

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Cohort Selection

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

1.	Select appropriate response - Protocol version	08 SEP 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: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Oct/2/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: DEMOGRAPHY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10371318]
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):	BLACK OR AFRICAN AMERICAN
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Oct/2/2020
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: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[BILATERAL CATARACTS]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HYPERTENSION]
	Start Date:	UNK/UNK/1990
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HEPATITIS B]
	Start Date:	UNK/UNK/1968
	Ongoing:	NO End Date: UNK/UNK/2014
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Gout]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Myocardial Infarct]
	Start Date:	UNK/UNK/2009
	Ongoing:	NO End Date: UNK/UNK/2009
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Chest Pain (unspecified cardiac)]
	Start Date:	UNK/UNK/2009
	Ongoing:	YES

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001	Form: HIV STATUS
Visit: V1_DAY1_VAX1_L	Form Status: Data Complete, Locked, Frozen, Verified
Form Version: 15-Sep-2020 21:57	Site Name: (1037) CNS Healthcare Memphis
Site No: 1037	Subject Initials: ---
Subject No: 10371318	Generated Time (GMT): 29-Mar-2021 04:44
Generated By: (b) (4)	

[eCRF Audit Trail History](#)

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Oct/2/2020
2.	Weight:	[99.79]
3.	Unit:	kg
4.	Height:	[185.42]
5.	Unit:	cm
6.	Body Mass Index:	[29.0]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[36.4]
	Unit:	C
	Temperature Location:	ORAL CAVITY

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Oct/2/2020
2.	Randomization Number:	[266779]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/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	[BK6YKG]
5.b	Sample ID	[BLBB7H]
5.c	Sample ID	[BKP21D]

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/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	[BM8SGR]
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090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/2/2020 11:55
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

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (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: (1037) CNS Healthcare Memphis
Site No: 1037	Subject Initials: ---
Subject No: 10371318	Generated Time (GMT): 29-Mar-2021 04:44
Generated By: (b) (4)	

[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: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/23/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Oct/23/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.9]
	Unit:	C
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/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	[BM8SMX]
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090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/23/2020 09:50
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

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/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	[BRJPC8]
5.b	Sample ID	[BS6M65]
5.c	Sample ID	[BRSN3S]

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (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: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_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: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (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: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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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: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (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: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Unplanned Assessments

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

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	ELEVATED BLOOD PRESSURE	Dec/15/2020 UNK:UNK	NO End Date Time: Dec/18/2020 UNK:UNK	Repeating Pages

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)
[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)	[ELEVATED BLOOD PRESSURE]
4.	Start Date Time:	Dec/15/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/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

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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: [PRE-EXISTING MEDICAL]
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	[2020508644]

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Medication Error

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

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Concomitant Medications

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

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Concomitant Medications

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

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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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: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001	Form: TRANSFUSIONS
Visit: Logs - Unscheduled	Form Status: Not Started
Form Version: 22-Apr-2020 21:03	Site Name: (1037) CNS Healthcare Memphis
Site No: 1037	Subject Initials: ---
Subject No: 10371318	Generated Time (GMT): 29-Mar-2021 04:44
Generated By: (b) (4)	

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition - Treatment

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Vaccination

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Contact Outcome

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 6

Form Version: 10-Oct-2020 16:01

Form Status: Not Started

Site No: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Disposition - Follow-Up

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

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: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[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: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is NOT willing to return for Vaccination 3 OR otherwise not eligible
----	---	--

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[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 Version: 22-Apr-2020 21:03

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Nov/20/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Audit Trail](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
Form	Oct-02-2020 12:01:55 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted] [Redacted]	Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Nov-20-2020 12:29:19 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

Lisa Usdan	Approved	Oct-28-2020 22:23:30 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
------------	----------	---	------	--------

Affidavit:

By my dated signature below, I, LisaUsdan, 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.

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:55

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Oct-02-2020 11:56:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 08 SEP 2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-02-2020 11:56:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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I. Consent Was:

Date	Location	User	Value	Reason
Oct-02-2020 11:59:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: OBTAINED Date Written Consent Obtain ed Oct/2/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Subject ID

Date	Location	User	Value	Reason
Oct-02-2020 11:56:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10371318	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Oct-02-2020 11:56:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1946	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Oct-02-2020 11:59:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Oct-02-2020 11:59:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	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
Oct-02-2020 11:59:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLACK OR AFRICAN AMERICAN	Initial Entry

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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I. Date of Visit

Date	Location	User	Value	Reason
Oct-02-2020 11:59:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Oct/2/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Oct-02-2020 12:45:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/2/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-02-2020 12:45:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-02-2020 12:45:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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I.a

Date	Location	User	Value	Reason
Oct-05-2020 10:41:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 1 ber: Medical Histor BILATERAL CA y Term: TARACTS Start Date: UNK/UNK/2018 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Oct-05-2020 10:41:27 (UTC-06:00) Central 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
Jan-22-2021 14:44:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-22-2021 13:53:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Jan-22-2021 12:16:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Per SAE report, subject has a history of MI, chest pain and gout. Please review and confirm med hx and onset dates and add to medical history as appropriate.
Oct-05-2020 10:41:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BILATERAL CATARACTS	Initial Entry

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.a Start Date:

Date	Location	User	Value	Reason
Oct-05-2020 10:41:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2018	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Oct-05-2020 10:41:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Oct-05-2020 10:43:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 2 Medical History Term: HYPERTENSION Start Date: UNK/UNK/1990 Ongoing: YES	Transcription Error
Oct-05-2020 10:43:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 2 Medical History Term: HYPERTENSION Start Date: UNK/UNK/1990 Ongoing: NO End Date: UNK/UNK/2014	Transcription Error
Oct-05-2020 10:41:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term: HYPERTENSION	Initial Entry

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

			Start Date: UNK/UNK/19 68	
			Ongoing: NO End Date: UNK/UNK /2014	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.b Line/MH Number:

Date	Location	User	Value	Reason
Oct-05-2020 10:41:55 (UTC-06:00) Central 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
Jan-22-2021 15:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-22-2021 14:05:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Jan-11-2021 19:00:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	CLINICAL Thank you; however the request is to add past med hx of MI and Chest pain here, on Med Hx CRF (currently only reported to SAE)
Dec-28-2020 15:11:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	UPDATED CRF PAGE TO BE UPLOADED TO FLORENCE
Dec-24-2020 22:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical On review of the SAE report for Elevated BP, medical history of MI and Chest pain were mentioned, yet do not appear in the CRF. Please review for clinical relevance to safety event and update Med Hx log CRF if appropriate.
Oct-05-2020 10:41:55	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	HYPERTENSION	
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I.b Start Date:

Date	Location	User	Value	Reason
Oct-05-2020 10:43:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1990	Transcription Error
Oct-05-2020 10:41:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1968	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Oct-05-2020 10:43:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Transcription Error
Oct-05-2020 10:41:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2014	Initial Entry

I.c

Date	Location	User	Value	Reason
Oct-05-2020 10:42:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History Term: HEPATITIS B Start Date: UNK/UNK/1968 Ongoing: NO End Date: UNK/UNK/2014	Initial Entry

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

I.c Line/MH Number:

Date	Location	User	Value	Reason
Oct-05-2020 10:42:35 (UTC-06:00) Central 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
Oct-05-2020 10:42:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEPATITIS B	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Oct-05-2020 10:42:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1968	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Oct-05-2020 10:42:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2014	Initial Entry

I.d

Date	Location	User	Value	Reason
Jan-22-2021 13:45:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: Gout Start Date: UNK/UNK/2019 Ongoing: YES	Initial Entry

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.d Line/MH Number:

Date	Location	User	Value	Reason
Jan-22-2021 13:45:44 (UTC-06:00) Central 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
Jan-22-2021 13:45:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Gout	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Jan-22-2021 13:45:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2019	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Jan-22-2021 13:45:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.e

Date	Location	User	Value	Reason
Jan-22-2021 13:47:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History Term: Myocardial Infarct Start Date: UNK/UNK/2009 Ongoing: NO End Date: UNK/UNK/2009	Initial Entry

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

I.e Line/MH Number:

Date	Location	User	Value	Reason
Jan-22-2021 13:47:22 (UTC-06:00) Central 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
Jan-22-2021 13:47:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Myocardial Infarct	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Jan-22-2021 13:47:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2009	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Jan-22-2021 13:47:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2009	Initial Entry

I.f

Date	Location	User	Value	Reason
Feb-09-2021 14:26:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Nu 6 mber: Medical Histo Chest Pain (unspec ry Term: ified cardiac) Start Date: UNK/UNK/2009 Ongoing: YES	Changed Information
Feb-09-2021 14:24:47 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Numb 6	Changed Information

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)		(b) (4), (b) (6)	er: Medical History Term: Chest Pain (unspecified) Start Date: UNK/UNK/2009 Ongoing: YES	
Jan-22-2021 13:50:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 6 Medical History Term: Chest Pain Start Date: UNK/UNK/2009 Ongoing: YES	Initial Entry

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.f Line/MH Number:

Date	Location	User	Value	Reason
Jan-22-2021 13:50:36 (UTC-06:00) Central 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
Feb-10-2021 10:41:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Feb-10-2021 10:03:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	New query already issued by safety. query is closed to avoid duplication.
Feb-09-2021 14:26:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Chest Pain (unspecified cardiac)	Changed Information
Feb-09-2021 14:24:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	Changed Information
Feb-09-2021 14:24:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Feb-09-2021 14:24:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Chest Pain (unspecified)	Changed Information
Feb-02-2021 12:47:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	Clinical Please clarify this history as Non-cardiac Chest pain, or presumed Cardiac Chest pain. SAE report states subject has been prescribed nitroglycerin for this medical condition
Feb-02-2021 12:46:45 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	rewording query

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)		(b) (4), (b) (6)		
Feb-02-2021 12:42:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Clinical Please clarify this history as Non-cardiac Chest pain, or presumed Cardiac Chest pain

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Jan-27-2021 08:32:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	GPDCLIN: Chest pain is listed as ongoing since 2009. Please confirm ongoing and advise whether a diagnosis can be added instead of symptom. Please also clarify if subject met inclusion criterion #3 (stable disease at study entry).
Jan-27-2021 06:43:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Candidate	GPDCLIN: Chest pain is listed as ongoing since 2009. Please confirm ongoing and advise whether a diagnosis can be added instead of symptom. Please also clarify if subject met inclusion criterion #3 (stable disease at study entry).
Jan-27-2021 06:42:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	re-open in candidate state.
Jan-25-2021 08:19:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPDCLIN: Chest pain is listed as ongoing since 2009. Please clarify if a diagnosis can be added instead of symptom and if indeed ongoing,

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

				please clarify if subject met inclusion criterion #3.
Jan-22-2021 13:50:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Chest Pain	Initial Entry

If Start Date:

Date	Location	User	Value	Reason
Jan-22-2021 13:50:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2009	Initial Entry

If Ongoing:

Date	Location	User	Value	Reason
Jan-22-2021 13:50:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Oct-05-2020 10:43:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: The subject is NOT known to be HIV POSITIVE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date:

Date	Location	User	Value	Reason
Oct-05-2020 10:44:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/2/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Oct-05-2020 10:44:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 99.79	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Oct-05-2020 10:44:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Oct-05-2020 10:44:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 185.42	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Oct-05-2020 10:44:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Oct-05-2020 10:44:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 29.0	Initial Entry

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

7.a

Date	Location	User	Value	Reason
Oct-05-2020 10:44:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: 1 : Temperature: 36.4 Temperature Unit C : Temperature Loc ORAL CAV ation:: ITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Oct-05-2020 10:44:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Oct-05-2020 10:44:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.4	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Oct-05-2020 10:44:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Oct-05-2020 10:44:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Randomization Date :

Date	Location	User	Value	Reason
Oct-05-2020 10:45:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/2/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Oct-05-2020 10:45:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 266779	Initial Entry

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (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: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Oct-02-2020 12:45:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-02-2020 12:45:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-02-2020 12:46:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-02-2020 12:45:37 (UTC-06:00) Central 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-02-2020 12:45:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: YES Date of Collection: Oct/2/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-02-2020 12:46:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Sample ID: BK6YKG	Initial Entry

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (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: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.a Sample ID

Date	Location	User	Value	Reason
Oct-02-2020 12:46:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BK6YKG	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-02-2020 12:46:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BLBB7H	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-02-2020 12:46:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BLBB7H	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-02-2020 12:47:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BKP21D	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-02-2020 12:47:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BKP21D	Initial Entry

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (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: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Oct-02-2020 12:47:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-02-2020 12:47:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-02-2020 12:47:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-02-2020 12:47:20 (UTC-06:00) Central 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-02-2020 12:47:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: YES Date of Collection: Oct/2/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-02-2020 12:47:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Sample ID: BM8SGR	Initial Entry

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (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: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.a Sample ID

Date	Location	User	Value	Reason
Oct-02-2020 12:47:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BM8SGR	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-05-2020 10:46:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Oct-05-2020 10:46:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-05-2020 10:46:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Oct-05-2020 10:46:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/2/2020 11:55	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-05-2020 10:46:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Oct-05-2020 10:46:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

7. Route:

Date	Location	User	Value	Reason
Oct-05-2020 10:46:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-05-2020 10:46:32 (UTC-06:00) Central 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
Oct-05-2020 10:46:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Oct-05-2020 10:46:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	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: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-23-2020 10:40:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Oct/23/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date:

Date	Location	User	Value	Reason
Oct-23-2020 11:21:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/23/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-23-2020 11:21:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: 1 : Temperature: 36.9 Temperature Unit C : Temperature Loc ORAL CAV ation:: ITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-23-2020 11:21:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Oct-23-2020 11:21:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.9	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Oct-23-2020 11:21:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

2.a Temperature Location:

Date	Location	User	Value	Reason
Oct-23-2020 11:21:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	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: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Oct-23-2020 10:41:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-23-2020 10:41:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-23-2020 10:41:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-23-2020 10:41:01 (UTC-06:00) Central 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-23-2020 10:41:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: YES Date of Collection: Oct/23/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-23-2020 10:41:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Sample ID: BM8SMX	Initial Entry

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (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: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.a Sample ID

Date	Location	User	Value	Reason
Oct-23-2020 10:41:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BM8SMX	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-23-2020 11:20:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Oct-23-2020 11:20:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-23-2020 11:20:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Oct-23-2020 11:20:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/23/2020 09:50	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-23-2020 11:20:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Oct-23-2020 11:20:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

7. Route:

Date	Location	User	Value	Reason
Oct-23-2020 11:20:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-23-2020 11:20:04 (UTC-06:00) Central 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
Oct-23-2020 11:20:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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I. Date of Visit

Date	Location	User	Value	Reason
Nov-23-2020 23:37:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed as data entered.
Nov-23-2020 09:27:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	DONE
Nov-23-2020 03:48:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The treatment period is defined as 1st vaccination visit through the 1-month post vaccination visit after the 2nd vaccination. Please complete treatment disposition CRF and update date of EOT to match date of visit at visit 3.
Nov-20-2020 12:29:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/20/2020	Initial Entry

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (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, Frozen, Verified

Site No: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Nov-20-2020 12:29:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-20-2020 12:29:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-20-2020 12:29:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-20-2020 12:29:28 (UTC-06:00) Central 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-20-2020 12:29:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/20/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-20-2020 12:29:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRJPC8	Initial Entry

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (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, Frozen, Verified

Site No: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.a Sample ID

Date	Location	User	Value	Reason
Nov-20-2020 12:29:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRJPC8	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-20-2020 12:29:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BS6M65	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-20-2020 12:29:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BS6M65	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-20-2020 12:30:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRSN3S	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-20-2020 12:30:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRSN3S	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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Date	Location	User	Value	Reason
Jan-04-2021 09:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Form Created	

Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

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1. Category:

Date	Location	User	Value	Reason
Jan-04-2021 09:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-04-2021 09:20:59 (UTC-06:00) Central 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-04-2021 11:00:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Mar-04-2021 11:00:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Mar-04-2021 10:59:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Mar-03-2021 10:32:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-02-2021 15:06:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Medical records not available and will not be available as not medical record release on file for this facility. Follow SAE submitted
Mar-02-2021 15:06:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Medical records not available and will not be available as

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

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				not medical record release on file for this facility. Subject withdrew consent, unknown if cardiac evaluation done.
Mar-02-2021 14:51:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	unknown blood pressure values
Mar-02-2021 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Records are not available and never will be available as subject withdrew consent. No medical record release on file for hospitalization facility
Mar-01-2021 08:47:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 4: Opened	Medical Monitor_ Pls advise blood pressure values. Thanks
Feb-23-2021 21:23:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Please follow up and attempt to obtain medical records.
Feb-09-2021 14:29:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	No hospital MR received
Feb-02-2021 12:46:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Clinical Please submit a SAE safety followup specifying if chest pain during event 'elevated BP' was cardiac or non-cardiac in origin
Jan-11-2021 19:07:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical Please submit a SAE safety followup with cardiac evaluation in hospital for this event and treatment.

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1037**Subject No:** 10371318**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Not Complete**Site Name:** (1037) CNS Healthcare Memphis**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:44

Jan-07-2021 14:54:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Reissued:Opened	Please leave query open until medical records are received.
Jan-05-2021 11:26:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Answered	subject first reported due to history of gout. Then reported to doctor chest pain. Will confirm once medical records are received.
Jan-04-2021 15:35:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	Also noted in source was hospitalization for gout. Source also notes hospitalized for chest pain. Please clarify if subject was hospitalized for gout, chest pain or both. Update source as appropriate. Are hospital records available for review?
Jan-04-2021 09:26:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: ELEVATED BLOOD PRESSUR E	Changed Information
Jan-04-2021 09:22:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: BLOOD PRESSURE INCREAS ED	Changed Information
Jan-04-2021 09:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: ELEVATED BLOOD PRESSUR E	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-04-2021 09:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Dec/15/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Header Text: c4591001

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Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Feb-23-2021 21:22:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-19-2021 11:37:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	PD was submitted
Jan-07-2021 14:54:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Please confirm PD has been reported to the IRB as SAE was not reported within 24 hours of site awareness.
Jan-05-2021 11:28:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Inadvertently missed
Jan-04-2021 15:36:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Was SAE reported with 24 hours of site knowledge? Per records was not. Please explain why event was not reported within 24 hours of site awareness of event.
Jan-04-2021 09:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Dec/18/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-04-2021 09:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Mar-04-2021 10:59:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Mar-02-2021 14:55:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Documented on Follow up report. Submitted 02MAR2021
Jan-11-2021 19:02:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical COVID test status (yes/no) during Hosp was not reported in the SAE. Please submit a follow-up SAE form [#2020508644] to document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results.
Jan-05-2021 05:38:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-04-2021 09:26:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE ELEVATED BLOOD PRESSURE: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-04-2021 09:22:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE BLOOD PRESSURE INCREASED: Response to "Is the adverse event serious?" is 'Yes' but

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

				"Serious Adverse Event Number" is blank.
Jan-04-2021 09:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE ELEVATED BLOOD PRESSURE: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-04-2021 09:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<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

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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 09:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-05-2021 22:48:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-05-2021 10:49:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jan-05-2021 10:49:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatme nt(s), this event is due to: OTHER If Other, specify: PRE-EXISTING MEDIC AL	Transcription Error
Jan-04-2021 23:49:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for "Is this event related to study treatment" Is reported as 'Not Related', however response for, 'Please indicate what this event is due to' is missing. Kindly review and update.
Jan-04-2021 09:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED	Initial Entry

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-04-2021 09:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-04-2021 09:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-04-2021 09:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Jan-04-2021 09:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Jan-04-2021 09:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Jan-05-2021 05:38:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020508644	Initial Entry

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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, Frozen, Verified

Site No: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Nov-23-2020 09:14:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/20/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Nov-23-2020 09:14:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-23-2020 09:14:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (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: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-15-2021 07:42:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-15-2021 07:42:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	unfrozen. please update
Feb-11-2021 10:25:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/20/2021	Transcription Error
Feb-10-2021 11:10:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	PLEASE UNFREEZE BOTH DATES SO THEY CAN BE CHANGED.
Feb-09-2021 12:22:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Per source, date of visit 20Jan2021. Please review and update as appropriate.
Jan-28-2021 12:43:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/25/2021	Initial Entry

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail
History

Form Status: Data Complete, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Jan-28-2021 12:44:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is NOT willing to return for Vaccination 3 OR otherwise not eligible	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-11-2021 10:25:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/20/2021	Transcription Error
Jan-28-2021 12:43:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/25/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Mar-03-2021 22:17:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-03-2021 13:05:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	CONFIRMED SUBJECT RECEIVED PLACEBO. SUBJECT RTC ON 20 NOV FOR V3 FU. SUBJ CONTACTED FOR ELIG CALL AND WITHDREW CONSENT ON 20 JAN.
Mar-02-2021 21:59:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	As Subject is NOT willing to return for Vax 3, please confirm if participant was assigned to placebo and returned to safety FUP or treatment Unblinded before subject contacted to confirm willingness/eligibility to proceed with Vax 3, Else, clarify.

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Mar-02-2021 14:53:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: An swere d	Subject moving, informed site will receive vaccine outside of study. Withdrew consent.
Feb-22-2021 04:14:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW7349053;Primary Reason for Unblinding is "ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION", but "Participant is willing to return for Vaccination 3" is not selected in the Further Vaccination Confirmation CRF. Please review and update as appropriate.
Jan-28-2021 12:43:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : ASSE SS EL IGIBI LITY FOR ADDI TION AL V ACCI NATI ON	Initial Entry

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (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: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Subject Status

Date	Location	User	Value	Reason
Nov-23-2020 09:14:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Oct-05-2020 10:45:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Oct-02-2020 12:45:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Jan-11-2021 19:00:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-04-2021 09:48:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	DONE
Dec-31-2020 08:10:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Clinical Thank you. The event has been reported by FAX as a SAE; now please enter it on the AE CRF.
Dec-28-2020 15:24:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	EVENT REPORTED
Dec-27-2020 09:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL SAE of Elevated BP has been reported (21020508644); however, there is no Event of Elevated BP reported on the AE CRF. Please

090177e196ae3d45\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1037

Subject No: 10371318

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1037) CNS Healthcare Memphis

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

				update AE CRF.
Nov-23-2020 09:14:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/20/2020	Initial Entry
Oct-05-2020 10:45:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/2/2020	Initial Entry
Oct-02-2020 12:45:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/2/2020	Initial Entry

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: 1037

Site Name: (1037) CNS Healthcare Memphis

Subject No: 10371318

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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I. Casebook Signature

Date	Location	User	Value	Reason
Oct-28-2020 14:24:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry