCG 8.31.7 If manufacturer/test kit name is not available, please indicate whether the test type was "SARS COV-2 test CLIA-certified lab" OR "SARS COV-2 test ISO 15189 accredited lab" in the Trade Name Other Specify Field on this form or clarify.
Nov-01-2020 17:01:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Campbell (pfe.campbm25)	Query 1: Closed	Update query text for clarity
Oct-30-2020 21:47:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Steven Finegan Prod (pfe.finegansm)	Query 1: Reissued:Opened	Trade name is not available as of today, keep in candidate and follow up later.
Oct-27-2020 15:12:08	ACV0PFEINFP6000	Erica Weaver	Query 1: Reissued:Candidate	Trade name is not

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
on Oct/19/2020**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:** 10811110**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 10:11

(UTC-05:00) Eastern Time (US & Canada)		(pfe.weavee01)		available as of today, keep in candidate and follow up later.
Oct-27-2020 14:34:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Query 1: Answered	We have reported several times this information is not available to us at this time.
Oct-26-2020 08:02:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pratiksha Mahadik (pfe.mahadp07)	Query 1: Reissued:Opened	DM1: Kindly review if data is available and provide 'Trade name' on this page to avoid yellow traffic light. Thank you.
Oct-23-2020 14:49:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Behnaz Yousefzadeh-Khiabani (pfe.youseb01)	Query 1: Reissued:Candidate	Records have been requested. Query the site later.
Oct-23-2020 10:05:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	records have been requested, no information available currently
Oct-23-2020 09:49:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Behnaz Yousefzadeh-Khiabani (pfe.youseb01)	Query 1: Reissued:Opened	DM: The response for "Trade name" is missing. Kindly review and update.
Oct-22-2020 06:35:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Teena Patra (pfe.patrat02)	Query 1: Reissued:Candidate	Will wait for trade name
Oct-21-2020 16:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Query 1: Answered	Information is not available. Records have been requested.
Oct-20-2020 07:20:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rajashekhar Reddy (pfe.reddy51)	Query 1: Opened	DM: The response for "Trade name" is missing. Kindly review and update.

7. Test Result:

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
on Oct/19/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Date	Location	User	Value	Reason
Oct-19-2020 10:47:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NEGATIVE	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Nov-04-2020 15:11:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pamela Benne prod (pfe.bennep07)	Query 1: Closed	Response satisfies query
Nov-04-2020 10:14:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Nov-04-2020 10:14:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NALT Unknown	Initial Entry
Nov-01-2020 17:11:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Campbell (pfe.campbm25)	Query 1: Opened	Per CCG 8.31.7 If manufacturer/test kit name is not available, please indicate whether the test type was "SARS COV-2 test CLIA-certified lab" OR "SARS COV-2 test ISO 15189 accredited lab" in the Trade Name Other Specify Field on this form or clarify

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Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit
on Oct/19/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1081**Subject No:** 10811110**Generated By:** pfe.lewissc**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF -
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[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-19-2020 15:22:28 (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-19-2020 15:22:28 (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-19-2020 15:22:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-19-2020 15:22:28 (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-19-2020 15:22:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Oct/19/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-19-2020 15:22:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: CV22425	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.a Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 15:22:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: CV22425	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit
on Oct/19/2020**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:** 10811110**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-19-2020 10:47:54 (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-19-2020 10:47:54 (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
Oct-19-2020 10:47:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Oct-19-2020 10:47:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: telehealth visit	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Oct/19/2020

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: 10811110

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-19-2020 10:48:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Type of Practitioner: SPECIA LIST Occurrence of Visits or NO Contacts:	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-19-2020 10:48:23 (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-19-2020 10:48:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Nov-09-2020 07:36:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of YES Visits or Conta Number of Vis cts: its or Contacts : 1	New Information
Oct-19-2020 10:48:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Type of Practitioner: EMERGEN CY ROOM	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Oct/19/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

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			Occurrence of Visits or Contacts:	
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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Oct/19/2020

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: 10811110

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-19-2020 10:48:23 (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
Nov-09-2020 11:21:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Maria Sullivan (pfe.sullim38)	Query 1: Closed	Response satisfies query
Nov-09-2020 07:36:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Nov-09-2020 07:36:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	New Information
Nov-08-2020 06:55:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	William Steward (pfe.stewaw06)	Query 1: Reissued:Opened	Page is unfrozen, please update as per CRA query. Thanks.
Nov-05-2020 14:57:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	Page is not allowing for changes, please unlock
Nov-05-2020 12:59:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nicholas Roosa (pfe.roosan)	Query 1: Opened	Per source, patient went to the emergency room on Oct 23. Please update as applicable.
Oct-19-2020 10:48:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

I.c

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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Oct/19/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Date	Location	User	Value	Reason
Oct-19-2020 10:48:23 (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: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-19-2020 10:48:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-19-2020 10:48:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

1.d

Date	Location	User	Value	Reason
Oct-19-2020 10:48:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: NO	Initial Entry

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Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Oct/19/2020**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:** 10811110**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11***1.d Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Oct-19-2020 10:48:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-19-2020 10:48:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Oct-19-2020 10:48:23 (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

1.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-19-2020 10:48:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-19-2020 10:48:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

1.f

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Oct/19/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Oct-19-2020 10:48:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Type of Practitioner: OTHE R Occurrence of Visits or C NO ontacts:	Initial Entry
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1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-19-2020 10:48:23 (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-19-2020 10:48:23 (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-19-2020 10:48:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit Form: RESPIRATORY TREATMENT - eCRF Audit Trail History on Oct/19/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. What is the treatment Identifier?

Date	Location	User	Value	Reason
Oct-19-2020 10:48:52 (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-19-2020 10:48:52 (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-19-2020 10:48:52 (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-19-2020 10:48:52 (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-19-2020 10:48:52 (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-19-2020 10:48:52	ACV0PFEINFP6000	James Fry	Data Entry:	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History on Oct/19/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

(UTC-05:00) Eastern
Time (US & Canada)

(pfe.jfry)

Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History
on Oct/19/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Oct-19-2020 10:49:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNES S	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Oct-22-2020 06:36:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Teena Patra (pfe.patrat02)	Query 2: Close d	Response satisfies query
Oct-21-2020 16:53:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Query 2: Ans wered	WE just received guidelines that say any COVID symptoms should generate a COVID illness visit.
Oct-20-2020 02:24:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Derrick Newton (pfe.newtod07)	Query 2: Open ed	DM: Please confirm if "Pneumonia" needs to be recorded as AE, Thank you.
Oct-19-2020 19:17:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Close d	Discrepancy has been closed.
Oct-19-2020 15:25:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ans wered	Changed Information

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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit Form: ILLNESS DETAILS - eCRF Audit Trail History on Oct/19/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

<p>Oct-19-2020 15:25:02 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>James Fry (pfe.jfry)</p>	<p>Data Entry: YES <i>Respiratory Illness Diagnosis:</i> Right lower lobe pneumonia Date of Diagnosis: Oct/16/2020</p>	<p>Changed Information</p>
<p>Oct-19-2020 14:07:09 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000.InFormAdapter.Discrepancy</p>	<p>PFETMS Oracle (pfe.PFETMS)</p>	<p>Query 1: Opened</p>	<p>Multiple concepts in the term RIGHT LOWER LOB PNEUMONIA WITH PLEURAL EFFUSION. Split the term into RIGHT LOWER LOB PNEUMONIA and PLEURAL EFFUSION and submit separately. Thank you.</p>
<p>Oct-19-2020 10:49:30 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>James Fry (pfe.jfry)</p>	<p>Data Entry: YES <i>Respiratory Illness Diagnosis:</i> Right lower lobe pneumonia with pleural effusion</p>	<p>Initial Entry</p>

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History
on Oct/19/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

			Date of Diagnosis: Oct/16/2020	
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3. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-19-2020 10:49:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> 2	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail History on Oct/19/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Oct-19-2020 10:49:43 (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-19-2020 10:49:43 (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-19-2020 10:49:43 (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-19-2020 10:49:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History on Oct/19/2020

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: 10811110

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-19-2020 10:50:09 (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-19-2020 10:50:09 (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-19-2020 10:50:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit
on Oct/19/2020**Form Version:** 06-Jul-2020 21:55**Site No:** 1081**Subject No:** 10811110**Generated By:** pfe.levissc**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - 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[Back to Form](#)**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Oct-19-2020 10:50:27 (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-19-2020 10:50:27 (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-19-2020 10:50:27 (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-19-2020 10:50:27 (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-19-2020 10:50:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1081

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Subject Initials: ---

Generated By: pfe.levisse

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Date	Location	User	Value	Reason
Oct-19-2020 10:50:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Not Applicable	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** IMAGING - Audit Trail
on Oct/19/2020

Form Version: 06-Jul-2020 21:53

Form Status:

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811110

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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Date	Location	User	Value	Reason
Oct-19-2020 10:51:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit Form: IMAGING - eCRF Audit Trail History on Oct/19/2020

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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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1. Date of Assessment:

Date	Location	User	Value	Reason
Oct-19-2020 10:51:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Oct/16/2020	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Oct-19-2020 10:51:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: CHEST	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Oct-19-2020 10:51:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: X-RAY	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Oct-19-2020 10:51:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: ABNORMAL <i>If abnormal, specify findings:</i> Right lower lobe pneumonia with pleural effusion	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Nov/17/2020

Form: DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811110

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Date of Visit

Date	Location	User	Value	Reason
Nov-17-2020 14:49:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Nov/17/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Nov-17-2020 14:49:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: COVID_B1	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled
Visit on Nov/17/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1081**Subject No:** 10811110**Generated By:** pfe.lewissc**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
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[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Nov-17-2020 14:50:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-17-2020 14:50:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-17-2020 14:51:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-17-2020 14:50:57 (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.
Nov-17-2020 14:50:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Nov/17/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-17-2020 14:51:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BKN9MD	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled
Visit on Nov/17/2020**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
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:** 10811110**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11**5.a Sample ID**

Date	Location	User	Value	Reason
Nov-17-2020 14:51:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: BKN9MD	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-17-2020 14:51:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: Sample ID: BKN9MF	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-17-2020 14:51:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: BKN9MF	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-17-2020 14:51:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: Sample ID: BS64R6	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-17-2020 14:51:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: BS64R6	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-17-2020 14:51:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: Sample ID: BS64R7	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Nov/17/2020

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
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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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.d Sample ID

Date	Location	User	Value	Reason
Nov-17-2020 14:51:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	<u>Data Entry:</u> BS64R7	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1081

Subject No: 10811110

Generated By: pfe.lewissc

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-14-2020 09:20:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Oct/14/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-14-2020 09:20:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-14-2020 09:20:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: COMPLETED	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1081

Subject No: 10811110

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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Subject Initials: ---

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Date	Location	User	Value	Reason
Oct-27-2020 14:52:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811110

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1081) Sterling Research Group - Mt. Auburn

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Date	Location	User	Value	Reason
Oct-27-2020 14:57:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1081

Subject No: 10811110

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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Subject Initials: ---

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1. Category:

Date	Location	User	Value	Reason
Oct-27-2020 14:52:00 (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
Oct-27-2020 14:52:00 (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
Oct-27-2020 14:52:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Right lower lobe pneumonia	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-01-2020 08:42:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	SDB onset date updated to 11Oct2020
Oct-28-2020 05:04:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON: AER#2020415413
Oct-27-2020 14:52:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Oct/11/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-20-2020 08:27:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO End Date Time:	New Information

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			Nov/18/2020 UNK:UNK	
Oct-27-2020 14:52:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-27-2020 14:52:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: 3	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-04-2020 12:03:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Closed	Response satisfies query
Nov-04-2020 12:02:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Closed	Query closed; will follow for SAE update with the requested COVID test info
Nov-04-2020 11:11:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 3: Answered	COVID testing results have been reported in the most recent SAE, per SI Jim Fry, MS, PA-C
Nov-04-2020 11:10:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 4: Answered	COVID testing results have been reported in the most recent SAE, per SI Jim Fry, MS, PA-C
Oct-28-2020 11:14:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Opened	Clinical COVID testing during HOSPITALIZATION

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1081**Subject No:** 10811110**Generated By:** pfe.levisse**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

				was not reported in the SAE submitted to safety. Please submit a follow-up SAE form [add AER#] to provide whether COVID testing was performed (yes/no) in Hosp and if yes, the results
Oct-28-2020 11:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	need to add 'clinical'
Oct-28-2020 11:13:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Opened	Clinical COVID testing PRIOR to hospital admission was reported in the SAE. Please confirm if this occurred on 16Oct2020 (primary MD appt) or other date, and submit date as a SAE followup.
Oct-28-2020 11:11:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	COVID testing during HOSPITALIZATION was not reported in the SAE submitted to safety. Please submit a follow-up SAE form [add AER#] to provide whether COVID testing was performed (yes/no) in Hosp and if yes, the results.
Oct-28-2020 04:59:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-27-2020 14:52:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Right lower lobe pneumonia: Response to "Is the adverse event serious?" is 'Yes' but

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				"Serious Adverse Event Number" is blank.
Oct-27-2020 14:52:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<p>Data Entry:</p> <p>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>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</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>NO</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
Oct-27-2020 14:52:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<p>Data Entry:</p> <p>NO</p>	Initial Entry

Header Text: c4591001

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Generated By: pfe.levisse

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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-27-2020 14:52:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: idiopathic	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-27-2020 14:52:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-27-2020 14:52:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-27-2020 14:52:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Nov-20-2020 12:30:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-20-2020 12:30:01 (UTC-05:00) Eastern	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: RECOVERED/RESOLVED	New Information

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Subject Initials: ---

Generated By: pfe.levissc

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Time (US & Canada)				
Nov-20-2020 08:27:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Right lower lobe pneumonia: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Oct-27-2020 14:52:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: RECOVERING/RESOLVING	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-27-2020 14:52:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Oct-28-2020 04:59:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Data Entry: 2020415413	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811110

Generated By: pfe.levisse

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
Oct-27-2020 14:57:11 (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
Oct-27-2020 14:57:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-03-2020 07:28:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	Response satisfies query
Nov-02-2020 13:35:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Nov-02-2020 13:35:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: loculated empyema	New Information
Nov-01-2020 09:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON: AER#2020415413, the term in Safety database was updated to 'loculate empyema' while retained as right pleural effusion in AE CRF. Please confirm correct term. If safety update is required, please submit a follow-up SAE form.

090177e196ae3efa\Final\On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1081**Subject No:** 10811110**Generated By:** pfe.levisse**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

Oct-27-2020 14:57:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Right pleural effusion	Initial Entry
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4. Start Date Time:

Date	Location	User	Value	Reason
Nov-01-2020 09:09:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	SDB onset date updated
Oct-28-2020 05:05:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON: AER#2020415413
Oct-27-2020 14:57:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Oct/11/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-20-2020 08:27:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO End Date Time: Nov/18/2020 UNK:UNK	New Information
Oct-27-2020 14:57:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-27-2020 14:57:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: 3	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**

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811110

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

require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-28-2020 05:03:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-27-2020 14:57:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Right pleural effusion: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Oct-27-2020 14:57:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/in capacity? NO Is this serious event life threatening? NO Other medically important serious event	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

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Subject No: 10811110

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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			NO	
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8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-27-2020 14:57:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-27-2020 14:57:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: idiopathic	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-27-2020 14:57:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-27-2020 14:57:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-27-2020 14:57:11 (UTC-05:00) Eastern	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (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: 10811110

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Time (US & Canada)

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Nov-20-2020 12:30:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-20-2020 12:30:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> RECOVERED/RESOLVED	New Information
Nov-20-2020 08:27:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE loculated empyema: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Oct-27-2020 14:57:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> RECOVERING/RESOLVING	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-27-2020 14:57:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Oct-28-2020 05:03:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	<u>Data Entry:</u> 2020415413	Initial Entry

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Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811110

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-18-2021 10:30:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Jan/18/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1081

Subject No: 10811110

Generated By: pfe.lewissc

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History

Form Status: Data Complete, Frozen

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 - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Jan-18-2021 10:31:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-18-2021 10:31:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-18-2021 10:31:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811110

Generated By: pfe.lewissc

Form: TREATMENT UNBLINDED - 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 Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-18-2021 10:31:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Jan/18/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-18-2021 10:31:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811110

Generated By: pfe.levisse

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, 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 Status

Date	Location	User	Value	Reason
Oct-14-2020 09:20:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-26-2020 17:08:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-26-2020 13:25:38 (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
Oct-14-2020 09:20:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/14/2020	Initial Entry
Aug-26-2020 17:08:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/26/2020	Initial Entry
Aug-26-2020 13:25:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/26/2020	Initial Entry

090177e196ae3efa\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811110

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Casebook Signature

Date	Location	User	Value	Reason
Oct-23-2020 14:30:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Click Here to Enable	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levissc

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: 10811135

Generated By: pfe.lewissc

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 Aug/31/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1081

Subject No: 10811135

Generated By: pfe.lewissc

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	[10811135]
2.	Birth Date:	(b) (6)/1971
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	BLACK OR AFRICAN AMERICAN
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811135

Generated By: pfe.lewissc

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	Aug/31/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1081

Subject No: 10811135

Generated By: pfe.lewissc

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 Applicable
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Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable
----	---	----------------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811135

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	Aug/31/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811135

Generated By: pfe.lewissc

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

Form Comments

Medical History Details

1.	Line/MH Number:	Not Applicable _____ []
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	Not Applicable _____ []
	Start Date:	Not Applicable _____ //
	Ongoing:	Not Applicable _____

090177e196ae3f02\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: 10811135

Generated By: pfe.lewissc

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:	Aug/31/2020
2.	Weight:	[243.8]
3.	Unit:	LB
4.	Height:	[70.0]
5.	Unit:	in
6.	Body Mass Index:	[35.0]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.3]
	Unit:	F
	Temperature Location:	FOREHEAD

090177e196ae3f02\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: 10811135

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 :	Aug/31/2020
2.	Randomization Number:	[75008]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811135

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: Aug/31/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP981W]
5.b	Sample ID	[BP981V]
5.c	Sample ID	[BP981T]
5.d	Sample ID	[BPHZNJ]
5.e	Sample ID	[BPHZNK]

090177e196ae3f02\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: 10811135

Generated By: pfe.lewissc

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: Aug/31/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP97L0]
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090177e196ae3f02\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: 10811135

Generated By: pfe.lewissc

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:	Aug/31/2020 12:15
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1081

Subject No: 10811135

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: 10811135

Generated By: pfe.lewissc

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/22/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1081

Subject No: 10811135

Generated By: pfe.lewissc

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/22/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.0]
	Unit:	F
	Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811135

Generated By: pfe.lewissc

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/22/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP97V6]
-----	-----------	----------

090177e196ae3f02\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: 10811135

Generated By: pfe.lewissc

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/22/2020 12:18
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

090177e196ae3f02\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: 10811135

Generated By: pfe.lewissc

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/21/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811135

Generated By: pfe.lewissc

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: Oct/21/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP1HYL]
5.b	Sample ID	[BP1HYM]
5.c	Sample ID	[BS64KK]
5.d	Sample ID	[BS64KL]

090177e196ae3f02\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET
on Oct/26/2020

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: 10811135

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

[Form Comments](#)
[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/26/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Oct/26/2020

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: 10811135

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

[Form Comments](#)
[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Oct/26/2020	Comments
2.	Date of First Symptom Started:	Oct/21/2020	Comments
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Oct/27/2020	Comments

Symptoms

4.a	Symptoms:	FEVER	
	Was symptom present?	NO	Comments
4.b	Symptoms:	NEW OR INCREASED COUGH	
	Was symptom present?	NO	Comments
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH	
	Was symptom present?	YES	Comments
4.d	Symptoms:	CHILLS	
	Was symptom present?	NO	Comments
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN	
	Was symptom present?	NO	Comments
4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL	
	Was symptom present?	NO	Comments
4.g	Symptoms:	NEW OR INCREASED SORE THROAT	
	Was symptom present?	NO	Comments
4.h	Symptoms:	DIARRHEA	
	Was symptom present?	NO	Comments

090177e196ae3f02\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
on Oct/26/2020

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: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

4.i	Symptoms:	VOMITING	
	Was symptom present?	NO	Comments

Symptoms - Other

5.a	Symptoms - Other Text:	[burning in chest]
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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: 10811135

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.	Oct/26/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN
on Oct/26/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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[Form Comments](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Microbiology Specimen

1.	Actual Date of Collection:	Oct/26/2020	Comments
2.	Specimen Type:	SWABBED MATERIAL	Comments
3.	Specimen Collection Location:	NASOPHARYNX	Comments
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	Comments
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST	Comments
6.	Trade Name:	OTHER	Comments
7.	Test Result:	NEGATIVE	Comments
8.	Comments/Findings/Details:	[all data is per pt, we have still not received the hospital records]	Comments
9.	Trade Name Other, Specify:	[NALT Unknown]	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Oct/26/2020

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: 10811135

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
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Self Swab was requested by office, subject not staying at home and did not have access to self swab kit]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3f02\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/26/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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: 10811135

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 was requested by office, subject not staying at home and did not have access to self swab kit]	Comments

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
----	-----------	-----

090177e196ae3f02\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION
on Oct/26/2020**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:** 10811135**Subject Initials:** ---**Generated By:** pfe.lewissc**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:	YES Number of Visits or Contacts: [1]
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [1]
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
----	--	----

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: 10811135

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.						Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT
on Oct/26/2020

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Respiratory Treatment

1.	What is the treatment Identifier?	[]
2.	Concomitant Non-drug Treatment Pre-specified:	
3.	Treatment:	
4.	Treatment:	[]
5.	Start Date:	//
6.	Ongoing?	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS
on Oct/26/2020

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: 10811135

Subject Initials: ---

Generated By: pfe.levisse

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:	4

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: 10811135

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.					Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE
on Oct/26/2020

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Illness Details

1.	Category of Clinical Event:	
2.	Subcategory of Clinical Event:	
3.	Was a diagnosis obtained?	
4.	Toxicity Grade:	

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 21-Aug-2020 02:49

Site No: 1081

Subject No: 10811135

Generated By: pfe.levissc

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	Repeating Pages

090177e196ae3f02\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Oct/26/2020

Form Version: 21-Aug-2020 02:49

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Lab Chemistry Details

1.	Lab Panel:	
2.	Laboratory Name and Address	[]
3.	Collection Date:	//
4.	Specimen Type:	

Lab Result

5.	Sponsor ID:	[]
	Test:	
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

090177e196ae3f02\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: 10811135

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

#	Category for Lab Test	Vendor Name (DE RIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	Repeating Pages

090177e196ae3f02\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
on Oct/26/2020

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Laboratory Data Hematology

1.	Lab Panel:	
2.	Laboratory Name and Address	[]
3.	Collection Date:	//
4.	Specimen Type:	

Lab Result

5.	Sponsor ID:	[]
	Test:	
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

090177e196ae3f02\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: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

#	Date:	Vital Signs Details			Form Instance
1.		Record Identifier:	Systolic:	Diastolic:	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Oct/26/2020

Form Version: 21-Aug-2020 02:50

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Vital Signs

1.	Date:	//
----	-------	----

Vital Signs Details

2.	Record Identifier:	
	Systolic:	[]
	Diastolic:	[]
	Respiratory Rate in respirations/minute:	[]
	Heart Rate in beats/minute:	[]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

#	Date:	Vital Signs Details		Form Instance
1.		Record Identifier:	Oxygen Saturation	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Oct/26/2020

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Vital Signs

1.	Date:	//
----	-------	----

Vital Signs Details

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

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.				Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS
on Oct/26/2020

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Oxygenation Parameters

1.	Date Time of Assessment:	//
2.	Arterial Blood Gases PaO2 (mmHg):	[]
3.	FiO2 (Fraction of Inhaled Oxygen):	[]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

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: POT_COVID_ILL 1 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
on Oct/26/2020

Form Version: 06-Jul-2020 21:55

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Concomitant Medications

1.	What is the medication identifier?	[]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[]
5.	Start Date:	//
6.	Ongoing?	

090177e196ae3f02\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: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING
on Oct/26/2020

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Imaging

1.	Date of Assessment:	//
2.	Location of Assessment:	
3.	Type of Imaging Exam:	
4.	Assessment:	

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Nov/23/2020

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Nov/23/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A1
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Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Nov/23/2020

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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: 10811135

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	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/23/2020
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	[BS64RG]
5.b	Sample ID	[BS64RH]
5.c	Sample ID	[BKN9MP]
5.d	Sample ID	[BKN9MR]

090177e196ae3f02\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Feb/19/2021

Form: DATE OF VISIT

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: 10811135

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Feb/19/2021
2.	Erroneous Visit	ERRONEOUS VISIT

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Feb/19/2021

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

[Form Comments](#)
[eCRF Audit Trail History](#)

Unplanned Assessments

1.	Assessments	Not Done	Comments
----	-------------	----------	--------------------------

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/19/2021

Form: CONTACT OUTCOME - UNPLANNED

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

[Form Comments](#)
[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	Not Done _____	Comments
2.	Was contact made?	Not Done _____	Comments
3.	Comments:	Not Done _____ []	Comments

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Feb/19/2021

Form: VITAL SIGNS - TEMP

Form Version: 20-Feb-2021 02:16

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

[Form Comments](#)
[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Not Done _____ //	Comments
----	-------	-------------------------	--------------------------

Vital Signs Details

2.a	Record Identifier:	Not Done _____ 1	
	Temperature:	Not Done _____ []	Comments
	Unit:	Not Done _____	Comments
	Temperature Location:	Not Done _____	Comments

090177e196ae3f02\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: 10811135

Generated By: pfe.lewissc

Form: DISPOSITION - TREATMENT

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 - Treatment

1.	Date of Completion/Discontinuation/Death :	Oct/21/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1081

Subject No: 10811135

Generated By: pfe.levissc

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Disposition - Follow-Up

1.	Date of Completion/Discontinuation/Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[]

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
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: 10811135

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 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: 10811135

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: 10811135

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Myocardial Infarction	Oct/21/2020 UNK:UNK	NO End Date Time: Oct/28/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	Type II Diabetes Mellitus	Oct/27/2020 UNK:UNK	YES	Repeating Pages
3. DELETED	ADVERSE EVENT	3	Coronary stent placement	Oct/21/2020 UNK:UNK	NO End Date Time: Oct/27/2020 UNK:UNK	Repeating Pages
4.	ADVERSE EVENT	4	New onset Essential Hypertension	Aug/31/2020 12:11	YES	Repeating Pages
5.	ADVERSE EVENT	5	New onset Unspecified Hyperlipidemia	Oct/29/2020 UNK:UNK	YES	Repeating Pages
6.	ADVERSE EVENT	6	Coronary Artery disease	Nov/4/2020 UNK:UNK	YES	Repeating Pages

090177e196ae3f02\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: 10811135

Generated By: pfe.levisse

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:	Oct/21/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/28/2020 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? NO Did this serious event require or prolong hospitalization? YES 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

090177e196ae3f02\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: 10811135

Generated By: pfe.levisse

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

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: [Cardiac Event]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED WITH SEQUELAE
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020423661]

090177e196ae3f02\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: 10811135

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Type II Diabetes Mellitus]
4.	Start Date Time:	Oct/27/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event YES
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

090177e196ae3f02\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: 10811135

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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: [Insulin Resistance]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020423661]

090177e196ae3f02\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001		
Visit: Logs - Unscheduled		Form: ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02		Form Status: Data Complete, Deleted, Verified
Site No: 1081		Site Name: (1081) Sterling Research Group - Mt. Auburn
Subject No: 10811135		Subject Initials: ---
Generated By: pfe.levisse		Generated Time (GMT): 29-Mar-2021 10:11
*** THIS REPEATING FORM HAS BEEN DELETED ***		
Back to Form eCRF Audit Trail History Form Audit Trail		
Adverse Event Report		
1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Coronary stent placement]
4.	Start Date Time:	Oct/21/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/27/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES 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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811135

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

*** THIS REPEATING FORM HAS BEEN DELETED ***

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: [Cardiac Event]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020423661]

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811135

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[New onset Essential Hypertension]
4.	Start Date Time:	Aug/31/2020 12:11
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Idiopathic]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae3f02\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: 10811135

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811135

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[New onset Unspecified Hyperlipidemia]
4.	Start Date Time:	Oct/29/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Idiopathic]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae3f02\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: 10811135

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae3f02\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: 10811135

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[6]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Coronary Artery disease]
4.	Start Date Time:	Nov/4/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Idiopathic]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811135

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae3f02\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: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1081

Subject No: 10811135

Generated By: pfe.levisse

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	[]

090177e196ae3f02\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: 10811135

Subject Initials: ---

Generated By: pfe.levisse

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.	1	VACCINATIONS	NO	Flu Vaccination	Oct/28/2020	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

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?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Flu Vaccination]
5.	Date:	Oct/28/2020

090177e196ae3f02\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: 10811135

Subject Initials: ---

Generated By: pfe.levisse

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: 10811135

Generated By: pfe.levisse

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?	

090177e196ae3f02\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: 10811135

Subject Initials: ---

Generated By: pfe.levisse

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: 10811135

Generated By: pfe.levisse

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: 10811135

Subject Initials: ---

Generated By: pfe.levisse

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: 10811135

Generated By: pfe.levisse

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

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: 10811135

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: 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: 10811135

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:** 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:** 10811135**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?	

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: 10811135

Subject Initials: ---

Generated By: pfe.lewissc

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: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Contact Outcome

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[]

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Feb/5/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Queries

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	---

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811135

Generated By: pfe.lewissc

Form: TREATMENT UNBLINDED

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

Treatment Unblinded

1.	Date Treatment Unblinded :	Feb/5/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001	Form: WITHDRAWAL OF CONSENT
Visit: Disposition - Unscheduled	Form Status: Not Started
Form Version: 22-Apr-2020 21:03	Site Name: (1081) Sterling Research Group - Mt. Auburn
Site No: 1081	Subject Initials: ---
Subject No: 10811135	Generated Time (GMT): 29-Mar-2021 10:11
Generated By: pfe.levisse	

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: 10811135

Generated By: pfe.levisse

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Death Details

1.	Date of Collection / Notification of Death:	//
----	---	----

Cause of Death

2.	Cause of Death Status:	
	Cause of Death:	[]

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811135

Generated By: pfe.lewissc

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: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1081

Subject No: 10811135

Generated By: pfe.lewissc

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Informed Consent - Further Vaccination

1.	Consent Was:	
----	--------------	--

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	
----	--	--

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	
----	--	--

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1081

Subject No: 10811135

Generated By: pfe.levisse

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation/Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[]

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811135

Generated By: pfe.levissc

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	FOLLOW-UP
2.	Subject Status Date	Oct/21/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
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Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

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
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1081

Subject No: 10811135

Generated By: pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-31-2020 14:16:41 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811135

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-31-2020 14:17:46 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - Comments on Oct/26/2020

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: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-02-2020 08:16:28 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Due to urgency of symptoms, complete telehealth visit was not performed. Multiple attempted have been made to contact the subject for f/u, all have been unsuccessful as of 29Oct2020. Waiting on records from hospital to update all data for this CRF
Form	Oct-29-2020 14:28:07 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Due to urgency of symptoms, complete telehealth visit was not performed. Multiple attempted have been made to contact the subject for f/u, all have been unsuccessful as of 29Oct2020
Form	Oct-29-2020 14:27:09 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Subject has been advised to go to ER immediately. Will follow-up with subject on 27Oct2020. Due to urgency of symptoms, complete telehealth visit was not performed
Form	Oct-27-2020 07:49:08 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Subject has been advised to go to ER immediately. Will follow-up with subject on 27Oct2020

090177e196ae3f02\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/26/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - Comments

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: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-02-2020 07:43:14 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Due to urgency of symptoms, a full telehealth visit was not completed. All attempts to contact subject have been unsuccessful as of 29Oct2020
Form	Oct-29-2020 14:32:07 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Due to urgency of symptoms, a full telehealth visit was not completed. All attempts to contact subject have been unsuccessful as of 29Oct2020 <hr/> Not Applicable
Form	Oct-29-2020 14:31:17 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Due to urgency of symptoms, a full telehealth visit was not completed. All attempts to contact subject have been unsuccessful as of 29Oct2020
Form	Oct-26-2020 14:50:46 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Subject has been advised to go to ER immediately. Will follow-up with subject on 27Oct2020

090177e196ae3f02\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -
Comments

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
1	Nov-02-2020 07:43:14 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Due to urgency of symptoms, a full telehealth visit was not completed. All attempts to contact subject have been unsuccessful as of 29Oct2020
1	Oct-29-2020 14:32:07 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Due to urgency of symptoms, a full telehealth visit was not completed. All attempts to contact subject have been unsuccessful as of 29Oct2020 <hr/> Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -
Comments

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
2	Nov-02-2020 07:43:14 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Due to urgency of symptoms, a full telehealth visit was not completed. All attempts to contact subject have been unsuccessful as of 29Oct2020
2	Oct-29-2020 14:32:07 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Due to urgency of symptoms, a full telehealth visit was not completed. All attempts to contact subject have been unsuccessful as of 29Oct2020 <hr/> Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -
Comments

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
3	Nov-02-2020 07:43:14 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Due to urgency of symptoms, a full telehealth visit was not completed. All attempts to contact subject have been unsuccessful as of 29Oct2020
3	Oct-29-2020 14:32:07 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Due to urgency of symptoms, a full telehealth visit was not completed. All attempts to contact subject have been unsuccessful as of 29Oct2020 <hr/> Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -
Comments

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
4.a	Nov-02-2020 07:43:14 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Due to urgency of symptoms, a full telehealth visit was not completed. All attempts to contact subject have been unsuccessful as of 29Oct2020
4.a	Oct-29-2020 14:32:07 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Due to urgency of symptoms, a full telehealth visit was not completed. All attempts to contact subject have been unsuccessful as of 29Oct2020 <hr/> Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -
Comments

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
4.b	Nov-02-2020 07:43:14 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Due to urgency of symptoms, a full telehealth visit was not completed. All attempts to contact subject have been unsuccessful as of 29Oct2020
4.b	Oct-29-2020 14:32:07 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Due to urgency of symptoms, a full telehealth visit was not completed. All attempts to contact subject have been unsuccessful as of 29Oct2020 <hr/> Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -
Comments

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
4.c	Nov-02-2020 07:43:14 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Due to urgency of symptoms, a full telehealth visit was not completed. All attempts to contact subject have been unsuccessful as of 29Oct2020
4.c	Oct-29-2020 14:32:07 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Due to urgency of symptoms, a full telehealth visit was not completed. All attempts to contact subject have been unsuccessful as of 29Oct2020 <hr/> Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -
Comments

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
4.d	Nov-02-2020 07:43:14 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Due to urgency of symptoms, a full telehealth visit was not completed. All attempts to contact subject have been unsuccessful as of 29Oct2020
4.d	Oct-29-2020 14:32:07 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Due to urgency of symptoms, a full telehealth visit was not completed. All attempts to contact subject have been unsuccessful as of 29Oct2020 <hr/> Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -
Comments

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
4.e	Nov-02-2020 07:43:14 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Due to urgency of symptoms, a full telehealth visit was not completed. All attempts to contact subject have been unsuccessful as of 29Oct2020
4.e	Oct-29-2020 14:32:07 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Due to urgency of symptoms, a full telehealth visit was not completed. All attempts to contact subject have been unsuccessful as of 29Oct2020 <hr/> Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -
Comments

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
4 f	Nov-02-2020 07:43:14 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Due to urgency of symptoms, a full telehealth visit was not completed. All attempts to contact subject have been unsuccessful as of 29Oct2020
4 f	Oct-29-2020 14:32:07 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Due to urgency of symptoms, a full telehealth visit was not completed. All attempts to contact subject have been unsuccessful as of 29Oct2020 <hr/> Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -
Comments

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
4.g	Nov-02-2020 07:43:14 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Due to urgency of symptoms, a full telehealth visit was not completed. All attempts to contact subject have been unsuccessful as of 29Oct2020
4.g	Oct-29-2020 14:32:07 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Due to urgency of symptoms, a full telehealth visit was not completed. All attempts to contact subject have been unsuccessful as of 29Oct2020 <hr/> Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -
Comments

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
4 h	Nov-02-2020 07:43:14 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Due to urgency of symptoms, a full telehealth visit was not completed. All attempts to contact subject have been unsuccessful as of 29Oct2020
4 h	Oct-29-2020 14:32:07 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Due to urgency of symptoms, a full telehealth visit was not completed. All attempts to contact subject have been unsuccessful as of 29Oct2020 <hr/> Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -
Comments

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
4.i	Nov-02-2020 07:43:14 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Due to urgency of symptoms, a full telehealth visit was not completed. All attempts to contact subject have been unsuccessful as of 29Oct2020
4.i	Oct-29-2020 14:32:07 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Due to urgency of symptoms, a full telehealth visit was not completed. All attempts to contact subject have been unsuccessful as of 29Oct2020 <hr/> Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Oct/26/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-23-2020 12:33:43 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Waiting on records from UC Health. Unsure if COVID testing was performed once subject admitted to ER
Form	Nov-02-2020 12:43:44 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Waiting on records from UC Health. Unsure if COVID testing was performed once subject admitted to ER <hr/> Unknown

090177e196ae3f02\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Oct/26/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
1	Nov-23-2020 12:33:43 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Waiting on records from UC Health. Unsure if COVID testing was performed once subject admitted to ER
1	Nov-02-2020 12:43:44 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Waiting on records from UC Health. Unsure if COVID testing was performed once subject admitted to ER <hr/> Unknown

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Oct/26/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
2	Nov-23-2020 12:33:43 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Waiting on records from UC Health. Unsure if COVID testing was performed once subject admitted to ER
2	Nov-02-2020 12:43:44 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Waiting on records from UC Health. Unsure if COVID testing was performed once subject admitted to ER <hr/> Unknown

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Oct/26/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
3	Nov-23-2020 12:33:43 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Waiting on records from UC Health. Unsure if COVID testing was performed once subject admitted to ER
3	Nov-02-2020 12:43:44 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Waiting on records from UC Health. Unsure if COVID testing was performed once subject admitted to ER <hr/> Unknown

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Oct/26/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
4	Nov-23-2020 12:33:43 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Waiting on records from UC Health. Unsure if COVID testing was performed once subject admitted to ER
4	Nov-02-2020 12:43:44 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Waiting on records from UC Health. Unsure if COVID testing was performed once subject admitted to ER <hr/> Unknown

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Oct/26/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
5	Nov-23-2020 12:33:43 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Waiting on records from UC Health. Unsure if COVID testing was performed once subject admitted to ER
5	Nov-02-2020 12:43:44 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Waiting on records from UC Health. Unsure if COVID testing was performed once subject admitted to ER <hr/> Unknown

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Oct/26/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
6	Nov-23-2020 12:33:43 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Waiting on records from UC Health. Unsure if COVID testing was performed once subject admitted to ER
6	Nov-02-2020 12:43:44 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Waiting on records from UC Health. Unsure if COVID testing was performed once subject admitted to ER <hr/> Unknown

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Oct/26/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
7	Nov-23-2020 12:33:43 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Waiting on records from UC Health. Unsure if COVID testing was performed once subject admitted to ER
7	Nov-02-2020 12:43:44 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Waiting on records from UC Health. Unsure if COVID testing was performed once subject admitted to ER <hr/> Unknown

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Oct/26/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
8	Nov-23-2020 12:33:43 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Waiting on records from UC Health. Unsure if COVID testing was performed once subject admitted to ER
8	Nov-02-2020 12:43:44 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Waiting on records from UC Health. Unsure if COVID testing was performed once subject admitted to ER <hr/> Unknown

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Oct/26/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
9	Nov-23-2020 12:33:43 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Waiting on records from UC Health. Unsure if COVID testing was performed once subject admitted to ER
9	Nov-02-2020 12:43:44 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Waiting on records from UC Health. Unsure if COVID testing was performed once subject admitted to ER <hr/> Unknown

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/26/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - Comments

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: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
Form	Nov-04-2020 11:46:40 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Self Swab was requested by office, subject not staying at home and did not have access to self swab kit. Multiple attempts have been made to get subject to complete nasal swab, subject is not returning calls as of 04Nov2020
Form	Nov-02-2020 08:15:34 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Self Swab was requested by office, subject not staying at home and did not have access to self swab kit

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/26/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

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: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
Form	Nov-02-2020 08:15:46 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Self Swab was requested by office, subject not staying at home and did not have access to self swab kit
Form	Nov-02-2020 08:15:03 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Self Swab was requested by office, subject not staying at home and did not have access to self swab kit
Form	Nov-02-2020 08:14:44 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Swab was requested by office, subject not staying at home and did not have access to self swab kit <hr/> Not Done
Form	Nov-02-2020 08:14:37 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Swab was requested by office, subject not staying at home and did not have access to self swab kit

090177e196ae3f02\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
1	Nov-02-2020 08:15:46 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Self Swab was requested by office, subject not staying at home and did not have access to self swab kit
1	Nov-02-2020 08:14:44 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Swab was requested by office, subject not staying at home and did not have access to self swab kit <hr/> Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
2	Nov-02-2020 08:15:46 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Self Swab was requested by office, subject not staying at home and did not have access to self swab kit
2	Nov-02-2020 08:14:44 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Swab was requested by office, subject not staying at home and did not have access to self swab kit <hr/> Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
3	Nov-02-2020 08:15:46 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Self Swab was requested by office, subject not staying at home and did not have access to self swab kit
3	Nov-02-2020 08:14:44 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Swab was requested by office, subject not staying at home and did not have access to self swab kit <hr/> Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
4	Nov-02-2020 08:15:46 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Self Swab was requested by office, subject not staying at home and did not have access to self swab kit
4	Nov-02-2020 08:14:44 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Swab was requested by office, subject not staying at home and did not have access to self swab kit <hr/> Not Done

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Feb/19/2021

Form: UNPLANNED VISIT - Comments

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
Form	Mar-05-2021 08:21:34 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	added in error <hr/> Not Done

Header Text: c4591001

Visit: Unplanned 1

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811135

Generated By: pfe.levisse

Form: UNPLANNED VISIT - 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	Mar-05-2021 08:21:34 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	added in error Not Done

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Feb/19/2021

Form: CONTACT OUTCOME - UNPLANNED - Comments

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
Form	Mar-05-2021 08:21:49 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Done

Header Text: c4591001

Visit: Unplanned 1

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811135

Generated By: pfe.levisse

Form: CONTACT OUTCOME - UNPLANNED - 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	Mar-05-2021 08:21:49 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Done

Header Text: c4591001

Visit: Unplanned 1

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811135

Generated By: pfe.levisse

Form: CONTACT OUTCOME - UNPLANNED - 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	Mar-05-2021 08:21:49 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Done

Header Text: c4591001

Visit: Unplanned 1

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811135

Generated By: pfe.levisse

Form: CONTACT OUTCOME - UNPLANNED - 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
3	Mar-05-2021 08:21:49 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Done

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Feb/19/2021

Form: VITAL SIGNS - TEMP - Comments

Form Version: 20-Feb-2021 02:16

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
Form	Mar-05-2021 08:19:42 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Done

Header Text: c4591001

Visit: Unplanned 1

Form Version: 20-Feb-2021 02:16

Site No: 1081

Subject No: 10811135

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - 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	Mar-05-2021 08:19:42 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Done

Header Text: c4591001

Visit: Unplanned 1

Form Version: 20-Feb-2021 02:16

Site No: 1081

Subject No: 10811135

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - 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.a	Mar-05-2021 08:19:42 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Done

Header Text: c4591001

Visit: Unplanned 1

Form Version: 20-Feb-2021 02:16

Site No: 1081

Subject No: 10811135

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - 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

[Back to Form](#)

Item	Date	User	Comment
2.a	Mar-05-2021 08:19:42 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Done

Header Text: c4591001

Visit: Unplanned 1

Form Version: 20-Feb-2021 02:16

Site No: 1081

Subject No: 10811135

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - 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

[Back to Form](#)

Item	Date	User	Comment
2.a	Mar-05-2021 08:19:42 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Done

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

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
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
Lora Morris	N/A	Feb-10-2021 07:42:32 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

James Fry	Approved	Jan-23-2021 12:12:07 (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-23-2020 12:33:43 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Michael Butcher	Approved	Nov-17-2020 14:14:05 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
-----------------	----------	---	------	--------

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.

090177e196ae3f02\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: 10811135

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
Aug-31-2020 14:14:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: 24 JUL 2020	Initial Entry

2. Select appropriate response - What cohort does the subject belong to?

Date	Location	User	Value	Reason
Aug-31-2020 14:14:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	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: 10811135

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Aug-31-2020 14:14:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: OBTAINED Date Written Consent Obtained Aug/31/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1081

Subject No: 10811135

Generated By: pfe.lewissc

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
Nov-03-2020 07:31:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Closed	event recorded in AE CRF
Nov-03-2020 07:31:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	event recorded in AE CRF
Nov-02-2020 08:30:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 2: Answered	awaiting records to complete/update all data
Nov-02-2020 08:29:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	awaiting records to update all data
Nov-02-2020 08:04:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Opened	SAE RECON:AER#2020423661 Diabetes Mellitus Type 2(onset date:26Oct2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Nov-02-2020 08:04:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON:AER#2020423661 Myocardial infarction with stent placement(onset date:21Oct2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Aug-31-2020 14:14:19 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10811135	Item copied from previous form

090177e196ae3f02\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Time (US & Canada)

2. Birth Date:

Date	Location	User	Value	Reason
Aug-31-2020 14:14:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1971	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-31-2020 14:15:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-31-2020 14:15:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Aug-31-2020 14:15:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: BLACK OR AFRICAN AMERICA N	Initial Entry

090177e196ae3f02\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: 10811135

Generated By: pfe.lewissc

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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1. Date of Visit

Date	Location	User	Value	Reason
Aug-31-2020 14:16:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Aug/31/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811135

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
Aug-31-2020 14:17:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Aug/31/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-31-2020 14:17:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-31-2020 14:17:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: COMPLETED	Initial Entry

090177e196ae3f02\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: 10811135

Generated By: pfe.lewissc

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
Aug-31-2020 14:19:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> Aug/31/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-31-2020 14:19:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> 243.8	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-31-2020 14:19:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-31-2020 14:19:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> 70.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-31-2020 14:19:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	<u>Data Entry:</u> in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-31-2020 14:19:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 35.0	Initial Entry

090177e196ae3f02\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: 10811135

Generated By: pfe.levisse

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

7.a

Date	Location	User	Value	Reason
Aug-31-2020 14:19:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Record Identifier:: 1 Temperature: 97.3 Temperature Unit: F Temperature Locatio n:: FOREHEA D	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-31-2020 14:19:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-31-2020 14:19:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: 97.3	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-31-2020 14:19:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-31-2020 14:19:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: FOREHEAD	Initial Entry

090177e196ae3f02\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: 10811135

Generated By: pfe.lewissc

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
Aug-31-2020 14:20:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Aug/31/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-31-2020 14:20:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: 75008	Initial Entry

090177e196ae3f02\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: 10811135

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Data Origin

Date	Location	User	Value	Reason
Aug-31-2020 17:01:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-31-2020 17:01:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-31-2020 17:01:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-31-2020 17:01:19 (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.
Aug-31-2020 17:01:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Aug/31/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-31-2020 17:01:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BP981W	Initial Entry

090177e196ae3f02\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: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.a Sample ID

Date	Location	User	Value	Reason
Aug-31-2020 17:01:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: BP981W	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-31-2020 17:01:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: Sample ID: BP981V	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-31-2020 17:01:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: BP981V	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-31-2020 17:01:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: Sample ID: BP981T	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-31-2020 17:01:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: BP981T	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-31-2020 17:02:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: Sample ID: BPHZNJ	Initial Entry

090177e196ae3f02\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: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.d Sample ID

Date	Location	User	Value	Reason
Aug-31-2020 17:02:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BPHZNJ	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-31-2020 17:02:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BPHZNK	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-31-2020 17:02:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BPHZNK	Initial Entry

090177e196ae3f02\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:** 10811135**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-31-2020 16:35:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-31-2020 16:35:42 (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
Aug-31-2020 16:36:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-31-2020 16:35:42 (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.
Aug-31-2020 16:35:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Aug/31/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-31-2020 16:36:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BP97L0	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811135

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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

5.a Sample ID

Date	Location	User	Value	Reason
Aug-31-2020 16:36:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BP97L0	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811135

Generated By: pfe.lewissc

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
Aug-31-2020 14:20:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-31-2020 14:20:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-31-2020 14:20:58 (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
Aug-31-2020 14:20:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Aug/31/2020 12:15	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-31-2020 14:20:58 (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
Aug-31-2020 14:20:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: RIGHT	Initial Entry

090177e196ae3f02\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: 10811135

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

7. Route:

Date	Location	User	Value	Reason
Aug-31-2020 14:20:58 (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
Aug-31-2020 14:20:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Aug-31-2020 14:20:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: YES	Initial Entry

090177e196ae3f02\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: 10811135

Generated By: pfe.lewissc

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
Aug-31-2020 14:21:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: NO - REACTOGENICITY E-DIA RY 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: 10811135

Generated By: pfe.lewissc

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-22-2020 12:41:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sep/22/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1081

Subject No: 10811135

Generated By: pfe.lewissc

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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1. Date:

Date	Location	User	Value	Reason
Sep-22-2020 12:43:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Sep-22-2020 12:43:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-22-2020 12:43:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sep/22/2020	Transcription Error
Sep-22-2020 12:43:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Vital signs Date 24/Sep/2020 is not same as Date of Visit 22/Sep/2020. Please review and update as appropriate or clarify.
Sep-22-2020 12:43:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Collection Date, 24/Sep/2020 is a future date relative to when it was entered on 22/Sep /2020. Please correct.
Sep-22-2020 12:43:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sep/24/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-22-2020 12:43:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Record Identifier:: 1 Temperature: 98.0 Temperature Unit: F	Initial Entry

090177e196ae3f02\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: 10811135

Generated By: pfe.levisse

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

			Temperature Location:	FOREHEAD
--	--	--	-----------------------	----------

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-22-2020 12:43:18 (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-22-2020 12:43:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> 98.0	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-22-2020 12:43:18 (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
Sep-22-2020 12:43:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> FOREHEAD	Initial Entry

090177e196ae3f02\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: 10811135

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-22-2020 12:54:53 (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-22-2020 12:54:53 (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-22-2020 12:55:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-22-2020 12:54:53 (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-22-2020 12:54:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Sep/22/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-22-2020 12:55:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: Sample ID: BP97V6	Initial Entry

090177e196ae3f02\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811135

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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

5.a Sample ID

Date	Location	User	Value	Reason
Sep-22-2020 12:55:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BP97V6	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811135

Generated By: pfe.lewissc

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-22-2020 12:44:15 (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-22-2020 12:44:15 (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-22-2020 12:44:15 (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-22-2020 12:44:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sep/22/2020 12:18	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-22-2020 12:44:15 (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-22-2020 12:44:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: RIGHT	Initial Entry

090177e196ae3f02\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: 10811135

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

7. Route:

Date	Location	User	Value	Reason
Sep-22-2020 12:44:15 (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-22-2020 12:44:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-22-2020 12:44:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

090177e196ae3f02\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: 10811135

Generated By: pfe.lewissc

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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1. Date of Visit

Date	Location	User	Value	Reason
Oct-21-2020 13:14:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Oct/21/2020	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: 10811135

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Data Origin

Date	Location	User	Value	Reason
Oct-21-2020 13:26:45 (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-21-2020 13:26:45 (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-21-2020 13:26:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-21-2020 13:26:45 (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-21-2020 13:26:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Oct/21/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-21-2020 13:26:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: Sample ID: BP1HYL	Initial Entry

090177e196ae3f02\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: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.a Sample ID

Date	Location	User	Value	Reason
Oct-21-2020 13:26:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> BP1HYL	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-21-2020 13:27:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BP1HYM	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-21-2020 13:27:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> BP1HYM	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-21-2020 13:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BS64KK	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-21-2020 13:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> BS64KK	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-21-2020 13:27:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BS64KL	Initial Entry

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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: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.d Sample ID

Date	Location	User	Value	Reason
Oct-21-2020 13:27:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BS64KL	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/26/2020

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: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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I. Date of Visit

Date	Location	User	Value	Reason
Nov-04-2020 15:48:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 6: Closed	Response satisfies query
Nov-04-2020 11:47:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 6: Answered	As of 04Nov2020, subject has not returned any phone calls. At this time, no swab has been collected due to noncompliance
Nov-03-2020 05:22:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Vikas Joshi (pfe.joshiv22)	Query 6: Reissued:Opened	DM: Thanks for the response. Please update self swab details once available.
Nov-02-2020 14:45:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 6: Answered	Self Swab has been requested again today. subject has not been staying at home and has not had his swab kit. He states he will do the swab tonight and call for pick-up tomorrow. Will f/u with him tomorrow to ensure done.
Nov-02-2020 14:41:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 6: Opened	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Nov-02-2020 13:11:11	ACV0PFEINFP6000	Erik Sundgaard	Query 3: Closed	Response satisfies

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Header Text: c4591001				
Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Oct/26/2020				
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: 10811135		Subject Initials: ---		
Generated By: pfe.levisse		Generated Time (GMT): 29-Mar-2021 10:11		
(UTC-05:00) Eastern Time (US & Canada)		(pfe.sundgaardea)		query
Nov-02-2020 08:15:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 6: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Nov-02-2020 07:42:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 3: Answered	Completing Illness visit now that information is available
Nov-02-2020 01:18:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Teena Patra (pfe.patrat02)	Query 1: Closed	erroneous visit
Nov-02-2020 01:16:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Teena Patra (pfe.patrat02)	Query 5: Deleted	erroneous visit
Oct-30-2020 10:35:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Behnaz Yousefzadeh-Khiabani (pfe.youseb01)	Query 3: Reissued:Opened	Thank you for your response. Please complete the required forms.
Oct-30-2020 10:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Behnaz Yousefzadeh-Khiabani (pfe.youseb01)	Query 1: Reissued:Candidate	Data is currently unavailable, as of 29Oct2020. Subject has not returned calls nor is answering outgoing calls. Please query later.
Oct-30-2020 08:17:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 3: Answered	AE will be entered as this has now turned into an SAE. subject was hospitalized
Oct-30-2020 07:58:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Vikas Joshi (pfe.joshiv22)	Query 3: Reissued:Opened	DM: Thanks for your response. Please complete

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Oct/26/2020

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: 10811135

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

				illness details once contact is made and respond to this query.
Oct-30-2020 04:36:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sonal K (pfe.ks66)	Query 4: Deleted	Query is invalid or does not apply
Oct-29-2020 14:28:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Oct-29-2020 14:26:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Candidate	Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this visit.
Oct-29-2020 10:44:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	Data is currently unavailable, as of 29Oct2020. Subject has not returned calls nor is answering outgoing calls. Will update data as soon as we make contact with subject
Oct-29-2020 10:38:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madhan Babu (pfe.babum05)	Query 1: Reissued:Opened	Kindly verify and confirm if data is available if yes please update data in both Nasal Swab Self and Nasal Swab. Thank you.
Oct-29-2020 08:05:19 (UTC-05:00) Eastern	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 3: Answered	clarify? Subject reported COVID

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Oct/26/2020

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: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Time (US & Canada)				symptom of SOB, subject was advised to go to ER immediately. We have been unable to contact subject since this therefore we are waiting to update Illness page with all data
Oct-28-2020 04:46:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Teena Patra (pfe.patrat02)	Query 3: Opened	DM: Please confirm if Comment entered needs to be recorded in appropriate data point. Please confirm and correct else clarify, thank you.
Oct-28-2020 01:41:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi (pfe.suryas18)	Query 1: Reissued:Candidate	Kindly verify and confirm if data is available if yes please update data in both Nasal Swab Self and Nasal Swab. Thank you.
Oct-27-2020 07:49:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	Subject was advised, by the Sub-I, Jim Fry MS, PA-C, to go to the ER immediately. Will follow up with subject today
Oct-27-2020 07:19:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madhan Babu (pfe.babum05)	Query 1: Opened	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Oct-26-2020 14:49:42 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query

090177e196ae3f02\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Oct/26/2020**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:** 10811135**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11

Time (US & Canada)				
Oct-26-2020 14:49:03 (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-26-2020 14:49:03 (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 missing. Please review and update as appropriate.
Oct-26-2020 14:49:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Oct/26/2020	Initial Entry

2. Erroneous Visit

Date	Location	User	Value	Reason
Nov-02-2020 07:42:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	New Information
Oct-29-2020 14:26:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: ERRONEOUS VISIT	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Oct-26-2020 14:49:03 (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/26/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1081**Subject No:** 10811135**Generated By:** pfe.lewissc**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Nov-02-2020 16:59:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nicholas Roosa (pfe.roosan)	Query 1: Closed	Response satisfies query
Nov-02-2020 07:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Nov-02-2020 07:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Oct/26/2020	Initial Entry
Nov-02-2020 07:43:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry
Oct-31-2020 10:48:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lisa Metschuleit (pfe.metscl)	Query 1: Opened	You had contact with the subject on 26OCT 2020 and they reported Shortness of Breath and chest burning since 21Oct2020. These symptoms need to go in this visit. Please enter accordingly
Oct-29-2020 14:32:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Applicable	Initial Entry
Oct-29-2020 14:28:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Changed Information
Oct-26-2020 14:49:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Oct/26/2020	Initial Entry

2. Date of First Symptom Started:

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit
on Oct/26/2020**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:** 10811135**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11

Date	Location	User	Value	Reason
Nov-02-2020 16:59:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nicholas Roosa (pfe.roosan)	Query 1: Closed	Response satisfies query
Nov-02-2020 07:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Nov-02-2020 07:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Oct/21/2020	Initial Entry
Nov-02-2020 07:43:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry
Oct-31-2020 11:06:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lisa Metschuleit (pfe.metscl)	Query 1: Opened	on 30Oct2020 an InForm query response states "AE will be entered as this has now turned into an SAE. subject was hospitalized". There is no SAE reported and no source in Complion. Please report SAE This pot covid visit took place and will need a conv vis
Oct-29-2020 14:32:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Applicable	Initial Entry
Oct-29-2020 14:28:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Changed Information
Oct-26-2020 14:49:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Oct/21/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/26/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1081**Subject No:** 10811135**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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

Nov-02-2020 08:13:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO Date of Last Symptom Resolved : Oct/27/2020	New Information
Nov-02-2020 07:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry
Nov-02-2020 07:43:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry
Oct-29-2020 14:32:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Applicable	Initial Entry
Oct-29-2020 14:28:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Changed Information
Oct-26-2020 14:49:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Nov-02-2020 07:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry
Nov-02-2020 07:43:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms: FEVER Symptom Present:	Initial Entry
Oct-29-2020 14:32:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms: FEVER Symptom Present: Not Applicable	Initial Entry
Oct-29-2020 14:28:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms: FEVER Symptom Present:	Changed Information

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit
on Oct/26/2020**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:** 10811135**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11

Oct-26-2020 14:49:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry
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4.a Symptoms:

Date	Location	User	Value	Reason
Oct-26-2020 14:49:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Nov-02-2020 07:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry
Nov-02-2020 07:43:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry
Oct-29-2020 14:32:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Applicable	Initial Entry
Oct-29-2020 14:28:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Changed Information
Oct-26-2020 14:49:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Nov-02-2020 07:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms: NEW OR INCREA SED COUGH Symptom Present: NO	Initial Entry
Nov-02-2020 07:43:14	ACV0PFEINFP6000	Lora Morris	Data Entry:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/26/2020

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Subject Initials: ---

Generated By: pfe.levisse

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(UTC-05:00) Eastern Time (US & Canada)		(pfe.lmorris)	Symptoms: NEW OR INCREASED COUGH Symptom Present:	
Oct-29-2020 14:32:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Present: Not Applicable	Initial Entry
Oct-29-2020 14:28:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Present:	Changed Information
Oct-26-2020 14:49:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Present: NO	Initial Entry

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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/26/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1081**Subject No:** 10811135**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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**4.b Symptoms:**

Date	Location	User	Value	Reason
Oct-26-2020 14:49:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Nov-02-2020 07:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry
Nov-02-2020 07:43:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry
Oct-29-2020 14:32:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Applicable	Initial Entry
Oct-29-2020 14:28:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Changed Information
Oct-26-2020 14:49:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Nov-02-2020 07:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: YES	Initial Entry
Nov-02-2020 07:43:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms: NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/26/2020

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Site No: 1081

Subject No: 10811135

Generated By: pfe.levisse

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

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			Symptom Present:	
Oct-29-2020 14:32:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: Not Applicable	Initial Entry
Oct-29-2020 14:29:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present:	Changed Information
Oct-26-2020 14:49:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: YES	Initial Entry

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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/26/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1081**Subject No:** 10811135**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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**4.c Symptoms:**

Date	Location	User	Value	Reason
Oct-26-2020 14:49:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NEW OR INCREASED SHORTN ESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Nov-02-2020 07:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry
Nov-02-2020 07:43:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry
Oct-29-2020 14:32:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Applicable	Initial Entry
Oct-29-2020 14:29:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Changed Information
Oct-26-2020 14:49:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

4.d

Date	Location	User	Value	Reason
Nov-02-2020 07:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry
Nov-02-2020 07:43:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms: CHILLS Symptom Present:	Initial Entry
Oct-29-2020 14:32:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms: CHILLS	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/26/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1081**Subject No:** 10811135**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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

			Symptom Present: Not Applicable	
Oct-29-2020 14:29:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms: CHILLS Symptom Present:	Changed Information
Oct-26-2020 14:49:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Oct-26-2020 14:49:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Nov-02-2020 07:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry
Nov-02-2020 07:43:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry
Oct-29-2020 14:32:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Applicable	Initial Entry
Oct-29-2020 14:29:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Changed Information
Oct-26-2020 14:49:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/26/2020

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Nov-02-2020 07:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom NEW OR INCREASED MUSCLE PAIN Symptom Present: NO	Initial Entry
Nov-02-2020 07:43:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom NEW OR INCREASED MUSCLE PAIN Symptom Present:	Initial Entry
Oct-29-2020 14:32:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom NEW OR INCREASED MUSCLE PAIN Symptom Present: Not Applicable	Initial Entry
Oct-29-2020 14:29:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom NEW OR INCREASED MUSCLE PAIN Symptom Present:	Changed Information
Oct-26-2020 14:49:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom NEW OR INCREASED MUSCLE PAIN Symptom Present: NO	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/26/2020

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4.e Symptoms:

Date	Location	User	Value	Reason
Oct-26-2020 14:49:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Nov-02-2020 07:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry
Nov-02-2020 07:43:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry
Oct-29-2020 14:32:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Applicable	Initial Entry
Oct-29-2020 14:29:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Changed Information
Oct-26-2020 14:49:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Nov-02-2020 07:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms NEW LOSS OF TASTE OR SMELL Symptom Present: NO	Initial Entry
Nov-02-2020 07:43:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms NEW LOSS OF TASTE OR SMELL	Initial Entry

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			Symptom Present:	
Oct-29-2020 14:32:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms NEW LOSS OF TASTE OR SMELL Symptom Present: Not Applicable	Initial Entry
Oct-29-2020 14:29:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms NEW LOSS OF TASTE OR SMELL Symptom Present:	Changed Information
Oct-26-2020 14:49:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms NEW LOSS OF TASTE OR SMELL Symptom Present: NO	Initial Entry

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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/26/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1081**Subject No:** 10811135**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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**4.f Symptoms:**

Date	Location	User	Value	Reason
Oct-26-2020 14:49:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NEW LOSS OF TASTE OR SME LL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Nov-02-2020 07:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry
Nov-02-2020 07:43:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry
Oct-29-2020 14:32:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Applicable	Initial Entry
Oct-29-2020 14:29:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Changed Information
Oct-26-2020 14:49:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Nov-02-2020 07:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom NEW OR INCREAS s: ED SORE THROAT Symptom NO Present:	Initial Entry
Nov-02-2020 07:43:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom NEW OR INCREAS s: ED SORE THROAT Symptom Present:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/26/2020

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Subject No: 10811135

Generated By: pfe.levisse

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Oct-29-2020 14:32:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom NEW OR INCREASED SORE THROAT Symptom Present: Not Applicable	Initial Entry
Oct-29-2020 14:29:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom NEW OR INCREASED SORE THROAT Symptom Present:	Changed Information
Oct-26-2020 14:49:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptom NEW OR INCREASED SORE THROAT Symptom Present: NO	Initial Entry

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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/26/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1081**Subject No:** 10811135**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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**4.g Symptoms:**

Date	Location	User	Value	Reason
Oct-26-2020 14:49:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NEW OR INCREASED SORE T HROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Nov-02-2020 07:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry
Nov-02-2020 07:43:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry
Oct-29-2020 14:32:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Applicable	Initial Entry
Oct-29-2020 14:29:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Changed Information
Oct-26-2020 14:49:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Nov-02-2020 07:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms: DIARRHEA Symptom Present: NO	Initial Entry
Nov-02-2020 07:43:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms: DIARRHEA Symptom Present:	Initial Entry
Oct-29-2020 14:32:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms: DIARRHEA	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/26/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1081**Subject No:** 10811135**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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

			Symptom Present: Not Applicable	
Oct-29-2020 14:29:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms: DIARRHEA Symptom Present:	Changed Information
Oct-26-2020 14:49:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms: DIARRHEA Symptom Present: NO	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Oct-26-2020 14:49:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Nov-02-2020 07:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry
Nov-02-2020 07:43:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry
Oct-29-2020 14:32:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Applicable	Initial Entry
Oct-29-2020 14:29:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Changed Information
Oct-26-2020 14:49:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/26/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

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Subject Initials: ---

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Nov-02-2020 07:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms: VOMITING Symptom Present: NO	Initial Entry
Nov-02-2020 07:43:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms: VOMITING Symptom Present:	Initial Entry
Oct-29-2020 14:32:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms: VOMITING Symptom Present: Not Applicable	Initial Entry
Oct-29-2020 14:30:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms: VOMITING Symptom Present:	Changed Information
Oct-26-2020 14:49:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms: VOMITING Symptom Present: NO	Initial Entry

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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/26/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1081**Subject No:** 10811135**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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**4.i Symptoms:**

Date	Location	User	Value	Reason
Oct-26-2020 14:49:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Nov-02-2020 07:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry
Nov-02-2020 07:43:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry
Oct-29-2020 14:32:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Applicable	Initial Entry
Oct-29-2020 14:30:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Changed Information
Oct-26-2020 14:49:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-02-2020 07:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms - Other: burning in chest	Initial Entry
Oct-29-2020 14:30:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms - Other:	Changed Information
Oct-26-2020 14:49:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Symptoms - Other: burning in chest	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/26/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

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Site Name: (1081) Sterling Research Group - Mt. Auburn

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5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Nov-02-2020 07:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: burning in chest	Initial Entry
Oct-29-2020 14:30:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Changed Information
Oct-26-2020 14:49:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: burning in chest	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/26/2020 **Form:** MICROBIOLOGY SPECIMEN - Audit Trail

Form Version: 06-Jul-2020 21:54

Form Status:

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levissc

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Date	Location	User	Value	Reason
Nov-23-2020 12:34:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Oct/26/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

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Subject Initials: ---

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I. Actual Date of Collection:

Date	Location	User	Value	Reason
Nov-23-2020 12:34:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 3: Deleted	Initial Entry
Nov-23-2020 12:34:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Oct/26/2020	Initial Entry
Nov-23-2020 12:33:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry
Nov-15-2020 13:29:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 3: Candidate	11/14/2020 per site may take 1-2 month to get medical records - please wait before re-query
Nov-15-2020 13:28:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 2: Closed	Response satisfies query
Nov-12-2020 06:00:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pratiksha Mahadik (pfe.mahadp07)	Query 2: Reissued:Candidate	It will be tracked per site response.
Nov-11-2020 12:12:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 2: Answered	It is out of our hand to give you a date. We hope to have it asap however it seems like most places are taking 1-2 months to get records to us
Nov-11-2020 11:47:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 2: Reissued:Opened	In order to put this issue on hold we need an date (or estimated date) as to when the missing information is available. Please a DATE as to when

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Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
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				we can expect the missing information. Thank you!
Nov-07-2020 16:54:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 2: Reissued:Candidate	DM - Previous response: "Waiting on records from UC Health. Unsure if COVID testing was performed once subject admitted to ER." Please review and update CRF with new information.
Nov-07-2020 14:11:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 2: Answered	No updated information is currently available, no records have been received.
Nov-07-2020 13:21:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cheryl Haseman (pfe.hasemc)	Query 2: Opened	Previous response: "Waiting on records from UC Health. Unsure if COVID testing was performed once subject admitted to ER." Please review and update CRF with new information.
Nov-07-2020 13:19:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cheryl Haseman (pfe.hasemc)	Query 1: Closed	Will write clearer query.
Nov-07-2020 13:19:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cheryl Haseman (pfe.hasemc)	Query 1: Reissued:Opened	DM: Per response, site is awaiting records. Review later for results.
Nov-04-2020 15:08:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Christian Mayfield (pfe.mayfic01)	Query 1: Reissued:Candidate	DM: Per response, site is awaiting records. Review later for results.

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Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Oct/26/2020

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Nov-04-2020 11:45:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	Still awaiting records. Unsure if testing was performed
Nov-04-2020 06:16:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Teena Patra (pfe.patrat02)	Query 1: Opened	DM: Per comment, please update microbiology specimen form once data is available. Thank you.
Nov-02-2020 12:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Unknown	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Nov-23-2020 12:34:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: SWABBED MATERIAL	Initial Entry
Nov-23-2020 12:33:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry
Nov-02-2020 12:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Unknown	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Nov-23-2020 12:34:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NASOPHARYNX	Initial Entry
Nov-23-2020 12:33:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry
Nov-02-2020 12:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Unknown	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Oct/26/2020

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Form Status: Data Complete, Frozen

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

4. Assay Code and Description:

Date	Location	User	Value	Reason
Nov-23-2020 12:34:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	Initial Entry
Nov-23-2020 12:33:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry
Nov-02-2020 12:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Unknown	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Nov-23-2020 12:34:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC TEST	Initial Entry
Nov-23-2020 12:33:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry
Nov-02-2020 12:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Unknown	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Nov-23-2020 12:34:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: OTHER	Initial Entry
Nov-23-2020 12:33:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry
Nov-02-2020 12:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Unknown	Initial Entry

7. Test Result:

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Oct/26/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

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Date	Location	User	Value	Reason
Nov-23-2020 12:34:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NEGATIVE	Initial Entry
Nov-23-2020 12:33:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry
Nov-02-2020 12:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Unknown	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Nov-23-2020 12:34:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: all data is per pt, we have still not r eceived the hospital records	Initial Entry
Nov-23-2020 12:33:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry
Nov-02-2020 12:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Unknown	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Nov-23-2020 12:34:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NALT Unknown	Initial Entry
Nov-23-2020 12:33:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry
Nov-02-2020 12:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Unknown	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/26/2020

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: 10811135

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-02-2020 08:15:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-02-2020 08:15:25 (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
Nov-02-2020 08:15:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Nov-02-2020 08:15:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Self Swab was requested by office, subject not staying at home and di d not have access to self swab kit	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/26/2020

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: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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1. Data Origin

Date	Location	User	Value	Reason
Nov-02-2020 08:16:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry
Nov-02-2020 08:15:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry
Nov-02-2020 08:14:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Done	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-02-2020 08:16:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry
Nov-02-2020 08:15:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry
Nov-02-2020 08:14:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Done	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-02-2020 08:16:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry
Nov-02-2020 08:15:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry
Nov-02-2020 08:14:44 (UTC-05:00) Eastern	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Done	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/26/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

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Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

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Time (US & Canada)				
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4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Nov-02-2020 08:16:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Self Swab was requested by office, subject not staying at home and di d not have access to self swab kit	Initial Entry
Nov-02-2020 08:15:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Initial Entry
Nov-02-2020 08:14:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Done	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/26/2020

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: 10811135

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

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1.a

Date	Location	User	Value	Reason
Nov-02-2020 07:46:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: YES Number of Visits or Contacts: 1	Initial Entry

1.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-02-2020 07:46:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: SPECIALIST	Initial Entry

1.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-02-2020 07:46:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES Number of Visits or Contacts: 1	Initial Entry

1.b

Date	Location	User	Value	Reason
Nov-02-2020 07:46:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: YES Number of Visits or Contacts: 1	Initial Entry

090177e196ae3f02\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Oct/26/2020**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:** 10811135**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11***1.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-02-2020 07:46:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: EMERGENCY ROOM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-02-2020 07:46:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

1.c

Date	Location	User	Value	Reason
Nov-02-2020 07:46:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN N Occurrence of Visits or Contacts: NO	Initial Entry

1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-02-2020 07:46:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-02-2020 07:46:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

1.d

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Oct/26/2020

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: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Date	Location	User	Value	Reason
Nov-02-2020 07:46:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: NO	Initial Entry

1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-02-2020 07:46:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-02-2020 07:46:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Nov-02-2020 07:46:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae3f02\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Oct/26/2020**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:** 10811135**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11***1.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-02-2020 07:46:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-02-2020 07:46:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

1.f

Date	Location	User	Value	Reason
Nov-02-2020 07:46:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Type of Practitioner: OTHER Occurrence of Visits or Contacts: NO	Initial Entry

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-02-2020 07:46:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-02-2020 07:46:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

3. Has the subject been hospitalized due to potential COVID-19 illness?

Date	Location	User	Value	Reason
Nov-02-2020 07:46:10 (UTC-05:00) Eastern	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
on Oct/26/2020

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: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Time (US & Canada)				
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090177e196ae3f02\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History
on Oct/26/2020

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: 10811135

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Nov-02-2020 07:49:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: POTENTIAL COVID-19 ILLNESS	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Nov-02-2020 07:49:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-02-2020 07:49:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: 4	Initial Entry

090177e196ae3f02\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Nov/23/2020

Form: DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit
Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Date of Visit

Date	Location	User	Value	Reason
Nov-23-2020 12:34:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Nov/23/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Nov-23-2020 12:34:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: COVID_A1	Initial Entry

090177e196ae3f02\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled
Visit on Nov/23/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1081**Subject No:** 10811135**Generated By:** pfe.lewissc**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
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[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Nov-23-2020 12:46:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-23-2020 12:46:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-23-2020 12:46:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-23-2020 12:46:06 (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.
Nov-23-2020 12:46:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Nov/23/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-23-2020 12:46:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BS64RG	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled
Visit on Nov/23/2020**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
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:** 10811135**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11**5.a Sample ID**

Date	Location	User	Value	Reason
Nov-23-2020 12:46:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: BS64RG	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-23-2020 12:46:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: Sample ID: BS64RH	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-23-2020 12:46:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: BS64RH	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-23-2020 12:46:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: Sample ID: BKN9MP	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-23-2020 12:46:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: BKN9MP	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-23-2020 12:46:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: Sample ID: BKN9MR	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Nov/23/2020

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
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: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.d Sample ID

Date	Location	User	Value	Reason
Nov-23-2020 12:46:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BKN9MR	Initial Entry

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/19/2021

Form: DATE OF VISIT - 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: 10811135

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-08-2021 01:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jayesh Yeole (pfe.yeolej)	Query 1: Deleted	Rest of forms marked as NA/ND.
Mar-05-2021 08:20:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark any forms containing data within this visit as Not Done/Not Applicable at the form level.
Mar-05-2021 08:17:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Feb/19/2021	Initial Entry

2. Erroneous Visit

Date	Location	User	Value	Reason
Mar-05-2021 08:20:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: ERRONEOUS VISIT	Initial Entry

090177e196ae3f02\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/19/2021

Form: UNPLANNED VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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I. Assessments

Date	Location	User	Value	Reason
Mar-05-2021 08:21:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Done	Initial Entry
Mar-05-2021 08:20:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Transcription Error
Mar-05-2021 08:18:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-05-2021 08:17:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Mar-05-2021 08:17:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: CONTACT OUTCOME	Initial Entry

090177e196ae3f02\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/19/2021

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811135

Generated By: pfe.lewissc

Form: CONTACT OUTCOME - UNPLANNED - 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. Contact Type:

Date	Location	User	Value	Reason
Mar-05-2021 08:21:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Done	Initial Entry
Mar-05-2021 08:21:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Mar-05-2021 08:18:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Mar-05-2021 08:21:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Done	Initial Entry
Mar-05-2021 08:21:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-05-2021 08:21:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Transcription Error
Mar-05-2021 08:18:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Contact Outcome' is selected as 'VISIT ARRANGED' but no 'VITAL SIGNS' and/or 'UNPLANNED ASSESSMENT OF LOCAL REACTION' form(s) is/are entered. Please review and update as appropriate.

090177e196ae3f02\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/19/2021

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811135

Generated By: pfe.levissc

Form: CONTACT OUTCOME - UNPLANNED - 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

Mar-05-2021 08:18:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES Date of Contact: Feb/19/2021 Contact Outcome: VISIT ARRANGED	Initial Entry
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3. Comments:

Date	Location	User	Value	Reason
Mar-05-2021 08:21:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Done	Initial Entry
Mar-05-2021 08:21:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry:	Transcription Error
Mar-05-2021 08:18:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: subject came in for v101 but infor med staff of recent heart stent plac ement so visit was delayed 2 wee ks per Sub-I	Initial Entry

090177e196ae3f02\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001**Visit:** Unplanned 1 - Unscheduled Visit on
Feb/19/2021**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History**Form Version:** 20-Feb-2021 02:16**Form Status:** Data Complete, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811135**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Mar-05-2021 08:19:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Done	Initial Entry

2.a

Date	Location	User	Value	Reason
Mar-05-2021 08:19:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Record Identifier:: Not Done Temperature: Not Done Temperature Unit: Not Done Temperature Location Not Done :: e	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Mar-05-2021 08:19:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Done	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Mar-05-2021 08:19:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Done	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Mar-05-2021 08:19:42 (UTC-05:00) Eastern	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Done	Initial Entry

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/19/2021

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:16

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Time (US & Canada)				
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2.a Temperature Location:

Date	Location	User	Value	Reason
Mar-05-2021 08:19:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Not Done	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1081

Subject No: 10811135

Generated By: pfe.lewissc

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-21-2020 13:14:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Oct/21/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-21-2020 13:14:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-21-2020 13:14:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: COMPLETED	Initial Entry

090177e196ae3f02\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: 10811135

Generated By: pfe.lewissc

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-02-2020 08:13:33 (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: 10811135

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-02-2020 13:28:49 (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: 10811135

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1081) Sterling Research Group - Mt. Auburn

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*** THIS REPEATING FORM HAS BEEN DELETED ***

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Date	Location	User	Value	Reason
Nov-09-2020 10:46:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Form Deleted	Per DM, stent procedure is not an AE/SAE
Nov-03-2020 09:13:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Form Created	

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Date	Location	User	Value	Reason
Nov-23-2020 13:53:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Form Created	

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Date	Location	User	Value	Reason
Nov-23-2020 13:54:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Form Created	

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Date	Location	User	Value	Reason
Nov-30-2020 15:21:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Form Created	

Header Text: c4591001

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Subject No: 10811135

Generated By: pfe.levisse

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1. Category:

Date	Location	User	Value	Reason
Nov-02-2020 08:13:33 (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-02-2020 08:13:33 (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 19:27:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 7: Clos ed	Response satisfies query
Mar-05-2021 08:15:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 7: Ans wered	symptoms began 21Oct2020, after subject was seen in office
Mar-03-2021 10:54:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 7: Ope ned	Medical Monitor_ Per report, "on 21oct2021 the subject reported no symptoms during his Visit 3". Please clarify date of onset for symptoms. Thanks
Nov-25-2020 09:53:55 (UTC-05:00)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 6: Clos ed	Response satisfies query

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Eastern Time (US & Canada)				
Nov-24-2020 09:36:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 6: Answered	No records from hospitalization. We only received a report of the medications that was prescribed by the cardiologist, which listed the new Dx's of hypertension and hyperlipidemia.
Nov-24-2020 07:03:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 6: Opened	CLINQUERY: Cardiovascular events have been added to AE listing as 'new onset'. Has any further information been obtained from treating hospital in regard to medical history of this subject?
Nov-12-2020 14:08:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 5: Closed	per site response
Nov-12-2020 11:15:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 5: Answered	No records have been received
Nov-12-2020 10:20:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 5: Opened	CLINQUERY: Reviewing if any further information has been obtained from this hospitalisation

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				that may necessitate any update to MH. Please advise if any unfreeze is required. Thanks
Nov-04-2020 17:56:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 3: Closed	to review when new source available
Nov-04-2020 10:40:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Closed	Response satisfies query
Nov-03-2020 15:24:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 3: Answered	Unknown at this time since we have not received any medical records. Once records are received, all data will be updated, including any previous medical dx's that may be documented
Nov-03-2020 15:07:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 3: Reissued: Opened	CLINQUERY: During hospitalisation for MI was any further information obtained that can be requested to review any medical history?
Nov-03-2020 09:19:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 4: Answered	Per Sub-I, Jim Fry, we are not the subjects treating physician therefore we can

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				not diagnosis the subject. No medical history was noted, by the subject, at V1
Nov-03-2020 08:59:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Opened	Clinical - Subject's BMI is recorded as 35.0; please review potential obesity as a prior medical Hx condition of relevance to safety/SAE; if applicable, please update med Hx on both CRF and SAE form
Nov-03-2020 07:20:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 3: Answered	No previous medical history was provided by subject
Nov-03-2020 06:59:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 3: Opened	CLINQUERY: MI has been reported. Please review if the subject had any pre-existing cardiovascular disease. Medical History at V1 currently does not have any entries. Please confirm if remains correct.
Nov-03-2020 00:27:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Nov-02-2020 22:44:00 (UTC-05:00)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 2: Closed	Discrepancy has been closed.

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Subject No: 10811135

Generated By: pfe.levissc

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Eastern Time (US & Canada)				
Nov-02-2020 15:22:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Ans wered	Changed Information
Nov-02-2020 15:22:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Myocardial In farction	Changed Information
Nov-02-2020 15:20:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 2: Ope ned	Multiple concepts in the term MYOCARDIAL INFARCTION WITH 3 STENTS. Split the term into MYOCARDIAL INFARCTION and MYOCARDIAL STENT INSERTION and submit separately. Thank you.
Nov-02-2020 13:31:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ans wered	Changed Information
Nov-02-2020 13:31:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Myocardial In farction with 3 stents	Changed Information
Nov-02-2020 13:12:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Ope ned	CLINICAL - SAE report states event term is Myocardial Infarct (with 3 stents). Please

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				revise this SAE term, or add a new term for MI/stent SAE.
Nov-02-2020 08:13:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Shortness of Breath	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-02-2020 08:13:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Oct/21/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-08-2020 10:52:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO End Date Time: Oct/28/2020 UNK:UNK	New Information
Nov-23-2020 12:35:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO End Date Time: Oct/26/2020 UNK:UNK	New Information
Nov-02-2020 13:29:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Transcription Error
Nov-02-2020 08:13:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO End Date Time: Oct/27/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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Nov-02-2020 08:13:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: 4	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Jan-11-2021 13:09:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 6: Closed	Response satisfies query
Jan-05-2021 16:08:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 6: Answered	Changed Information
Jan-05-2021 16:08:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES Is this serious event associate d with congenital anomaly or birth defect? NO Did this serious event result i n death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result i n persistent or significant disa bility/incapacity? NO Is this serious event life threat ening?	Changed Information

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			<p>YES</p> <p>Other medically important serious event</p> <p>NO</p>	
Jan-04-2021 16:31:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 6: Reissued:Opened	Clinical - the adverse event is unfrozen; please harmonize serious criteria reporting between AE and SAE report
Dec-30-2020 11:47:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 6: Answered	Please unlock this page to make the correction of removing 'other medically imp event'-thank you
Dec-27-2020 23:45:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Swetha Thangellapally (pfe.thangs22)	Query 6: Opened	Clinical Serious criteria for event of MI are Hosp, Life-threatening and Med Important/Significant; however, SAE has serious criteria of Hosp and Life-threatening. Please review, harmonize reporting, and update where applicable.
Dec-25-2020 11:34:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 6: Candidate	Clinical Serious criteria for event of MI are Hosp, Life-threatening and Med Important/Significant; however, SAE has serious criteria of Hosp and Life-threatening. Please review,

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				harmonize reporting, and update where applicable.
Dec-23-2020 17:22:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 5: Closed	Response satisfies query
Dec-23-2020 11:05:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 5: Answered	We are not seeing any smear test statement in the lab section of the SAE. The only mention of a test, is specifically stated in the narrative that it was per the subjects words that his test was negative. We have no documentation from the hospital
Dec-22-2020 23:13:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 5: Reissued:Opened	Clinical - this is the 2nd to last lab test in the Lab Data section, right before WBC count on Oct 28 of 8.2.
Dec-21-2020 16:34:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 5: Answered	Please clarify where "smear test" is noted for this subject. Unable to find this documentation in SAE report
Dec-17-2020 11:44:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 5: Opened	Clinical - please clarify if the SAE lab test section item "smear test_Nasal swab_negative" is a COVID test, and add testing date, in a SAE safety update
Nov-07-2020 07:57:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Charu Sabharwal (pfe.sabhac)	Query 4: Closed	SAE narrative report only states that COVID III visit was initiated; however, do see the test result is

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				documented as unknown in the COVID illness visit. In the next fu SAE form, kindly provide COVID testing unknown in the follow-up report as well.
Nov-05-2020 15:06:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 4: Answered	understood, all documented data in the SAE report is referring to this hospitalization COVID testing. As stated in the SAE, it is unknown if COVID testing was performed in the hospital
Nov-05-2020 15:01:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Reissued:Opened	Clinical - Thank you. The COVID test performed for COVID illness visit in the trial is not in question. Please report if the subject had a COVID test (yes/no; date and result if yes) performed in HOSP (DNC request)
Nov-04-2020 13:50:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 4: Answered	This has been documented in the most current SAE report, as of 04Nov2020

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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Nov-04-2020 12:00:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Reissued:Opened	Clinical - Thank you. Please document in SAE report that you are awaiting medical records to determine if a COVID test was performed (DMC request)
Nov-03-2020 09:20:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 4: Answered	Still waiting on records from hospital. All data will be updated at the time of receipt
Nov-03-2020 08:52:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Opened	Clinical - COVID testing in the Hospital has not been reported in the SAE submitted to safety. Please submit a follow-up SAE form (#2020423661] to provide whether COVID testing was performed (yes/no) and if yes, the results.
Nov-03-2020 07:29:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-03-2020 00:49:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query

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Nov-03-2020 00:22:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Closed	Query closed; will follow for SAE update with the requested COVID test info
Nov-02-2020 15:22:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Myocardial Infarction: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-02-2020 13:31:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Myocardial Infarction with 3 stents: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-02-2020 13:30:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Changed Information
Nov-02-2020 13:30:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Nov-02-2020 13:30:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES Is this serious event associated with congenital anomaly or bir th defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES	Changed Information

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			<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>YES</p>	
Nov-02-2020 13:17:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Opened	Clinical COVID testing in the Hospital has not been reported in the SAE submitted to safety. Please submit a follow-up SAE form [add AER#] to provide whether COVID testing was performed (yes/no) and if yes, the results.
Nov-02-2020 13:14:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	CLINICAL - SAE report #2020423661 reports a second SAE (serious criterion = hospitalization) based on new diagnosis of type 2 diabetes mellitus. Please record this newly diagnosed event and review serious criteria to confirm SAE status.
Nov-02-2020 08:13:33 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Shortness of Breath: Response to

090177e196ae3f02\Final\Final On: 01-Apr-2021 05:06 (GMT)

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Generated By: pfe.levisse

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Time (US & Canada)				"Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-02-2020 08:13:33 (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>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</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-02-2020 08:13:33 (UTC-05:00) Eastern	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<p>Data Entry: NO</p>	Initial Entry

Header Text: c4591001

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Time (US & Canada)				
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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-05-2020 05:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.QUITOR)	Query 1: Closed	SDB causality updated
Nov-04-2020 13:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	#18. Causality Assessment has been noted as no for each Dose. #19. has also been noted as no, on the SAE report
Nov-04-2020 02:07:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.QUITOR)	Query 1: Opened	SAE RECON:AER#2020423661
Nov-03-2020 07:44:49 (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> Cardiac Event	Transcription Error
Nov-02-2020 08:13:33 (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> Cardiac Even	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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Nov-02-2020 08:13:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NOT APPLICABLE	Initial Entry
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-02-2020 08:13:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-02-2020 08:13:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Dec-11-2020 07:02:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 3: Closed	outcome updated. issue resolved
Dec-09-2020 15:42:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: RECOVERED/RESO LVED WITH SEQUE LAE	Changed Information
Dec-09-2020 08:48:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 3: Answered	Please unlock this page so that we can update to 'recovered with sequelae'. thank you
Dec-09-2020 05:11:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 3: Opened	SAE RECON:AER#2020423661,outcome was updated to RECOVERED/RESOLVED WITH SEQUELAE Safety DB while reported as

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				RECOVERED/RESOLVED in AE CRF.Please confirm outcome.If safety update is required, please submit a follow-up form to Safety
Nov-23-2020 12:36:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Nov-23-2020 12:36:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: RECOVERED/RESOLVED	New Information
Nov-23-2020 12:35:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE Myocardial Infarction: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Nov-02-2020 13:29:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-02-2020 13:29:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Shortness of Breath: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Nov-02-2020 13:29:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: RECOVERING/RESOLVING	Transcription Error
Nov-02-2020 08:13:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

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Date	Location	User	Value	Reason
Nov-02-2020 08:13:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Nov-03-2020 07:29:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Data Entry: 2020423661	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Nov-02-2020 13:28:49 (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-02-2020 13:28:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-11-2021 13:16:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Jan-07-2021 08:41:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Type II Diabetes Mellitus	changed term per Diana-Alexandra Marinescu
Jan-05-2021 16:21:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 2: Answered	Vaccination log has been completed
Dec-31-2020 19:34:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	Clinical - SAE report reports Influenza vaccination occurred on 28 Oct 2020; please complete a vaccination log form for this medication
Nov-09-2020 10:47:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: New Onset Type II Diabetes Mellitus	Changed Information
Nov-04-2020 04:59:18	ACV0PFEINFP6000	Nandini	Query 1: Closed	No medical history

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(UTC-05:00) Eastern Time (US & Canada)		Cossons (pfe.cossons_n)		reported by subject.
Nov-03-2020 15:25:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	No medical history was reported by subject at time of consent. Therefore, no history of DM type II noted.
Nov-03-2020 13:32:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nandini Cossons (pfe.cossons_n)	Query 1: Opened	GPD CLINQUERY: Please confirm if there is a previous history of type II diabetes mellitus or impaired glucose tolerance, and update medical history accordingly if appropriate.
Nov-02-2020 13:28:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Type II Diabetes Mellitus	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-31-2020 19:29:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Dec-30-2020 11:49:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Dec-30-2020 11:49:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Oct/27/2020 UNK:UNK	New Information
Dec-25-2020 11:31:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	Clinical Event of Diabetes mellitus onset date is 21Oct20; however, SAE reports event onset of 27Oct2020. Please review, harmonize reporting

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				and update where applicable
Nov-05-2020 01:25:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	Response satisfies query
Nov-04-2020 07:34:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-04-2020 07:34:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Oct/21/2020 UNK:UNK	Changed Information
Nov-04-2020 05:26:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON: AER#2020423661 ,onset date was updated to 21Oct2020 in SDB however, recorded as 26Oct2020 on AE CRF. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form.
Nov-02-2020 13:28:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Oct/26/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-02-2020 13:28:49 (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-05-2020 13:36:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nicholas Roosa (pfe.roosan)	Query 1: Closed	Response satisfies query

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Nov-03-2020 07:39:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-03-2020 07:39:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: 3	Transcription Error
Nov-02-2020 17:02:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nicholas Roosa (pfe.roosan)	Query 1: Opened	Per source AE log, grade 3 severe. Please confirm and update as applicable.
Nov-02-2020 13:28:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: 2	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
Jan-18-2021 15:27:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Closed	Response satisfies query
Jan-15-2021 07:53:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 3: Answered	This was updated on the december 30th SAE update.
Jan-11-2021 13:31:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Closed	Response satisfies query
Jan-11-2021 13:27:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Reissued:Opened	CLINICAL The most recent SAE update (07Jan21) still gives SAE criterion of Hospitalization for Diabetes event, without Med Important. Please review, harmonize

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				reporting, and update as required
Jan-08-2021 13:33:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 4: Answered	This has been completed
Dec-31-2020 19:31:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Reissued:Opened	Clinical Thank you; please submit this information to the SAE in a safety update (ER test on xx date; subject verbally reports negative result)
Dec-30-2020 11:57:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 4: Answered	Please see note from Nov 23rd. Subject verbally stated that he had testing performed in the ER and results were negative. the medical records did not contain the record of the test.
Dec-30-2020 11:54:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 3: Answered	Will update SAE report to also reflect medically important event
Dec-25-2020 11:36:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Opened	Clinical COVID testing in the Hospital has not been reported in the SAE submitted to safety. Please submit a follow-up SAE form [#2020423661] to provide whether COVID testing was performed (yes/no) and if yes, the results.
Dec-25-2020 11:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Opened	Clinical - Serious criteria for Diabetes are Hosp & Med

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				important; however, in SAE report (23Dec20 update) the only criteria is Hosp. Please review, harmonize reporting, and update in the appropriate location
Dec-23-2020 17:15:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Dec-23-2020 08:48:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 2: Answered	Removed Life Threatening from the SAE report. this report was faxed this morning with updates
Dec-17-2020 11:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	Clinical - Serious criteria for Diabetes (severity Gr 3) are Hosp & Med important; however, in SAE report the criteria are Hosp and Live threatening. Please review, harmonize reporting, and update in the appropriate location.
Nov-03-2020 07:30:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-02-2020 13:28:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Type II Diabetes Mellitus: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-02-2020 13:28:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES Is this serious event associated	Initial Entry

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			with congenital anomaly or birth defect?	
			NO	
			Did this serious event result in death?	
			NO	
			Did this serious event require or prolong hospitalization?	
			YES	
			Did this serious event result in persistent or significant disability/incapacity?	
			NO	
			Is this serious event life threatening?	
			NO	
			Other medically important serious event	
			YES	

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Nov-02-2020 13:28:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-09-2020 07:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query

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Nov-09-2020 07:33:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	We are not the diagnosing physician therefore we can not say that the DM is due to weight or any other cause other than that their body has become insulin resistant
Nov-09-2020 07:33:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NOT RELATED If Not Related to study treatme nt(s), this event is due to: OTHER <i>If Other, specify:</i> Insulin Resistance	We are not the diagnosing physician therefore we can not say that the DM is due to weight or any other cause other than that their body has become insulin resistant
Nov-08-2020 14:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL - Elevated blood sugar would be the symptom of DM, rather than a cause; please consider reported BMI of 35.0 c/w Obesity for potential relevance to new DM onset, and update if appropriate.
Nov-02-2020 13:28:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NOT RELATED If Not Related to study treatme nt(s), this event is due to: OTHER <i>If Other, specify:</i> elevated blood sugar	Initial Entry

10. Latest Action Taken with Study Treatment:

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Date	Location	User	Value	Reason
Nov-02-2020 13:28:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NOT APPLICABLE	Initial Entry

II. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-02-2020 13:28:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

Header Text: c4591001

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Subject No: 10811135

Generated By: pfe.levisse

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Form Status: Data Complete, Verified

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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-02-2020 13:28:49 (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-05-2020 01:24:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	Response satisfies query
Nov-04-2020 07:33:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-04-2020 07:33:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: RECOVERING/RESOLVING	Changed Information
Nov-04-2020 02:09:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON:AER#2020423661,Diabetes Mellitus,outcome was reported as Recovering/Resolving to Safety DB however, recorded as NOT RECOVERED/NOT RESOLVED on AE CRF. Please confirm correct outcome.If safety update is required, please submit a follow-up form
Nov-02-2020 13:37:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NOT RECOVERED/ NOT RESOLVED	Changed Information
Nov-02-2020	ACV0PFEINFP6000	Lora Morris	Data Entry:	Initial Entry

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13:28:49 (UTC-05:00) Eastern Time (US & Canada)		(pfe.lmorris)	RECOVERING/RES OLVING	
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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Nov-02-2020 13:28:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Nov-03-2020 07:30:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Data Entry: 2020423661	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Nov-03-2020 09:13:37 (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-03-2020 09:13:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-09-2020 10:46:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 2: Del eted	Per DM, stent procedure is not an AE/SAE
Nov-07-2020 10:42:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Rei ssued:Candid ate	SAE RECON: For Clinical review
Nov-06-2020 11:58:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 2: Ans wered	This specific term was entered at the request of data management
Nov-05-2020 22:02:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Ope ned	SAE RECON: AER#2020423661 event term cannot be a surgical procedure but the underlying

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				diagnosis. Please review and enter the AE term for which the procedure was performed and submit a follow up AEM form to update the same in Safety database
Nov-03-2020 17:31:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Closed	Discrepancy has been closed.
Nov-03-2020 12:19:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-03-2020 12:19:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Coronary stent placement	Changed Information
Nov-03-2020 12:01:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Opened	Multiple concepts. Split the term into MYOCARDIAL INFARCTION \ CORONARY STENT PLACEMENT
Nov-03-2020 09:13:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Myocardial Infarction with stent placement	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
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Nov-13-2020 05:44:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quoter)	Query 1: Closed	The event term were updated in SDB. Event now matched in both database.Issue resolved
Nov-10-2020 06:30:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quoter)	Query 1: Reissued:Candidate	Event inactivated. to check next SAE listing
Nov-09-2020 07:30:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-09-2020 07:30:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Oct/21/2020 UNK:UNK	Changed Information
Nov-09-2020 05:24:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quoter)	Query 1: Opened	SAE RECON: AER#2020423661 ,onset date was reported as 21Oct2020 in SDB however, recorded as 27Oct2020 on AE CRF. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form.
Nov-03-2020 09:13:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Oct/27/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-03-2020 09:13:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO End Date Time: Oct/27/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

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Date	Location	User	Value	Reason
Nov-03-2020 09:13:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: 3	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-04-2020 07:21:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-03-2020 12:19:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Coronary stent placement: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-03-2020 09:13:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Myocardial Infarction with stent placement: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-03-2020 09:13:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO	Initial Entry

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			Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES 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	
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8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Nov-03-2020 09:13:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-03-2020 09:13:37 (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	Initial Entry

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			<i>If Other, specify:</i>	
			Cardiac Event	

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-03-2020 09:13:37 (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
Nov-03-2020 09:13:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-03-2020 09:13:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Nov-13-2020 05:44:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Closed	The event term were updated in SDB. Event now matched in both database.Issue resolved
Nov-10-2020 06:30:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Reissued:Can didate	Event inactivated. to check next SAE listing
Nov-09-2020 07:35:26 (UTC-05:00)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 2: Answered	Safety report will be updated with stop date and re-submitted

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Eastern Time (US & Canada)				
Nov-09-2020 05:29:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quiror)	Query 2: Opened	SAE RECON:AER#2020423661,outcome was reported as RECOVERING/RESOLVING to Safety DB however, recorded as RECOVERED/RESOLVED on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Nov-03-2020 09:14:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-03-2020 09:14:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: RECOVERED/RESOLVED	Transcription Error
Nov-03-2020 09:13:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Myocardial Infarction with stent placement: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Nov-03-2020 09:13:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: RECOVERING/RESOLVING	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Nov-03-2020 09:13:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

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Date	Location	User	Value	Reason
Nov-04-2020 07:21:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	<u>Data Entry:</u> 2020423661	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Nov-23-2020 13:53:18 (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-23-2020 13:53:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-23-2020 13:53:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: New onset Essential Hypertension	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-21-2020 16:23:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Dec-21-2020 16:23:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Aug/31/2020 12:11	Changed Information
Dec-21-2020 16:22:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE New onset Essential Hypertension: Start Date is the same as a Vaccination Date, but time is not provided. Please review and update as appropriate.

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Dec-21-2020 16:22:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Aug/31/2020 UNK:UNK	Changed date, per DM query, to match with first HBP reading in office
Dec-17-2020 11:31:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Dec-09-2020 15:19:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 1: Opened	GPD CLINQUERY: Information included in Serious Adverse Event report 2020423661 indicates that participant was found to have elevated blood pressure at visit 3 which was 21 Oct 2020. Please confirm onset date.
Dec-09-2020 12:41:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nandini Cossons (pfe.cossons_n)	Query 1: Candidate	GPD CLINQUERY: Information included in Serious Adverse Event report 2020423661 indicates that participant was found to have elevated blood pressure at visit 3 which was 21 Oct 2020. Please confirm onset date.
Nov-23-2020 13:53:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Oct/29/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-23-2020 13:53:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

Header Text: c4591001

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6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-23-2020 13:53:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: 2	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-23-2020 13:53:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Nov-23-2020 13:53:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-23-2020 13:53:18 (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> Idiopathic	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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Nov-23-2020 13:53:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NOT APPLICABLE	Initial Entry
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-23-2020 13:53:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-23-2020 13:53:18 (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-23-2020 13:53:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: RECOVERING/RESOLVING	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Nov-23-2020 13:53:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Nov-23-2020 13:54:23 (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-23-2020 13:54:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-23-2020 13:54:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: New onset Unspecified Hyperlipid emia	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-23-2020 13:54:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Oct/29/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-23-2020 13:54:23 (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-23-2020 13:54:23 (UTC-05:00) Eastern	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: 2	Initial Entry

090177e196ae3f02\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: 10811135

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Time (US & Canada)

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-23-2020 13:54:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Nov-23-2020 13:54:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-23-2020 13:54:23 (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 If Other, specify: Idiopathic	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-23-2020 13:54:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NOT APPLICABLE	Initial Entry

090177e196ae3f02\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: 10811135

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-23-2020 13:54:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-23-2020 13:54:23 (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-23-2020 13:54:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: RECOVERING/RESOLVING	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Nov-23-2020 13:54:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

090177e196ae3f02\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, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Nov-30-2020 15:21:43 (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-30-2020 15:21:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-30-2020 15:21:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Coronary Artery disease	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-30-2020 15:21:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Nov/4/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-30-2020 15:21:43 (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-30-2020 15:21:43 (UTC-05:00) Eastern	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: 2	Initial Entry

090177e196ae3f02\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: 10811135

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Time (US & Canada)

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-30-2020 15:21:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Nov-30-2020 15:21:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-30-2020 15:21:43 (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 If Other, specify: Idiopathic	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-30-2020 15:21:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NOT APPLICABLE	Initial Entry

090177e196ae3f02\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: 10811135

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-30-2020 15:21:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-30-2020 15:21:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Nov-30-2020 15:21:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NOT RECOVERED/NOT RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Nov-30-2020 15:21:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

090177e196ae3f02\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

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Date	Location	User	Value	Reason
Jan-05-2021 16:21:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Jan-05-2021 16:21:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jan-05-2021 16:21:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Jan-05-2021 16:21:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Jan-05-2021 16:21:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Flu Vaccination	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Jan-05-2021 16:21:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Oct/28/2020	Initial Entry

090177e196ae3f02\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811135

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-10-2021 07:42:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Feb/5/2021	Initial Entry

Header Text: c4591001**Visit:** Potential ReVax Initial Contact -
Unscheduled**Form Version:** 10-Dec-2020 02:25**Site No:** 1081**Subject No:** 10811135**Generated By:** pfe.levissc**Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History**Form Status:** Data Complete, Queries**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Select appropriate response - Is participant willing to return for Vaccination 3?**

Date	Location	User	Value	Reason
Mar-08-2021 05:19:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Malerato Moloji (pfe.moloim)	Query 1: Reissued:Opened	DM: Please confirm when will the visit happen.
Mar-05-2021 14:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	visit has been delayed
Mar-05-2021 13:33:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Behnaz Yousefzadeh- Khiabani (pfe.youseb01)	Query 1: Reissued:Opened	Please update once data is available.
Mar-05-2021 08:24:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	subject scheduled for V101 3/5/2021
Mar-05-2021 07:39:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pratiksha Mahadik (pfe.mahadp07)	Query 1: Opened	DM: Participant is eligible and confirmed to have received Placebo, but Date Written Consent Obtained is missing in Informed Consent - Further Vaccination CRF. Please review and update as appropriate.
Feb-10-2021 07:42:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Participant is willing to return fo r Vaccination 3 Participant is: eligible per local/national rec ommendations and confirme d to have received only place bo at Vaccination 1/2	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811135

Generated By: pfe.lewissc

Form: TREATMENT UNBLINDED - 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

[Back to Form](#)

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-24-2021 00:46:48 (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_DS001_36
Feb-23-2021 13:45:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: An swere d	Transcription Error
Feb-23-2021 13:45:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry : Feb/5/ 2021	Transcription Error
Feb-22-2021 21:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Op ened	DMW7351034;Date Treatment Unblinded should be equal to or after DOV in REVAX CONTACT visit when Reason is ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION.Please review and update as appropriate.
Feb-10-2021 07:42:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry : Feb/3/ 2021	Initial Entry

2. Primary Reason for Unblinding:

090177e196ae3f02\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811135

Generated By: pfe.levisse

Form: TREATMENT UNBLINDED - 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

Date	Location	User	Value	Reason
Feb-10-2021 07:42:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry

090177e196ae3f02\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001**Visit:** Subject Status - Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1081**Subject No:** 10811135**Generated By:** pfe.levissc**Form:** SUBJECT STATUS - eCRF Audit Trail History**Form Status:** Data Complete, Verified**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)***1. Subject Status***

Date	Location	User	Value	Reason
Mar-08-2021 17:36:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 1: Closed	Response satisfies query
Mar-05-2021 14:44:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	subject states since 2006
Mar-03-2021 11:13:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 1: Opened	Medical Monitor_ The subject has a BMI of 35. Pls advise how many years the subject has been obese? Thanks
Oct-21-2020 13:14:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-31-2020 14:20:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-31-2020 14:17:10 (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
Oct-21-2020 13:14:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/21/2020	Initial Entry
Aug-31-2020 14:20:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/31/2020	Initial Entry
Aug-31-2020 14:17:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/31/2020	Initial Entry

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811135

Generated By: pfe.lewissc

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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I. Casebook Signature

Date	Location	User	Value	Reason
Nov-13-2020 12:18:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Click Here to Enable	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1081

Subject No: 10811170

Generated By: pfe.levissc

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: 10811170

Generated By: pfe.lewissc

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/3/2020
----	--------------	---

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1081

Subject No: 10811170

Generated By: pfe.lewissc

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	[10811170]
2.	Birth Date:	(b) (6)/1946
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811170

Generated By: pfe.levissc

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/3/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1081

Subject No: 10811170

Generated By: pfe.lewissc

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: 10811170

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/3/2020
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: 10811170

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

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Dyslipidemia]
	Start Date:	Jan/UNK/2001
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Obesity]
	Start Date:	Mar/17/2014
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Nonspecific Seasonal Allergies]
	Start Date:	UNK/UNK/2013
	Ongoing:	YES

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811170

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

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Benign Prostatic Hyperplasia]
	Start Date:	Apr/UNK/2013
	Ongoing:	YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1081

Subject No: 10811170

Generated By: pfe.lewissc

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/3/2020
2.	Weight:	[276.6]
3.	Unit:	LB
4.	Height:	[73.0]
5.	Unit:	in
6.	Body Mass Index:	[36.5]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.5]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811170

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/3/2020
2.	Randomization Number:	[250888]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811170

Generated By: pfe.lewissc

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/3/2020
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	[BRTXKX]
5.b	Sample ID	[BRTXKY]
5.c	Sample ID	[BP985C]
5.d	Sample ID	[BP985D]
5.e	Sample ID	[BP985F]

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811170

Generated By: pfe.lewissc

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/3/2020
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	[BP97MW]
-----	-----------	----------

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811170

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/3/2020 10:48
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

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1081

Subject No: 10811170

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
----	--	--

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811170

Generated By: pfe.lewissc

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/23/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1081

Subject No: 10811170

Generated By: pfe.levissc

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/23/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.0]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811170

Generated By: pfe.lewissc

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/23/2020
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	[BP97VG]
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090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811170

Generated By: pfe.lewissc

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/23/2020 09:43
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811170

Generated By: pfe.lewissc

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/22/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811170

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: Oct/22/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRDCNS]
5.b	Sample ID	[BRDCNT]
5.c	Sample ID	[BS64LC]
5.d	Sample ID	[BS64LD]

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811170

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_ILL - New Unscheduled Visit

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811170

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

Signs and Symptoms

1.	Date of Assessment:	//
2.	Date of First Symptom Started:	//
3.	Symptoms Ongoing?	

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

5.	Symptoms - Other Text:	[]
----	------------------------	-----

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811170

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: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811170

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	[]
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Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811170

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

Health Care Utilization

1.	Physician or Healthcare Professional:	
	Occurrence of Visits or Contacts:	

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[]
----	-------------------------------------	-----

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	
----	--	--

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811170

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Illness Details

1.	Category of Clinical Event:	
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	
3.	Toxicity Grade:	

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811170

Subject Initials: ---

Generated By: pfe.lewissc

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:	
----	-------------------------	--

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811170

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: 10811170

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: 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: 10811170

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Unplanned Assessments

1.	Assessments	
----	-------------	--

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1081

Subject No: 10811170

Generated By: pfe.lewissc

Form: DISPOSITION - TREATMENT

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 - Treatment

1.	Date of Completion/Discontinuation/Death :	Oct/22/2020
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: 10811170

Generated By: pfe.levissc

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Disposition - Follow-Up

1.	Date of Completion/Discontinuation/Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[]

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
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: 10811170

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 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: 10811170

Subject Initials: ---

Generated By: pfe.lewissc

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: 10811170

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1. DELETED	ADVERSE EVENT	1	elevate prostate specific antigen	Oct/UNK/2020 UNK:UNK	YES	Repeating Pages
2.	ADVERSE EVENT	2	Malignant Neoplasm of Prostate	Nov/4/2020 UNK:UNK	YES	Repeating Pages

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811170

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

*** THIS REPEATING FORM HAS BEEN DELETED ***

[Back to Form](#)
[eCRF Audit Trail History](#)
[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[+]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[elevate prostate specific antigen]
4.	Start Date Time:	Oct/UNK/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [possible cancer. not currently confirmed]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811170

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

*** THIS REPEATING FORM HAS BEEN DELETED ***

11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811170

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, 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:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Malignant Neoplasm of Prostate]
4.	Start Date Time:	Nov/4/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? NO Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event YES
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811170

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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: [Idiopathic]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021005957]

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (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: 10811170

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1081

Subject No: 10811170

Generated By: pfe.levisse

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

[Back to Form](#)

Medication Error

1.	Category:	
2.	Medication Error (Type of Medication Error):	[]
3.	Start Date:	//
4.	Is the medication error still ongoing?	
5.	Latest Action Taken with Study Treatment:	
6.	Was a Concomitant Medication given?	
7.	Was a Non-Drug Treatment given?	
8.	Did the Medication Error cause the subject to be discontinued from the study?	
9.	Was this medication error associated with any adverse events?	
10.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (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: 10811170

Subject Initials: ---

Generated By: pfe.levisse

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.	1	VACCINATIONS	NO	flu vaccine	Oct/13/2020	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811170

Generated By: pfe.levisse

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

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](#)
[eCRF Audit Trail History](#)
[Form Audit Trail](#)

Concomitant Medications

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[flu vaccine]
5.	Date:	Oct/13/2020

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (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: 10811170

Subject Initials: ---

Generated By: pfe.levisse

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: 10811170

Generated By: pfe.levisse

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

[Back to Form](#)

Concomitant Medications

1.	What is the medication identifier?	[]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[]
5.	Dose:	[]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
10.	Ongoing?	

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (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: 10811170

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: 10811170

Generated By: pfe.levisse

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

[Back to Form](#)

Radiation Treatment

1.	Category:	
2.	What is the treatment Identifier?	[]
3.	Concomitant Non-drug Treatment Pre-specified:	
4.	Treatment:	[]
5.	Start Date:	//
6.	Ongoing?	

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811170

Subject Initials: ---

Generated By: pfe.levisse

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: 10811170

Generated By: pfe.levisse

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

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: 10811170

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: 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: 10811170

Subject Initials: ---

Generated By: pfe.lewissc

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: 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: 10811170

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?	

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (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: 10811170

Subject Initials: ---

Generated By: pfe.lewissc

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: 10811170

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

Contact Outcome

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[]

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811170

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Jan/22/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811170

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	---

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811170

Generated By: pfe.lewissc

Form: TREATMENT UNBLINDED

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

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/22/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811170

Generated By: pfe.levissc

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: 10811170

Generated By: pfe.lewissc

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Death Details

1.	Date of Collection / Notification of Death:	//
----	---	----

Cause of Death

2.	Cause of Death Status:	
	Cause of Death:	[]

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811170

Generated By: pfe.lewissc

Form: DATE OF VISIT

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

Date of Visit

1.	Date of Visit	Jan/29/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1081

Subject No: 10811170

Generated By: pfe.levissc

Form: INFORMED CONSENT - FURTHER VACCINATION

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](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/29/2021
----	--------------	--

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811170

Subject Initials: ---

Generated By: pfe.lewissc

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: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1081

Subject No: 10811170

Generated By: pfe.levissc

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

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 - Screening for Further Vaccination

1.	Date of Completion/Discontinuation/Death :	Jan/29/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811170

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/29/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP1J0Y]
5.b	Sample ID	[BP1J0Z]
5.c	Sample ID	[BS64VF]
5.d	Sample ID	[BS64VG]

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811170

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/29/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BKN9RL]
-----	-----------	----------

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1081

Subject No: 10811170

Generated By: pfe.levissc

Form: VACCINATION

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](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/29/2021 13:08
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811170

Generated By: pfe.lewissc

Form: DATE OF VISIT

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

Date of Visit

1.	Date of Visit	Feb/18/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811170

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/18/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BKW75F]
-----	-----------	----------

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1081

Subject No: 10811170

Generated By: pfe.lewissc

Form: VACCINATION

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](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/18/2021 11:26
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811170

Generated By: pfe.lewissc

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: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811170

Generated By: pfe.lewissc

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Contact Outcome

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[]

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811170

Generated By: pfe.levissc

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: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811170

Generated By: pfe.lewissc

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Contact Outcome

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[]

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811170

Generated By: pfe.levisc

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	Form: CONTACT OUTCOME
Visit: V105_MONTH18	Form Status: Not Started
Form Version: 22-Apr-2020 21:04	Site Name: (1081) Sterling Research Group - Mt. Auburn
Site No: 1081	Subject Initials: ---
Subject No: 10811170	Generated Time (GMT): 29-Mar-2021 10:11
Generated By: pfe.lewissc	

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[]

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811170

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[]

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811170

Generated By: pfe.lewissc

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	FOLLOW-UP
2.	Subject Status Date	Oct/22/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811170

Generated By: pfe.lewissc

Form: CASEBOOK SIGNATURE FORM

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](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
----	--------------------	--------------------------------------

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811170

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
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1081

Subject No: 10811170

Generated By: pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-03-2020 11:06:07 (UTC-05:00) Eastern Time (US & Canada)	Tawnyn Ebner (pfe.tebner)	All inclusions and exclusions met <hr/> Not Done

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER
VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811170

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-29-2021 14:54:35 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Not Done

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811170

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

This form requires signing by a member of each of the following signature groups:

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
Lora Morris	N/A	Jan-29-2021 14:50:01 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

James Fry	Approved	Jan-23-2021 12:16:17 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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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	Dec-08-2020 10:39:41 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Michael Butcher	Approved	Nov-09-2020 08:40:43 (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.

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811170

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

Marcel Lanton	N/A	Nov-06-2020 09:38:48 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

James Fry	Approved	Oct-29-2020 16:59:27 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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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.

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1081

Subject No: 10811170

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

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-03-2020 10:56:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын 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-03-2020 10:56:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын 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: 10811170

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Sep-03-2020 10:57:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawryn Ebner (pfe.tebner)	Data Entry: OBTAINED Date Written Consent Obtained Sep/3/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1081

Subject No: 10811170

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Sep-03-2020 10:56:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10811170	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-03-2020 10:56:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1946	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-03-2020 11:04:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-03-2020 11:04:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Sep-03-2020 11:04:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: WHITE	Initial Entry

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811170

Generated By: pfe.levisc

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Sep-03-2020 11:05:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sep/3/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811170

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-03-2020 11:07:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: Sep/3/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-03-2020 11:07:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-03-2020 11:07:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: COMPLETED	Initial Entry

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1081**Subject No:** 10811170**Generated By:** pfe.lewissc**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-03-2020 14:43:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: Hypertension Start Date: UNK/UNK/2000 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 14:43:22 (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-03-2020 14:43:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Diane Broadnax (pfe.dbroadnax)	Data Entry: Hypertension	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 14:43:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Diane Broadnax (pfe.dbroadnax)	Data Entry: UNK/UNK/2000	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 14:43:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Diane Broadnax (pfe.dbroadnax)	Data Entry: YES	Initial Entry

I.b

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811170

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Sep-03-2020 14:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term: Dyslipidemia Start Date: Jan/UNK/2001 Ongoing: YES	Initial Entry

1.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 14:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-03-2020 14:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Diane Broadnax (pfe.dbroadnax)	Data Entry: Dyslipidemia	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 14:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Diane Broadnax (pfe.dbroadnax)	Data Entry: Jan/UNK/2001	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 14:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Diane Broadnax (pfe.dbroadnax)	Data Entry: YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Sep-03-2020 14:44:15 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3	Initial Entry

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811170

Generated By: pfe.levisse

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

Time (US & Canada)			Medical History Term:	Obesity
			Start Date:	Mar/17/2014
			Ongoing:	YES

I.c Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 14:44:15 (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-03-2020 14:44:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Diane Broadnax (pfe.dbroadnax)	Data Entry: Obesity	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 14:44:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Diane Broadnax (pfe.dbroadnax)	Data Entry: Mar/17/2014	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 14:44:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Diane Broadnax (pfe.dbroadnax)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Sep-03-2020 14:44:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: Nonspecific Seasonal Allergies	Initial Entry

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811170

Generated By: pfe.levisse

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/2013	
			Ongoing: YES	

1.d Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 14:44:58 (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-03-2020 14:44:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Diane Broadnax (pfe.dbroadnax)	Data Entry: Nonspecific Seasonal Allergies	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 14:44:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Diane Broadnax (pfe.dbroadnax)	Data Entry: UNK/UNK/2013	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 14:44:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Diane Broadnax (pfe.dbroadnax)	Data Entry: YES	Initial Entry

1.e

Date	Location	User	Value	Reason
Dec-09-2020 08:44:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Line/MH Number: 5 Medical History Term: Benign Prostatic Hyperplasia Start Date: Apr/UNK/2013 Ongoing: YES	Transcription Error

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811170

Generated By: pfe.levisse

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

Dec-09-2020 08:43:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 5 mber: Medical Histo Benign Prostatic ry Term: Hyperplasia Start Date: UNK/UNK/2013 Ongoing: YES	Initial Entry
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I.e Line/MH Number:

Date	Location	User	Value	Reason
Dec-09-2020 08:43:48 (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
Dec-09-2020 08:43:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Benign Prostatic Hyperplasia	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Dec-09-2020 08:44:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Apr/UNK/2013	Transcription Error
Dec-09-2020 08:43:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: UNK/UNK/2013	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Dec-09-2020 08:43:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1081

Subject No: 10811170

Generated By: pfe.levisse

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Sep-03-2020 14:02:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Diane Broadnax (pfe.dbroadnax)	Data Entry: Sep/3/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-03-2020 14:02:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Diane Broadnax (pfe.dbroadnax)	Data Entry: 276.6	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-03-2020 14:02:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Diane Broadnax (pfe.dbroadnax)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-03-2020 14:02:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Diane Broadnax (pfe.dbroadnax)	Data Entry: 73.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-03-2020 14:02:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Diane Broadnax (pfe.dbroadnax)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-03-2020 14:02:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: 36.5	Initial Entry

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1081

Subject No: 10811170

Generated By: pfe.levisse

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

7.a

Date	Location	User	Value	Reason
Sep-03-2020 14:02:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Diane Broadnax (pfe.dbroadnax)	Data Entry: Record Identifier 1 : Temperature: 97.5 Temperature Unit F : Temperature Loc ORAL CAV ation:: ITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-03-2020 14:02:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Diane Broadnax (pfe.dbroadnax)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-03-2020 14:02:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Diane Broadnax (pfe.dbroadnax)	Data Entry: 97.5	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-03-2020 14:02:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Diane Broadnax (pfe.dbroadnax)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-03-2020 14:02:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Diane Broadnax (pfe.dbroadnax)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811170

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

[Back to Form](#)

1. Randomization Date :

Date	Location	User	Value	Reason
Sep-03-2020 14:04:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Diane Broadnax (pfe.dbroadnax)	Data Entry: Sep/3/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-03-2020 14:04:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Diane Broadnax (pfe.dbroadnax)	Data Entry: 250888	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:** 10811170**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-03-2020 11:08:14 (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-03-2020 11:08:14 (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-03-2020 13:20:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-03-2020 11:08:14 (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-03-2020 11:08:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Sep/3/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-03-2020 13:20:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: Sample ID: BRTXKX	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: 10811170

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.a Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 13:20:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: BRTXKX	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-03-2020 13:21:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: Sample ID: BRTXKY	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 13:21:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: BRTXKY	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-03-2020 13:21:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: Sample ID: BP985C	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 13:21:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: BP985C	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-03-2020 13:21:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: Sample ID: BP985D	Initial Entry

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (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: 10811170

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.d Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 13:21:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: BP985D	Initial Entry

5.e

Date	Location	User	Value	Reason
Sep-03-2020 13:21:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: Sample ID: BP985F	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 13:21:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: BP985F	Initial Entry

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (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:** 10811170**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
Sep-03-2020 11:07:30 (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-03-2020 11:07:30 (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-03-2020 11:07:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-03-2020 11:07:30 (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-03-2020 11:07:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Sep/3/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-03-2020 11:07:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: Sample ID: BP97MW	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811170

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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

5.a Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 11:07:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BP97MW	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811170

Generated By: pfe.lewissc

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-03-2020 14:04:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Diane Broadnax (pfe.dbroadnax)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-03-2020 14:04:49 (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-03-2020 14:04:49 (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-03-2020 14:04:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Diane Broadnax (pfe.dbroadnax)	Data Entry: Sep/3/2020 10:48	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-03-2020 14:04:49 (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-03-2020 14:04:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Diane Broadnax (pfe.dbroadnax)	Data Entry: LEFT	Initial Entry

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811170

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

7. Route:

Date	Location	User	Value	Reason
Sep-03-2020 14:04:49 (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-03-2020 14:04:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION 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-03-2020 14:04:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Diane Broadnax (pfe.dbroadnax)	Data Entry: YES	Initial Entry

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1081

Subject No: 10811170

Generated By: pfe.lewissc

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-03-2020 14:05:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Diane Broadnax (pfe.dbroadnax)	Data Entry: NO - REACTOGENICITY E-DI ARY 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: 10811170

Generated By: pfe.lewissc

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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1. Date of Visit

Date	Location	User	Value	Reason
Sep-23-2020 09:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sep/23/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1081

Subject No: 10811170

Generated By: pfe.lewissc

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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1. Date:

Date	Location	User	Value	Reason
Sep-23-2020 09:48:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sep/23/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-23-2020 09:48:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Record Identifier:: 1 Temperature: 98.0 Temperature Unit: F Temperature Location:: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-23-2020 09:48:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-23-2020 09:48:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: 98.0	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-23-2020 09:48:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: F	Initial Entry

2.a Temperature Location:

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1081

Subject No: 10811170

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Sep-23-2020 09:48:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: ORAL CAVITY	Initial Entry

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:** 10811170**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
Sep-23-2020 10:03:33 (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-23-2020 10:03:33 (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-23-2020 10:03:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-23-2020 10:03:33 (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-23-2020 10:03:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Sep/23/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-23-2020 10:03:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: Sample ID: BP97VG	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811170

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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

5.a Sample ID

Date	Location	User	Value	Reason
Sep-23-2020 10:03:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BP97VG	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811170

Generated By: pfe.lewissc

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-23-2020 10:25:00 (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-23-2020 10:25:00 (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-23-2020 10:25:00 (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-23-2020 10:25:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sep/23/2020 09:43	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-23-2020 10:25:00 (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-23-2020 10:25:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: LEFT	Initial Entry

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811170

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

7. Route:

Date	Location	User	Value	Reason
Sep-23-2020 10:25:00 (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-23-2020 10:25:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION 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-23-2020 10:25:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811170

Generated By: pfe.lewissc

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-22-2020 11:00:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jenni Steinbrunner (pfe.jsteinbrunner)	Data Entry: Oct/22/2020	Initial Entry

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811170**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-22-2020 11:30:10 (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-22-2020 11:30:10 (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-22-2020 11:31:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-22-2020 11:30:10 (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-22-2020 11:30:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Oct/22/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-22-2020 11:31:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: Sample ID: BRDCNS	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: 10811170

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.a Sample ID

Date	Location	User	Value	Reason
Oct-22-2020 11:31:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> BRDCNS	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-22-2020 11:31:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BRDCNT	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-22-2020 11:31:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> BRDCNT	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-22-2020 11:31:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BS64LC	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-22-2020 11:31:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> BS64LC	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-22-2020 11:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BS64LD	Initial Entry

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (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: 10811170

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.d Sample ID

Date	Location	User	Value	Reason
Oct-22-2020 11:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BS64LD	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811170

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-22-2020 11:00:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jenni Steinbrunner (pfe.jsteinbrunner)	Data Entry: Oct/22/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-22-2020 11:00:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-22-2020 11:00:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jenni Steinbrunner (pfe.jsteinbrunner)	Data Entry: COMPLETED	Initial Entry

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811170

Generated By: pfe.lewissc

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

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Date	Location	User	Value	Reason
Dec-08-2020 10:39:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Form Deleted	Event should not have been captured as an AE. this is only CS abnormal lab finding and per PI does not need captured since subject has MH of BPH since 2013
Nov-06-2020 09:38:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Form Created	

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811170

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1081) Sterling Research Group - Mt. Auburn

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Date	Location	User	Value	Reason
Jan-04-2021 16:08:53 (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: 10811170

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

*** THIS REPEATING FORM HAS BEEN DELETED ***

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1. Category:

Date	Location	User	Value	Reason
Nov-06-2020 09:38:48 (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-06-2020 09:38:48 (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
Dec-18-2020 12:11:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nicholas Roosa (pfe.roosan)	Query 1: Closed	Response satisfies query
Dec-08-2020 10:38:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	Per PI, Dr Butcher, this is considered medical history and should not have been captured as an AE, as this is considered a CS abnormal lab finding and per protocol this does not need to be captured as an AE unless judged by the PI. Page will be removed.
Dec-03-2020 15:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nicholas Roosa (pfe.roosan)	Query 1: Opened	Per Medical Hx, patient has Benign Prostatic Hyperplasia since 2013, please

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1081**Subject No:** 10811170**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Deleted, Verified**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:11***** THIS REPEATING FORM HAS BEEN DELETED *****

				confirm if elevated PSA is a part of this medical history or is worsening and update as applicable.
Nov-06-2020 09:38:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: elevate prostate specific antigen	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-06-2020 09:38:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: Oct/UNK/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-06-2020 09:38:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-06-2020 09:38:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: 2	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-06-2020 09:38:48 (UTC-05:00) Eastern	ACV0PFEINFP6000	Marcel Lanton	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1081

Subject No: 10811170

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

*** THIS REPEATING FORM HAS BEEN DELETED ***

Time (US & Canada)		(pfe mlanton)	
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8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Nov-06-2020 09:38:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-06-2020 09:38:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Data Entry: NOT RELATED If Not Related to study treatment (s), this event is due to: OTHER If Other, specify: possible cancer. not currentl y confirmed	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-06-2020 09:38:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-06-2020 09:38:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe mlanton)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
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*** THIS REPEATING FORM HAS BEEN DELETED ***

Nov-06-2020 09:38:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	<u>Data Entry:</u> YES	Initial Entry
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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Nov-06-2020 12:02:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-06-2020 12:02:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> NOT RECOVERED/NOT RESO LVED	Changed Information
Nov-06-2020 09:38:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE elevate prostate specific antigen: Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Nov-06-2020 09:38:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	<u>Data Entry:</u> UNKNOWN	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Nov-06-2020 09:38:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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Subject No: 10811170

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

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1. Category:

Date	Location	User	Value	Reason
Jan-04-2021 16:08:53 (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
Jan-04-2021 16:08:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-14-2021 23:58:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Jan-08-2021 13:46:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	Changed data per query
Jan-07-2021 08:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL Subject has Med Hx of Obesity [BMI 36.5]; however, SAE Med Hx does not include Obesity. Please submit a SAE safety update with this additional Med Hx.
Jan-06-2021 12:59:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Malignant Neoplasm of Prostate	Changed Information
Jan-04-2021 16:08:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Prostate Cancer	Initial Entry

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Header Text: c4591001

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Site No: 1081

Subject No: 10811170

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-06-2021 12:59:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Nov/4/2020 UNK:UNK	Changed Information
Jan-04-2021 16:08:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Nov/10/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-04-2021 16:08:53 (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
Jan-04-2021 16:08:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: 3	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
Jan-05-2021 22:07:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Deleted	Query can be addressed internally
Jan-04-2021 16:08:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Prostate Cancer: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.

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Header Text: c4591001

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Site No: 1081

Subject No: 10811170

Generated By: pfe.levisse

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Form Status: Data Complete, Verified

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Subject Initials: ---

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Jan-04-2021 16:08:53 (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>NO</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>NO</p> <p>Other medically important serious event</p> <p>YES</p>	Initial Entry
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8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Jan-04-2021 16:08:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<p>Data Entry: NO</p>	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
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Generated By: pfe.levisse

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Form Status: Data Complete, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Jan-04-2021 16:08:53 (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> Idiopathic	Initial Entry
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-04-2021 16:08:53 (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
Jan-04-2021 16:08:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-06-2021 07:38:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Changed Information
Jan-04-2021 16:08:53 (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
Jan-04-2021 16:08:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NOT RECOVERED/NOT RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

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Date	Location	User	Value	Reason
Jan-04-2021 16:08:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	<u>Data Entry:</u> NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Jan-06-2021 06:03:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	<u>Data Entry:</u> 2021005957	Initial Entry

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811170

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

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Date	Location	User	Value	Reason
Oct-22-2020 11:01:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jenni Steinbrunner (pfe.jsteinbrunner)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811170

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Oct-22-2020 11:01:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Oct-22-2020 11:01:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Oct-22-2020 11:01:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Oct-22-2020 11:01:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jenni Steinbrunner (pfe.jsteinbrunner)	Data Entry: flu vaccine	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Oct-22-2020 11:01:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jenni Steinbrunner (pfe.jsteinbrunner)	Data Entry: Oct/13/2020	Initial Entry

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Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811170

Subject Initials: ---

Generated By: pfe.levissc

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I. Date of Visit

Date	Location	User	Value	Reason
Jan-22-2021 15:50:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Jan/22/2021	Initial Entry

Header Text: c4591001**Visit:** Potential ReVax Initial Contact -
Unscheduled**Form Version:** 10-Dec-2020 02:25**Site No:** 1081**Subject No:** 10811170**Generated By:** pfe.levissc**Form:** FURTHER VACCINATION CONFIRMATION - 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[Back to Form](#)**1. Select appropriate response - Is participant willing to return for Vaccination 3?**

Date	Location	User	Value	Reason
Jan-22-2021 15:50:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-22-2021 15:50:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-22-2021 15:50:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811170

Generated By: pfe.lewissc

Form: TREATMENT UNBLINDED - 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 Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-24-2021 00:46:48 (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_DS001_36
Feb-23-2021 13:54:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: An swere d	Transcription Error
Feb-23-2021 13:54:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry : Jan/22 /2021	Transcription Error
Feb-22-2021 21:49:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Op ened	DMW7351046;Date Treatment Unblinded should be equal to or after DOV in REVAX CONTACT visit when Reason is ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION.Please review and update as appropriate.
Jan-22-2021 15:50:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry : Jan/21 /2021	Initial Entry

2. Primary Reason for Unblinding:

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

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Subject No: 10811170

Generated By: pfe.levisse

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

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Date	Location	User	Value	Reason
Jan-22-2021 15:50:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry

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Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811170

Generated By: pfe.lewissc

Form: DATE OF VISIT - 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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I. Date of Visit

Date	Location	User	Value	Reason
Jan-29-2021 14:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Jan/29/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION - eCRF
Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811170

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Consent Was:

Date	Location	User	Value	Reason
Jan-29-2021 14:52:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: OBTAINED Date Written Consent Obtained Jan/29/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811170

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Jan-29-2021 14:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Jan/29/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-29-2021 14:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-29-2021 14:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: COMPLETED	Initial Entry

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001**Visit:** V101_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811170**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-29-2021 16:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-29-2021 16:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-29-2021 16:02:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-29-2021 16:02:08 (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.
Jan-29-2021 16:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Jan/29/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-29-2021 16:02:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BP1J0Y	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811170

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.a Sample ID

Date	Location	User	Value	Reason
Jan-29-2021 16:02:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> BP1J0Y	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-29-2021 16:02:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BP1J0Z	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-29-2021 16:02:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> BP1J0Z	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-29-2021 16:02:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BS64VF	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-29-2021 16:02:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> BS64VF	Initial Entry

5.d

Date	Location	User	Value	Reason
Jan-29-2021 16:02:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	<u>Data Entry:</u> Sample ID: BS64VG	Initial Entry

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811170

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.d Sample ID

Date	Location	User	Value	Reason
Jan-29-2021 16:02:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BS64VG	Initial Entry

Header Text: c4591001**Visit:** V101_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811170**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-29-2021 16:03:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-29-2021 16:03:16 (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
Jan-29-2021 16:03:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-29-2021 16:03:16 (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.
Jan-29-2021 16:03:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Jan/29/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-29-2021 16:03:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: Sample ID: BKN9RL	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811170

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.a Sample ID

Date	Location	User	Value	Reason
Jan-29-2021 16:03:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BKN9RL	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1081

Subject No: 10811170

Generated By: pfe.lewissc

Form: VACCINATION - 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. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-29-2021 15:01:54 (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
Jan-29-2021 15:01:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-29-2021 15:01:54 (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
Jan-29-2021 15:01:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Jan/29/2021 13:08	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-29-2021 15:01:54 (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
Jan-29-2021 15:01:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: LEFT	Initial Entry

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1081

Subject No: 10811170

Generated By: pfe.levisse

Form: VACCINATION - 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

7. Route:

Date	Location	User	Value	Reason
Jan-29-2021 15:01:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-29-2021 15:01:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-29-2021 15:01:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-29-2021 15:01:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Jan-29-2021 15:01:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811170

Generated By: pfe.lewissc

Form: DATE OF VISIT - 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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I. Date of Visit

Date	Location	User	Value	Reason
Feb-18-2021 12:09:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jenni Steinbrunner (pfe.jsteinbrunner)	Data Entry: Feb/18/2021	Initial Entry

Header Text: c4591001**Visit:** V102_VAX4**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811170**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-19-2021 07:52:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-19-2021 07:52:12 (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
Feb-19-2021 07:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-19-2021 07:52:12 (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.
Feb-19-2021 07:52:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Feb/18/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-19-2021 07:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: Sample ID: BKW75F	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811170

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.a Sample ID

Date	Location	User	Value	Reason
Feb-19-2021 07:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BKW75F	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1081

Subject No: 10811170

Generated By: pfe.levissc

Form: VACCINATION - 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. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-18-2021 12:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jenni Steinbrunner (pfe.jsteinbrunner)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-18-2021 12:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-18-2021 12:10:31 (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
Feb-18-2021 12:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jenni Steinbrunner (pfe.jsteinbrunner)	Data Entry: Feb/18/2021 11:26	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-18-2021 12:10:31 (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
Feb-18-2021 12:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jenni Steinbrunner (pfe.jsteinbrunner)	Data Entry: LEFT	Initial Entry

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1081

Subject No: 10811170

Generated By: pfe.levisse

Form: VACCINATION - 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

7. Route:

Date	Location	User	Value	Reason
Feb-18-2021 12:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-18-2021 12:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-18-2021 12:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-18-2021 12:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Feb-18-2021 12:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jenni Steinbrunner (pfe.jsteinbrunner)	Data Entry: YES	Initial Entry

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811170

Generated By: pfe.levissc

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, 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 Status

Date	Location	User	Value	Reason
Oct-22-2020 11:00:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-03-2020 14:04:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-03-2020 11:07:04 (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
Oct-22-2020 11:00:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/22/2020	Initial Entry
Sep-03-2020 14:04:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/3/2020	Initial Entry
Sep-03-2020 11:07:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/3/2020	Initial Entry

090177e196ae3ef9\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811170

Generated By: pfe.lewissc

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Casebook Signature

Date	Location	User	Value	Reason
Oct-29-2020 16:59:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	James Fry (pfe.jfry)	Data Entry: Click Here to Enable	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

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

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/3/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10811179]
2.	Birth Date:	(b) (6) 1951
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:	

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811179

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/3/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1081

Subject No: 10811179

Generated By: pfe.levisse

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 _____
----	---	-------------------

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811179

Generated By: pfe.levisse

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/3/2020
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: 10811179

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 Urinary Tract Infections]
	Start Date:	UNK/UNK/2006
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Diabetes Mellitus Type 2]
	Start Date:	Oct/UNK/2011
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Dyslipidemia]
	Start Date:	UNK/UNK/2004
	Ongoing:	YES

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL 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: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

1.d	Line/MH Number:	[4]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Gastroesophageal reflux disease]
	Start Date:	UNK/UNK/2007
	Ongoing:	YES
1.e	Line/MH Number:	[5]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Hysterectomy]
	Start Date:	UNK/UNK/1992
	Ongoing:	NO End Date: UNK/UNK/1992
1.f	Line/MH Number:	[6]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Obesity]
	Start Date:	Mar/18/2014
	Ongoing:	YES

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811179

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

1.g	Line/MH Number:	[7]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Osteoarthritis of the Left foot]
	Start Date:	UNK/UNK/2009
	Ongoing:	YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/3/2020
2.	Weight:	[195.0]
3.	Unit:	LB
4.	Height:	[66.5]
5.	Unit:	in
6.	Body Mass Index:	[31.0]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[98.0]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1081

Subject No: 10811179

Generated By: pfe.levisse

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/3/2020
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

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811179

Generated By: pfe.levisse

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/3/2020
2.	Randomization Number:	[251548]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

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: Sep/3/2020
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	[BRTXLK]
5.b	Sample ID	[BRTXLL]
5.c	Sample ID	[BP986C]
5.d	Sample ID	[BP986D]
5.e	Sample ID	[BP986F]

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811179**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	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/3/2020
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	[BP97NG]
-----	-----------	----------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811179

Generated By: pfe.levisse

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/3/2020 16:01
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

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1081

Subject No: 10811179

Generated By: pfe.levisse

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
----	---	---

Header Text: c4591001

Visit: V2_VAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

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	Sep/24/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1081

Subject No: 10811179

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/24/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.0]
	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: 10811179

Generated By: pfe.levisse

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/24/2020
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

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811179**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	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/24/2020
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	[BP97W0]
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811179

Generated By: pfe.levisse

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/24/2020 11:58
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

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1081 **Site Name:** (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179 **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/29/2020
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:** 10811179**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/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	[BS64MX]
5.b	Sample ID	[BS64MY]
5.c	Sample ID	[BRDCR9]
5.d	Sample ID	[BRDCRB]

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

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:	
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Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 20-Feb-2021 02:17

Site No: 1081

Subject No: 10811179

Generated By: pfe.levisse

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Signs and Symptoms

1.	Date of Assessment:	//
2.	Date of First Symptom Started:	//
3.	Symptoms Ongoing?	

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

5.	Symptoms - Other Text:	[]
----	------------------------	-----

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL - New
Unscheduled Visit**Form:** ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811179**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	[]
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Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

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	[]
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090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Health Care Utilization

1.	Physician or Healthcare Professional:	
	Occurrence of Visits or Contacts:	

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[]
----	-------------------------------------	-----

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	
----	--	--

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Illness Details

1.	Category of Clinical Event:	
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	
3.	Toxicity Grade:	

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

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 Visit**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:** 10811179**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	[]
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Header Text: c4591001

Visit: Unplanned - New Unscheduled **Form:** DATE OF VISIT
Visit

Form Version: 22-Apr-2020 21:02 **Form Status:** Not Started

Site No: 1081 **Site Name:** (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179 **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: 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: 10811179 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 10:11

Unplanned Assessments

1.	Assessments	
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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: 10811179 **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/29/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Disposition - Follow-Up

1.	Date of Completion/Discontinuation/Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[]

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB **Form:** DATE OF VISIT - REPEAT SWAB
- New Unscheduled Visit

Form Version: 10-Oct-2020 15:57 **Form Status:** Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

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 Repeat Swab

3.	COVID-19 Repeat Swab:	
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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:** 10811179**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	[]
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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: 10811179

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 Ongoing	Form Instance
1.	ADVERSE EVENT	1	worsening-Left Big Toe Osteoarthritis	Oct/14/2020 UNK:UNK	NO End Date Time: Oct/14/2020 UNK:UNK	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

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)	[worsening-Left Big Toe Osteoarthritis]
4.	Start Date Time:	Oct/14/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/14/2020 UNK:UNK
6.	Toxicity Grade:	2

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1081**Subject No:** 10811179**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:11

7.	<p>Is the adverse event serious?</p> <p>If Yes, NOTIFY PFIZER IMMEDIATELY.</p> <p>Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).</p>	NO
8.	<p>Is this adverse event the result of a study Medication Error?</p> <p>If Yes, record the type of medication error on the Medication Error Log.</p>	NO
9.	<p>Is this event related to study treatment:</p>	<p>NOT RELATED</p> <p>If Not Related to study treatment(s), this event is due to: OTHER</p> <p>If Other, specify: [Left big toe bone fusion]</p>
10.	<p>Latest Action Taken with Study Treatment:</p>	NOT APPLICABLE

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (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: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Medication Error

1.	Category:	
2.	Medication Error (Type of Medication Error):	[]
3.	Start Date:	//
4.	Is the medication error still ongoing?	
5.	Latest Action Taken with Study Treatment:	
6.	Was a Concomitant Medication given?	
7.	Was a Non-Drug Treatment given?	
8.	Did the Medication Error cause the subject to be discontinued from the study?	
9.	Was this medication error associated with any adverse events?	
10.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (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: 10811179

Subject Initials: ---

Generated By: pfe.levisse

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: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Concomitant Medications

1.	What is the medication identifier?	[]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[]
5.	Date:	//

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (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: 10811179

Subject Initials: ---

Generated By: pfe.lewissc

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: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Concomitant Medications

1.	What is the medication identifier?	[]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[]
5.	Dose:	[]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
10.	Ongoing?	

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (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: 10811179

Subject Initials: ---

Generated By: pfe.levisse

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: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Radiation Treatment

1.	Category:	
2.	What is the treatment Identifier?	[]
3.	Concomitant Non-drug Treatment Pre-specified:	
4.	Treatment:	[]
5.	Start Date:	//
6.	Ongoing?	

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

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: 10811179

Subject Initials: ---

Generated By: pfe.levisse

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: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

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: 10811179

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: 10811179

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:	

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001**Visit:** Unplanned Vaccination -
Unscheduled**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Version:** 20-Feb-2021 02:14**Form Status:** Not Started**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811179**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: 10811179

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?	

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (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: 10811179

Subject Initials: ---

Generated By: pfe.levisse

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: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Contact Outcome

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[]

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT
Unscheduled

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1081 **Site Name:** (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Jan/25/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION
Unscheduled

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	--

Header Text: c4591001

Visit: V101_VAX3

Form: DATE OF VISIT

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: 10811179

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	Jan/29/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER
VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/29/2021
----	--------------	--

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable _____
----	--	-------------------------

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable _____
----	--	-------------------------

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation/Death :	Jan/29/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1081

Subject No: 10811179

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST

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](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Jan/29/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	
	Not Done:	NOT DONE

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

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: Jan/29/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP1J0P]
5.b	Sample ID	[BP1J0R]
5.c	Sample ID	[BS64VC]
5.d	Sample ID	[BS64VD]

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

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	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/29/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BKN9RK]
-----	-----------	----------

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

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	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/29/2021 13:06
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

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: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/25/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	//
----	---------------------------------	----

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Death Details

1.	Date of Collection / Notification of Death:	//
----	---	----

Cause of Death

2.	Cause of Death Status:	
	Cause of Death:	[]

Header Text: c4591001

Visit: V102_VAX4

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

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	Feb/18/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

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:	Feb/18/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	
	Not Done:	NOT DONE

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

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	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/18/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BKW75D]
-----	-----------	----------

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

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	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/18/2021 11:12
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811179

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: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811179

Generated By: pfe.levisse

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Contact Outcome

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[]

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811179

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: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811179

Generated By: pfe.levisse

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Contact Outcome

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[]

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811179

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: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811179

Generated By: pfe.levisse

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Contact Outcome

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[]

Header Text: c4591001

Visit:
FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Not Started

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[]

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/29/2020

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

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
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Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levissc

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
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-03-2020 16:14:29 (UTC-05:00) Eastern Time (US & Canada)	Tawнын Ebner (pfe.tebner)	All inclusions and exclusions met <hr/> Not Done

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-29-2021 13:46:01 (UTC-05:00) Eastern Time (US & Canada)	Jenni Steinbrunner (pfe.jsteinbrunner)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

This form requires signing by a member of each of the following signature groups:

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
Jenni Steinbrunner	N/A	Jan-29-2021 13:38:56 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

James Fry	Approved	Jan-23-2021 12:17:23 (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.

Tawnyn Ebner	N/A	Dec-18-2020 09:34:53 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Affidavit:

N/A

Michael Butcher	Approved	Nov-09-2020 08:41:10 (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.

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-03-2020 16:12:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn 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-03-2020 16:12:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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1. Consent Was:

Date	Location	User	Value	Reason
Sep-03-2020 16:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawryn Ebner (pfe.tebner)	Data Entry: OBTAINED Date Written Consen t Obtained Sep/3/2020	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1081

Subject No: 10811179

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Sep-03-2020 16:12:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10811179	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-03-2020 16:12:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1951	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-03-2020 16:13:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
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090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Sep-03-2020 16:13:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF S PANISH ORIGIN	Initial Entry
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5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Sep-03-2020 16:13:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: WHITE	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811179

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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1. Date of Visit

Date	Location	User	Value	Reason
Sep-03-2020 16:14:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sep/3/2020	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811179

Generated By: pfe.levisse

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-03-2020 16:15:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sep/3/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-03-2020 16:15:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-03-2020 16:15:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: COMPLETED	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1081**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject No:** 10811179**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)***1.a***

Date	Location	User	Value	Reason
Sep-03-2020 18:04:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 1 Number: Medical History Term: Chronic Urinary Tract Infections Start Date: UNK/UNK/2006 Ongoing : YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 18:04:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

1.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-04-2020 13:47:29 (UTC-05:00)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Closed	Response satisfies query

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Eastern Time (US & Canada)				
Sep-04-2020 13:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marcel Lanton (pfe.mlanton)	Query 1: Answered	Subject confirmed during the visit that there have been no symptoms within the past 6 weeks nor has the subject had an acute event within 48hrs prior to study visit.
Sep-04-2020 11:41:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	CLINQUERY: Per IC3 and Criteria for Temporary Delay of Enrolment (Protocol 5.5), please confirm stability of symptoms within 6 weeks of enrolment and no acute event within 48h before study intervention administration

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Sep-03-2020 18:04:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Chronic Urinary Tr act Infections	Initial Entry
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1.a Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 18:04:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2006	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 18:04:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Sep-03-2020 18:04:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 2 Number:	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811179

Generated By: pfe.levisse

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: Diabetes Mellitus Type 2	
			Start Date: Oct/UNK/2011	
			Ongoing: YES	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

1.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 18:04:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-03-2020 18:04:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Diabetes Mellitus Type 2	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 18:04:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Oct/UNK/2011	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 18:04:44	ACV0PFEINFP6000	Phillip Ross	Data Entry: YES	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

(UTC-05:00) Eastern Time (US & Canada)		(pfe.pross)		
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I.c

Date	Location	User	Value	Reason
Sep-03-2020 18:05:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 3 umber: Medical His Dyslipid tory Term: emia Start Date: UNK/U NK/200 4 Ongoing: YES	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

1.c Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 18:05:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

1.c Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-03-2020 18:05:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Dyslipidemia	Initial Entry

1.c Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 18:05:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2004	Initial Entry

1.c Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 18:05:20	ACV0PFEINFP6000	Phillip Ross	Data Entry: YES	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

(UTC-05:00)
Eastern Time (US
& Canada)

(pfe.pross)

1.d

Date	Location	User	Value	Reason
Sep-03-2020 18:05:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 4 Number: Medical History Gastroesop hageal reflu Term: x disease Start Date: UNK/UNK/ 2007 Ongoing YES :	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

1.d Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 18:05:50 (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-03-2020 18:05:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Gastroesophageal reflu x disease	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 18:05:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/2007	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 18:05:50	ACV0PFEINFP6000	Phillip Ross	Data Entry: YES	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

(UTC-05:00)
Eastern Time (US
& Canada)

(pfe.pross)

I.e

Date	Location	User	Value	Reason
Sep-08-2020 07:24:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawny Ebner (pfe.tebner)	Data Entry: Line/MH 5 Number: Medical History Term: Hysterectomy Start Date: UNK/UNK/1992 Ongoing: NO End Date:	Transcription Error
Sep-03-2020 18:06:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 5 Number: Medical History Term: Hysterectomy Start Date: UNK/UNK/1992	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

			Ongoing: YES	
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090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

1.e Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 18:06:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

1.e Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-03-2020 18:06:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Hysterectomy	Initial Entry

1.e Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 18:06:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: UNK/UNK/1992	Initial Entry

1.e Ongoing:

Date	Location	User	Value	Reason
Sep-08-2020 15:39:09	ACV0PFEINFP6000	Hayley Wyper	Query 1: Closed	Response satisfies query

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L **Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1081 **Site Name:** (1081) Sterling Research Group - Mt. Auburn
Subject No: 10811179 **Subject Initials:** ---
Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 10:11

(UTC-05:00) Eastern Time (US & Canada)		(pfe.wyperh)		
Sep-08-2020 07:24:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-08-2020 07:24:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: NO End Date: UNK/UNK/199 2	Transcription Error
Sep-07-2020 11:15:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	CLINQUERY: Please review the ongoing status of this procedure.
Sep-03-2020 18:06:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

<i>If</i>				
Date	Location	User	Value	Reason
Sep-03-2020 18:06:47 (UTC-05:00)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 6 mber:	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Eastern Time (US & Canada)			Medical History Term: Obesity Start Date: Mar/18 /2014 Ongoing: YES	
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

1.f Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 18:06:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

1.f Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-03-2020 18:06:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Obesity	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 18:06:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Mar/18/2014	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Nov-03-2020 14:42:02	ACV0PFEINFP6000	Hayley Wyper	Query 1: Closed	Response satisfies query

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L **Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1081 **Site Name:** (1081) Sterling Research Group - Mt. Auburn
Subject No: 10811179 **Subject Initials:** ---
Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 10:11

(UTC-05:00) Eastern Time (US & Canada)		(pfe.wyperh)		
Nov-03-2020 07:18:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	OA of the Lt Foot has been added to MH
Nov-03-2020 02:15:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sathenapalli Suguna Srujan (pfe.srujas)	Query 1: Opened	CLINQUERY: MH to be updated with information on osteoarthritis per AE entry
Nov-02-2020 15:08:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Candidate	CLINQUERY: MH to be updated with information on osteoarthritis per AE entry
Sep-03-2020 18:06:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

<i>I.g</i>				
Date	Location	User	Value	Reason
Nov-03-2020 07:18:33	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 7	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

(UTC-05:00)
Eastern Time (US
& Canada)

Number:
Medical History: Osteoarthritis of the Left foot
Start Date: UNK/UNK /2009
Ongoing: YES

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

1.g Line/MH Number:

Date	Location	User	Value	Reason
Nov-03-2020 07:18:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

1.g Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Nov-03-2020 07:18:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Osteoarthritis of the Left foot	Initial Entry

1.g Start Date:

Date	Location	User	Value	Reason
Nov-03-2020 07:18:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: UNK/UNK/2009	Initial Entry

1.g Ongoing:

Date	Location	User	Value	Reason
Nov-03-2020 07:18:33	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

(UTC-05:00) Eastern Time (US & Canada)				
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1081

Subject No: 10811179

Generated By: pfe.levisse

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-03-2020 18:07:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Sep/3/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-03-2020 18:07:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: 195.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-03-2020 18:07:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
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090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Sep-03-2020 18:07:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: 66.5	Initial Entry
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5. Unit:

Date	Location	User	Value	Reason
Sep-03-2020 18:07:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-03-2020 18:07:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 31.0	Initial Entry

7.a

Date	Location	User	Value	Reason
Sep-03-2020 18:07:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Record Identifier:: 1 Temperature: 98.0	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

			Temperature Unit: Temperature ORAL Location: CAVITY	
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7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-03-2020 18:07:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-03-2020 18:07:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: 98.0	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-03-2020 18:07:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: F	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-03-2020 18:07:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: ORAL CAVITY	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1081

Subject No: 10811179

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST -
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. Lab Panel:

Date	Location	User	Value	Reason
Sep-03-2020 18:07:42 (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-03-2020 18:07:42 (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-03-2020 18:07:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Sep/3/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (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: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Sep-03-2020 18:07:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry
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5. Specimen Type:

Date	Location	User	Value	Reason
Sep-03-2020 18:07:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-03-2020 18:07:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined I dentifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: Not Done NOT DON :: E	Initial Entry

6.a Sponsor ID:

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (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: 10811179

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

Date	Location	User	Value	Reason
Sep-03-2020 18:07:42 (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-03-2020 18:07:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Choriogonadotropin B eta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-03-2020 18:07:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NOT DONE	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811179

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-03-2020 18:07:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Sep/3/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-03-2020 18:07:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: 251548	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811179

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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. Data Origin

Date	Location	User	Value	Reason
Sep-03-2020 16:16:45 (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-03-2020 16:16:45 (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-03-2020 16:16:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-03-2020 16:16:45 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (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: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-03-2020 16:16:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawyn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Sep/3/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-03-2020 16:16:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawyn Ebner (pfe.tebner)	Data Entry: Sample ID BRTXL : K	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 16:16:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawyn Ebner (pfe.tebner)	Data Entry: BRTXLK	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (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: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Sep-03-2020 16:17:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID BRTXL : L	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 16:17:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BRTXLL	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-03-2020 16:18:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BP986C	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 16:18:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BP986C	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (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: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.d

Date	Location	User	Value	Reason
Sep-03-2020 16:18:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawyn Ebner (pfe.tebner)	Data Entry: Sample ID: BP986D	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 16:18:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawyn Ebner (pfe.tebner)	Data Entry: BP986D	Initial Entry

5.e

Date	Location	User	Value	Reason
Sep-03-2020 16:18:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawyn Ebner (pfe.tebner)	Data Entry: Sample ID: BP986F	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (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: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

5.e Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 16:18:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BP986F	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811179

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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. Data Origin

Date	Location	User	Value	Reason
Sep-03-2020 16:19:09 (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-03-2020 16:19:09 (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-03-2020 16:19:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-03-2020 16:19:09 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (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: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-03-2020 16:19:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Sep/3/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-03-2020 16:19:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID BP97N : G	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 16:19:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BP97NG	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811179

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-03-2020 18:08:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-03-2020 18:08:06 (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-03-2020 18:08:06 (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
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090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811179

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

Sep-03-2020 18:08:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: Sep/3/2020 16:01	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-03-2020 18:08:06 (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-03-2020 18:08:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-03-2020 18:08:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-03-2020 18:08:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N 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-03-2020 18:08:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: YES	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1081

Subject No: 10811179

Generated By: pfe.levisse

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-03-2020 18:08:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Phillip Ross (pfe.pross)	Data Entry: NO - REACTOGENIC ITY E-DIARY NOT C OLLECTED FOR THI S SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811179

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Sep-24-2020 11:53:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sep/24/2020	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1081

Subject No: 10811179

Generated By: pfe.levisse

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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1. Date:

Date	Location	User	Value	Reason
Sep-24-2020 11:54:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sep/24/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-24-2020 11:54:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Record Identifier:: Temperature: 98.0 Temperature Unit: Temperature Location: ORAL CAVIT Y	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-24-2020 11:54:11 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: 1	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

& Canada)

2.a Temperature:

Date	Location	User	Value	Reason
Sep-24-2020 11:54:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: 98.0	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-24-2020 11:54:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-24-2020 11:54:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (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: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Sep-24-2020 11:53:48 (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-24-2020 11:53:48 (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-24-2020 11:53:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sep/24/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (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: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Sep-24-2020 11:53:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry
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5. Specimen Type:

Date	Location	User	Value	Reason
Sep-24-2020 11:53:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-24-2020 11:53:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined Identifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: Not Done NOT DON :: E	Initial Entry

6.a Sponsor ID:

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (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: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Date	Location	User	Value	Reason
Sep-24-2020 11:53:48 (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-24-2020 11:53:48 (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-24-2020 11:53:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NOT DONE	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (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: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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1. Data Origin

Date	Location	User	Value	Reason
Sep-24-2020 13:45:26 (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-24-2020 13:45:26 (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-24-2020 13:45:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-24-2020 13:45:26 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (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: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-24-2020 13:45:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Sep/24/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-24-2020 13:45:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID BP97W : 0	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-24-2020 13:45:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BP97W0	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811179

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-24-2020 12:21:25 (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-24-2020 12:21:25 (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-24-2020 12:21:25 (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
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090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Sep-24-2020 12:21:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sep/24/2020 11:58	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-24-2020 12:21:25 (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-24-2020 12:21:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-24-2020 12:21:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811179

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

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-24-2020 12:21:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N 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-24-2020 12:21:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1081 **Site Name:** (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 10:11

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-29-2020 13:01:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Oct/29/2020	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (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: 10811179 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 10:11

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1. Data Origin

Date	Location	User	Value	Reason
Oct-29-2020 13:43:15 (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-29-2020 13:43:15 (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-29-2020 13:43:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-29-2020 13:43:15 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (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: 10811179 Subject Initials: ---

Generated By: pfe.levisse Generated Time (GMT): 29-Mar-2021 10:11

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Oct-29-2020 13:43:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES Date of Collection: Oct/29/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-29-2020 13:43:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sample ID BS64M : X	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-29-2020 13:43:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: BS64MX	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (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: 10811179 Subject Initials: ---

Generated By: pfe.levisse Generated Time (GMT): 29-Mar-2021 10:11

Oct-29-2020 13:43:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sample ID BS64M : Y	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Oct-29-2020 13:43:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: BS64MY	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-29-2020 13:43:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sample ID BRDCR : 9	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-29-2020 13:43:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: BRDCR9	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (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: 10811179 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 10:11

5.d

Date	Location	User	Value	Reason
Oct-29-2020 13:44:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Sample I BRDCR D: B	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Oct-29-2020 13:44:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: BRDCRB	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-29-2020 13:01:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Oct/29/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-29-2020 13:01:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-29-2020 13:01:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: COMPLETED	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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Date	Location	User	Value	Reason
Oct-29-2020 13:04:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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1. Category:

Date	Location	User	Value	Reason
Oct-29-2020 13:04:22 (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
Oct-29-2020 13:04:22 (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
Nov-03-2020 14:41:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 2: Closed	Response satisfies query
Nov-03-2020 07:20:08 (UTC-05:00)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 2: Answer ed	This is a worsening of the condition

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Eastern Time (US & Canada)				that resulted in surgery
Nov-02-2020 16:52:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 2: Reissued:Opened	CLINQUERY: MH unfreeze is in process. Please clarify for this AE: that this is indeed a 'worsening' of the MH condition occurring on one day only, or if this is pre-planned surgery (fusion) taking place on the 14th that is being recorded.
Nov-02-2020 13:41:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 2: Answered	Yes this should be added to medical history. please unlock page and this will be added.
Nov-02-2020 13:15:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 2: Reissued:Opened	CLINQUERY: 'Worsening' added to event term suggests an entry of Left Big Toe OA should perhaps

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen

Site No: 1081

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Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

				be present in the MH. Please clarify; do you require the MH page to be updated?
Nov-02-2020 11:47:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Nov-02-2020 11:47:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: worsening-Left Big Toe Osteoarthritis	New Information
Nov-02-2020 10:39:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 2: Opened	CLINQUERY: Left Big Toe Osteoarthritis is reported as a one day event (14Oct20). Please clarify. If this is the date of toe fusion surgery, please clarify when the symptoms of OA started for which fusion was indicated

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

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Nov-02-2020 10:37:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nandini Cossons (pfe.cossons_n)	Query 1: Closed	Response satisfies query
Oct-30-2020 12:05:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answer ed	Changed Information
Oct-30-2020 12:05:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Left Big Toe Oste oarthritis	Changed Information
Oct-30-2020 11:51:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nandini Cossons (pfe.cossons_n)	Query 1: Opened	GPD CLINQUERY: Please clarify underlying medical condition for adverse event 'bone on bone' e.g. hallux rigidis arthritis, and if there is a previous medical history of the same?
Oct-29-2020 13:07:16	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Left Big Toe bone	Changed Information

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen

Site No: 1081

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Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

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(UTC-05:00) Eastern Time (US & Canada)			on bone	
Oct-29-2020 13:04:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Left Big Toe bone fusion	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-29-2020 13:04:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Oct/14/2020 UNK:U NK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-29-2020 13:04:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO End Date Time: Oct/14/2020 UNK :UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

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Oct-29-2020 13:04:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: 2	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-29-2020 13:04:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-29-2020 13:04:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Date	Location	User	Value	Reason
Oct-29-2020 13:07:41 (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> Left big toe bone fusion	Changed Information
Oct-29-2020 13:04:22 (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> Bone on Bone	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-29-2020 13:04:22 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NOT APPLICABLE	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

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& Canada)

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-29-2020 13:04:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-29-2020 13:04:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: YES	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-29-2020 13:04:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

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Subject Initials: ---

Generated By: pfe.levissc

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Oct-29-2020 13:04:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: NO	Initial Entry
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090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT - eCRF Audit Trail History
Unscheduled

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-02-2021 13:33:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jenni Steinbrunner (pfe.jsteinbrunner)	Data Entry: Jan/25/2021	New Information
Jan-29-2021 14:47:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Closed	subject decided finally to crossover - vax3 visit completed
Jan-20-2021 10:24:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	Subject is proceeding with normal schedule, next visit will be visit 4/6mo f/u
Jan-19-2021 16:31:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Reissued:Opened	CLINQUERY: Thank you - was it discussed about any future visit/follow up to see if willing to proceed or had subject decided to

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Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT - eCRF Audit Trail History
Unscheduled

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

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				withdraw from study?
Jan-19-2021 08:58:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 1: Answered	subject did not want to proceed with vax at this time
Jan-19-2021 08:14:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	CLINQUERY: Revax Confirmation was completed 16Dec20 yet V101/Vax 3 has not yet been completed per CRF. Please review if delay in data entry or clarify if visit delay has occurred.
Jan-07-2021 16:07:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Dec/16/2020	Transcription Error
Dec-18-2020 09:34:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Dec/17/2020	Initial Entry

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Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen, Verified

Site No: 1081 **Site Name:** (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 10:11

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1. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Jan-29-2021 14:48:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 2: Closed	V101/vax3 completed 29Jan21 - data entered
Jan-29-2021 14:43:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Query 2: Answered	Subject has proceeded with cross-over. please unlock date form to make changes
Jan-29-2021 14:42:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 2: Opened	CLINQUERY: If subject has decided post revax conversation to instead remain in initial schedule of events, please amend this selection to be "Participant Not Willing" in order for the prior schedule to return (V4

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen, Verified

Site No: 1081 **Site Name:** (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179 **Subject Initials:** ---

Generated By: pfe.lewissc **Generated Time (GMT):** 29-Mar-2021 10:11

				onwards)
Jan-29-2021 14:29:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 2: Candid ate	CLINQUERY: If subject has decided post revax conversation to instead remain in initial schedule of events, please amend this selection to be "Participant Not Willing" in order for the prior schedule to return (V4 onwards)
Jan-08-2021 13:17:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-08-2021 00:53:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madhan Babu (pfe.babum05)	Query 1: Opene d	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen, Verified

Site No: 1081 **Site Name:** (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 10:11

				visit. Please complete this date.
Jan-07-2021 16:08:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candid ate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-07-2021 16:08:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811179

Generated By: pfe.lewissc

Form: DATE OF VISIT - 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 Visit

Date	Location	User	Value	Reason
Jan-29-2021 13:38:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jenni Steinbrunner (pfe.jsteinbrunner)	Data Entry: Jan/29/2021	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER
VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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1. Consent Was:

Date	Location	User	Value	Reason
Jan-29-2021 13:45:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jenni Steinbrunner (pfe.jsteinbrunner)	Data Entry: OBTAINED Date Written Co nsent Obtained Jan/29/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Jan-29-2021 13:46:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jenni Steinbrunner (pfe.jsteinbrunner)	Data Entry: Jan/29/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-29-2021 13:46:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-29-2021 13:46:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jenni Steinbrunner (pfe.jsteinbrunner)	Data Entry: COMPLETED	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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1. Lab Panel:

Date	Location	User	Value	Reason
Jan-29-2021 13:47:02 (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
Jan-29-2021 13:47:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-29-2021 13:47:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jenni Steinbrunner (pfe.jsteinbrunner)	Data Entry: Jan/29/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Jan-29-2021 13:47:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry
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5. Specimen Type:

Date	Location	User	Value	Reason
Jan-29-2021 13:47:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Jan-29-2021 13:47:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined Identifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: Not Done NOT DON :: E	Initial Entry

6.a Sponsor ID:

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Date	Location	User	Value	Reason
Jan-29-2021 13:47:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jan-29-2021 13:47:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jenni Steinbrunner (pfe.jsteinbrunner)	Data Entry: Choriogonadotrop in Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Jan-29-2021 13:47:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jenni Steinbrunner (pfe.jsteinbrunner)	Data Entry: NOT DONE	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jan-29-2021 15:59:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-29-2021 15:59:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-29-2021 16:00:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-29-2021 15:59:50 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Jan-29-2021 15:59:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Jan/29/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-29-2021 16:00:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: Sample ID: BP1J0P	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-29-2021 16:00:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын Ebner (pfe.tebner)	Data Entry: BP1J0P	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Jan-29-2021 16:00:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BP1J0R	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Jan-29-2021 16:00:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BP1J0R	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-29-2021 16:00:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID: BS64VC	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-29-2021 16:00:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BS64VC	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

5.d

Date	Location	User	Value	Reason
Jan-29-2021 16:00:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawryn Ebner (pfe.tebner)	Data Entry: Sample ID BS64V : D	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Jan-29-2021 16:00:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawryn Ebner (pfe.tebner)	Data Entry: BS64VD	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jan-29-2021 16:01:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-29-2021 16:01:14 (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
Jan-29-2021 16:01:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-29-2021 16:01:14 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Jan-29-2021 16:01:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Jan/29/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-29-2021 16:01:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID BKN9R : K	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-29-2021 16:01:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BKN9RK	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1081

Subject No: 10811179

Generated By: pfe.levisse

Form: VACCINATION - 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. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-29-2021 13:47:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jenni Steinbrunner (pfe.jsteinbrunner)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-29-2021 13:47:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-29-2021 13:47:50 (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
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090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Jan-29-2021 13:47:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jenni Steinbrunner (pfe.jsteinbrunner)	Data Entry: Jan/29/2021 13:06	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-29-2021 13:47:50 (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
Jan-29-2021 13:47:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jenni Steinbrunner (pfe.jsteinbrunner)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jan-29-2021 13:47:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-29-2021 13:47:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-29-2021 13:47:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-29-2021 13:47:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Jan-29-2021 13:47:50	ACV0PFEINFP6000	Jenni Steinbrunner	Data Entry: YES	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

(UTC-05:00)
Eastern Time
(US & Canada)

(pfe.jsteinbrunner)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-02-2021 13:34:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jenni Steinbrunner (pfe.jsteinbrunner)	Data Entry: Jan/25/2021	New Information
Jan-08-2021 13:17:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Dec/16/2020	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-08-2021 13:17:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: ASSESS ELIGIBILI TY FOR ADDITION AL VACCINATION	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1081

Subject No: 10811179

Generated By: pfe.levissc

Form: DATE OF VISIT - 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 Visit

Date	Location	User	Value	Reason
Feb-18-2021 11:50:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jenni Steinbrunner (pfe.jsteinbrunner)	Data Entry: Feb/18/2021	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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1. Lab Panel:

Date	Location	User	Value	Reason
Feb-18-2021 11:50:38 (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
Feb-18-2021 11:50:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Feb-18-2021 11:50:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jenni Steinbrunner (pfe.jsteinbrunner)	Data Entry: Feb/18/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Feb-18-2021 11:50:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry
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5. Specimen Type:

Date	Location	User	Value	Reason
Feb-18-2021 11:50:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Feb-18-2021 11:50:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined Identifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: Not Done NOT DON :: E	Initial Entry

6.a Sponsor ID:

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:11

Date	Location	User	Value	Reason
Feb-18-2021 11:50:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Feb-18-2021 11:50:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jenni Steinbrunner (pfe.jsteinbrunner)	Data Entry: Choriogonadotrop in Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Feb-18-2021 11:50:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jenni Steinbrunner (pfe.jsteinbrunner)	Data Entry: NOT DONE	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Feb-19-2021 07:50:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-19-2021 07:50:58 (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
Feb-19-2021 07:51:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-19-2021 07:50:58 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Feb-19-2021 07:50:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: YES Date of Collection: Feb/18/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-19-2021 07:51:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: Sample ID BKW75 : D	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-19-2021 07:51:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawnyn Ebner (pfe.tebner)	Data Entry: BKW75D	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1081

Subject No: 10811179

Generated By: pfe.levisse

Form: VACCINATION - 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. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-18-2021 11:51:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jenni Steinbrunner (pfe.jsteinbrunner)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-18-2021 11:51:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-18-2021 11:51:14 (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
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090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

Feb-18-2021 11:51:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jenni Steinbrunner (pfe.jsteinbrunner)	Data Entry: Feb/18/2021 11:1 2	Initial Entry
---	-----------------	--	---	---------------

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-18-2021 11:51:14 (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
Feb-18-2021 11:51:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jenni Steinbrunner (pfe.jsteinbrunner)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Feb-18-2021 11:51:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-18-2021 11:51:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-18-2021 11:51:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-18-2021 11:51:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Feb-18-2021 11:51:14	ACV0PFEINFP6000	Jenni Steinbrunner	Data Entry: YES	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

(UTC-05:00)
Eastern Time
(US & Canada)

(pfe.jsteinbrunner)

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Oct-29-2020 13:01:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-03-2020 18:07:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-03-2020 16:15:04 (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
Oct-29-2020 13:01:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/29/2020	Initial Entry
Sep-03-2020 18:07:52	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/3/2020	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1081

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject No: 10811179

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:11

(UTC-05:00) Eastern Time (US & Canada)				
Sep-03-2020 16:15:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/3/2020	Initial Entry

090177e196ae3f05\Final\Final On: 01-Apr-2021 05:07 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1081

Subject No: 10811179

Generated By: pfe.lewissc

Form: CASEBOOK SIGNATURE FORM - eCRF Audit
Trail History

Form Status: Data Complete, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Casebook Signature

Date	Location	User	Value	Reason
Nov-09-2020 07:50:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Click Here to Enable	Initial Entry

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

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.levisse

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	Form: REACTOGENICITY DIARY
Visit: V1_DAY1_VAX1_L	Form Status: Data Complete, Locked, Frozen, Verified
Form Version: 06-Jul-2020 21:53	Site Name: (1081) Sterling Research Group - Mt. Auburn
Site No: 1081	Subject Initials: ---
Subject No: 10811194	Generated Time (GMT): 29-Mar-2021 10:11
Generated By: pfe.levissc	

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
----	---	--

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

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

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 Version: 22-Apr-2020 21:03

Site No: 1081

Subject No: 10811194

Generated By: pfe.levisse

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: 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]

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.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	[]
----	-----------	-----

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	[]
----	-----------	-----

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
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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]
-----	------------------------	-----------

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

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[eCRF Audit Trail History](#)

Microbiology Specimen

1.	Actual Date of Collection:	Not Done _____ //	Comments
2.	Specimen Type:	Not Done _____	Comments
3.	Specimen Collection Location:	Not Done _____	Comments
4.	Assay Code and Description:	Not Done _____	Comments
5.	Device Type:	Not Done _____	Comments
6.	Trade Name:	Not Done _____	Comments
7.	Test Result:	Not Done _____	Comments
8.	Comments/Findings/Details:	Not Done _____ []	Comments
9.	Trade Name Other, Specify:	Not Done _____ []	Comments

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]
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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 **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	[]
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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
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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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[Form Comments](#)

[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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[Form Comments](#)

[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.levisc

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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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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[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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[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 Version: 15-Sep-2020 21:55

Site No: 1081

Subject No: 10811194

Generated By: pfe.levisse

Form: DISPOSITION - TREATMENT

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 - 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 :	(b) (6)/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	(b) (6)/2020 UNK:UNK	NO End Date Time: (b) (6)/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:	(b) (6)/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: (b) (6)/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.levissc

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 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: 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:	
----	--------------	--

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.levisse

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	(b) (6)/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

[Back to Form](#)

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

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-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

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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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
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
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

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.levisse

Generated Time (GMT): 29-Mar-2021 10:11

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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
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
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
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

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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
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
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: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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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
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
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

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
3	Nov-07-2020 19:26:57 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Telehealth Visit
3	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
4	Nov-07-2020 19:26:57 (UTC-05:00) Eastern Time (US & Canada)	Lora Morris (pfe.lmorris)	Telehealth Visit
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

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 13:00:23 (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

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 13:00:23 (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

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 13:00:23 (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

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 13:00:23 (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

Subject No: 10811194

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
5	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

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 13:00:23 (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

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 13:01:10 (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:** ILLNESS DETAILS - SEVERE - Comments

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
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
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
3	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

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 13:01:10 (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

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Form	Oct-12-2020 13:01:38 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

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5.a	Oct-12-2020 13:02:08 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

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Item	Date	User	Comment
2.a	Oct-12-2020 13:02:38 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID - Comments
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

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Item	Date	User	Comment
2.a	Oct-12-2020 13:02:38 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID - Comments
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

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Item	Date	User	Comment
2.a	Oct-12-2020 13:02:38 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID - Comments
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

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Item	Date	User	Comment
2.a	Oct-12-2020 13:02:38 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments
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.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
Form	Oct-12-2020 13:03:00 (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:** VITAL SIGNS - PULSE OX ROOM AIR - Comments
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.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
1	Oct-12-2020 13:03:00 (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:** VITAL SIGNS - PULSE OX ROOM AIR - Comments
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.levissc

Generated Time (GMT): 29-Mar-2021 10:11

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Item	Date	User	Comment
2.a	Oct-12-2020 13:03:00 (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
Form	Oct-12-2020 13:03:21 (UTC-05:00) Eastern Time (US & Canada)	James Fry (pfe.jfry)	Not Applicable

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

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
1	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 Oct/12/2020 **Form:** OXYGENATION PARAMETERS - Comments

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
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

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 - 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.levisse

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	Tawnyn 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	Tawnyn 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	Tawнын 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)	<u>Data Entry:</u> 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)	<u>Data Entry:</u> (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)	<u>Data Entry:</u> 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)	<u>Data Entry:</u> 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)	<u>Data Entry:</u> 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	Tawyn 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

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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

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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

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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: 4 Medical History Term: Osteoarthritis of the knees Start Date: Jan/1/2018 Ongoing: YES	Initial Entry

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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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

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Header Text: c4591001

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Site No: 1081

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Generated Time (GMT): 29-Mar-2021 10:11

			Medical History Term: Postmenopausal Start Date: Jan/1/2018 Ongoing: 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

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Header Text: c4591001

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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

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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

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Site No: 1081

Subject No: 10811194

Generated By: pfe.levissc

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Subject Initials: ---

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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

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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

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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	Tawnyn 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	Tawnyn 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	Tawnyn 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	Tawnyn 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	Tawnyn 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	Tawnyn 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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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

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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: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

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

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[Back to Form](#)**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)	Data Entry: 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)	Data Entry: 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)	Data Entry: 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)	Data Entry: 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)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
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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.levissc

Generated Time (GMT): 29-Mar-2021 10:11

Sep-29-2020 13:48:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Tawнын 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.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

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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[Back to Form](#)**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

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)	<u>Data Entry:</u> 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)	<u>Data Entry:</u> 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)	<u>Data Entry:</u> 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)	<u>Data Entry:</u> 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)	<u>Data Entry:</u> 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)	<u>Data Entry:</u> Symptoms - Other: Fatigue	Initial Entry

5.a Symptoms - Other Text:

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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

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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

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

(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)	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

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)	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

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)	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

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)	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

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	Tawyn Ebner (pfe.tebner)	Data Entry: CV34836	Initial Entry
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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 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

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

5.c 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.c 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.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

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

			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

5.d 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.d 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.d 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.d 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.e

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

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.e 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.e 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.e 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.e 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.e 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.f

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

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

			Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	
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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)	Data Entry: Not Applicable	Initial Entry

5.f 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.f 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.f 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.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)	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 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

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.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

5.g 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.g 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.g 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.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

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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

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.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
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 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.c

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.c 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.c 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.c 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.c 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.c 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.d

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.d 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.d 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.d 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.d 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.d 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.e

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

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**5.e 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.e 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.e 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.e 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.e 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.f

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

5.f 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.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

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

[Back to Form](#)

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)				
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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

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: 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

[Back to Form](#)

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[Back to Form](#)**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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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

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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

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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: ---

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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: (b) (6)/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

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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

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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

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Subject No: 10811194

Generated By: pfe.levissc

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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

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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

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 (b) (6) 2020
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 : (b) (6) /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 (b) (6) 2020 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: (b) (6) /20 20 U N K: U N K	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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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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Subject No: 10811194

Generated By: pfe.levissc

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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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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 - 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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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 (b) (6)/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

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED - 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

				review and update as appropriate
Nov-11-2020 15:19:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lora Morris (pfe.lmorris)	Data Entry: Nov/11/2020	Initial Entry

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

090177e196ae3f03\Final\Final On: 01-Apr-2021 05:06 (GMT)

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 - eCRF Audit Trail History**Form Status:** Data Complete, Verified**Site Name:** (1081) Sterling Research Group - Mt. Auburn**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**I. Subject Status**

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: (b) (6)/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

Site No: 1081

Subject No: 10811194

Generated By: pfe.levisse

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Status: Data Complete, Signed, Verified

Site Name: (1081) Sterling Research Group - Mt. Auburn

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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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