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: 1019	**Site Name:** (1019) Diagnostics Research Group
Subject No: 10191229	**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:** MAIN INFORMED CONSENT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1019	**Site Name:** (1019) Diagnostics Research Group
Subject No: 10191229	**Subject Initials:** ---
Generated By: (b) (4)	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/24/2020

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** DEMOGRAPHY

Form Version: 15-Sep-2020 21:54 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Demography

1.	Subject ID	[10191229]
2.	Birth Date:	(b) (6)/1957
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	BLACK OR AFRICAN AMERICAN
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DATE OF VISIT

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **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	Sep/24/2020
2.	Erroneous Visit	

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** INCLUSION/EXCLUSION CRITERIA
Form Version: 15-Sep-2020 21:53	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1019	**Site Name:** (1019) Diagnostics Research Group
Subject No: 10191229	**Subject Initials:** ---
Generated By: (b) (4)	**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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DISPOSITION - SCREENING

Form Version: 15-Sep-2020 21:52 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Sep/24/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **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:	[Myopia]
	Start Date:	UNK/UNK/1988
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Septal deviation - nasal]
	Start Date:	Aug/UNK/2018
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Asthma]
	Start Date:	UNK/UNK/2013
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Recurrent abdominal pain]
	Start Date:	UNK/UNK/2012
	Ongoing:	YES

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Chronic constipation]
	Start Date:	UNK/UNK/2012
	Ongoing:	NO End Date: UNK/UNK/2015
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hemorrhoids]
	Start Date:	UNK/UNK/1998
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Cyst - bilateral breasts]
	Start Date:	UNK/UNK/2001
	Ongoing:	NO End Date: UNK/UNK/2001
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Insomnia]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES

1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Bilateral carpal tunnel syndrome]
	Start Date:	UNK/UNK/2006
	Ongoing:	YES
1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Osteoarthritis - knees]
	Start Date:	UNK/UNK/1995
	Ongoing:	YES
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Osteoporosis]
	Start Date:	UNK/UNK/2013
	Ongoing:	YES
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Recurrent lumbar pain]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES

1.m

Line/MH Number:	[13]
Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Anxiety]
Start Date:	UNK/UNK/2001
Ongoing:	YES

1.n

Line/MH Number:	[14]
Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Allergic rhinitis]
Start Date:	UNK/UNK/1995
Ongoing:	YES

1.o

Line/MH Number:	[15]
Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Cystectomy - bilateral breasts]
Start Date:	UNK/UNK/2001
Ongoing:	NO End Date: UNK/UNK/2001

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** HIV STATUS
Form Version: 15-Sep-2020 21:57	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1019	**Site Name:** (1019) Diagnostics Research Group
Subject No: 10191229	**Subject Initials:** ---
Generated By: (b) (4)	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

HIV Status

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VITAL SIGNS - BASELINE

Form Version: 15-Sep-2020 21:56 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vital Signs		
1.	Date:	Sep/24/2020
2.	Weight:	[117.7]
3.	Unit:	LB
4.	Height:	[62.5]
5.	Unit:	in
6.	Body Mass Index:	[21.2]

Vital Signs Details

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** LAB URINALYSIS - PREGNANCY TEST

Form Version: 15-Sep-2020 21:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/24/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** RANDOMIZATION
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1019	**Site Name:** (1019) Diagnostics Research Group
Subject No: 10191229	**Subject Initials:** ---
Generated By: (b) (4)	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition

1.	Randomization Date :	Sep/24/2020
2.	Randomization Number:	[264155]
3.	Randomization Group:	[ ]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1019	**Site Name:** (1019) Diagnostics Research Group
Subject No: 10191229	**Subject Initials:** ---
Generated By: (b) (4)	**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: Sep/24/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP98GT]
5.b	Sample ID	[BPRWV5]
5.c	Sample ID	[BPRWV6]
5.d	Sample ID	[BPRWV7]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **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: Sep/24/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP98N1]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **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:	Sep/24/2020 13:40
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** REACTOGENICITY DIARY
Form Version: 06-Jul-2020 21:53	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1019	**Site Name:** (1019) Diagnostics Research Group
Subject No: 10191229	**Subject Initials:** ---
Generated By: (b) (4)	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT

Header Text: c4591001	
Visit: V2_VAX2_L	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1019	**Site Name:** (1019) Diagnostics Research Group
Subject No: 10191229	**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	Oct/15/2020
2.	Erroneous Visit	

Header Text: c4591001	
Visit: V2_VAX2_L	**Form:** VITAL SIGNS - TEMP
Form Version: 10-Oct-2020 16:01	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1019	**Site Name:** (1019) Diagnostics Research Group
Subject No: 10191229	**Subject Initials:** ---
Generated By: (b) (4)	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vital Signs

1.	Date:	Oct/15/2020

Vital Signs Details

2.a

Record Identifier:	1
Temperature:	[97.1]
Unit:	F
Temperature Location:	EAR

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** LAB URINALYSIS - PREGNANCY TEST

Form Version: 15-Sep-2020 21:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Oct/15/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **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/15/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP98T2]

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **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/15/2020 11:09
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

Header Text: c4591001

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

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

Site No: 1019 **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 **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: V3_MONTH1_POSTVAX2_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Not Started

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **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: V4_MONTH6_L | **Form:** DATE OF VISIT

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **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: V4_MONTH6_L	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1019	**Site Name:** (1019) Diagnostics Research Group
Subject No: 10191229	**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: V5_MONTH12_L	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1019	**Site Name:** (1019) Diagnostics Research Group
Subject No: 10191229	**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: V5_MONTH12_L	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1019	**Site Name:** (1019) Diagnostics Research Group
Subject No: 10191229	**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: V6_MONTH24_L | **Form:** DATE OF VISIT

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **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: V6_MONTH24_L	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1019	**Site Name:** (1019) Diagnostics Research Group
Subject No: 10191229	**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_ILL - New Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191229

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: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191229

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:	[ ]

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: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191229

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_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191229

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_ILL - New Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191229

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: 1019	**Site Name:** (1019) Diagnostics Research Group
Subject No: 10191229	**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: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191229

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: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191229

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: 1019	**Site Name:** (1019) Diagnostics Research Group
Subject No: 10191229	**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: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191229

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: 1019 **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 **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: 1019	**Site Name:** (1019) Diagnostics Research Group
Subject No: 10191229	**Subject Initials:** ---
Generated By: (b) (4)	**Generated Time (GMT):** 29-Mar-2021 04:44

Unplanned Assessments		
1.	Assessments	

Header Text: c4591001
Visit: Logs **Form:** ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02
Site No: 1019 **Site Name:** (1019) Diagnostics Research Group
Subject No: 10191229 **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. DELETED	ADVERSE EVENT	1	Motor Vehicle Collision	Nov/4/2020 UNK:UNK	NO End Date Time: Nov/4/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	Small Parafalcine Subdural hematoma	Nov/4/2020 UNK:UNK	NO End Date Time: Dec/3/2020 UNK:UNK	Repeating Pages
3.	ADVERSE EVENT	3	Severe T2 Distraction Injury	Nov/4/2020 UNK:UNK	YES	Repeating Pages
4.	ADVERSE EVENT	4	Right Hemopneumothorax	Nov/4/2020 UNK:UNK	NO End Date Time: Dec/4/2020 UNK:UNK	Repeating Pages
5.	ADVERSE EVENT	5	Left Pneumothorax	Nov/4/2020 UNK:UNK	NO End Date Time: Dec/4/2020 UNK:UNK	Repeating Pages
6.	ADVERSE EVENT	6	Bilateral Rib Fractures	Nov/4/2020 UNK:UNK	YES	Repeating Pages
7.	ADVERSE EVENT	7	Left Pulmonary Emboli	Nov/4/2020 UNK:UNK	NO End Date Time:	Repeating Pages

Header Text: c4591001
Visit: Logs **Form:** ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02
Site No: 1019 **Site Name:** (1019) Diagnostics Research Group
Subject No: 10191229 **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
					Dec/4/2020 UNK:UNK	
8.	ADVERSE EVENT	8	Left Superficial Femoral Vein Deep Vein Thrombosis	Nov/4/2020 UNK:UNK	NO End Date Time: Dec/4/2020 UNK:UNK	Repeating Pages
9.	ADVERSE EVENT	9	Sigmoid Volvulus	Nov/4/2020 UNK:UNK	NO End Date Time: Nov/5/2020 UNK:UNK	Repeating Pages
10.	ADVERSE EVENT	10	Injury Secondary to Pedestrian-Car Accident	Nov/4/2020 UNK:UNK	YES	Repeating Pages
11.	ADVERSE EVENT	11	Spinal Cord Compression	Nov/4/2020 UNK:UNK	YES	Repeating Pages
12.	ADVERSE EVENT	12	Hyperemic Bowel	Nov/4/2020 UNK:UNK	NO End Date Time: Nov/5/2020 UNK:UNK	Repeating Pages
13.	ADVERSE EVENT	13	Cardiac Arrest	Nov/21/2020 UNK:UNK	NO End Date Time: Nov/21/2020 UNK:UNK	Repeating Pages

Header Text: c4591001
Visit: Logs **Form:** ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02
Site No: 1019 **Site Name:** (1019) Diagnostics Research Group
Subject No: 10191229 **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
14.	ADVERSE EVENT	14	Cardiac Arrest	Nov/23/2020 UNK:UNK	NO End Date Time: Nov/23/2020 UNK:UNK	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Deleted

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

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

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eCRF Audit Trail History
Form Audit Trail

Adverse Event Report

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

Header Text: c4591001

Visit: Logs - Unscheduled	**Form:** ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Deleted
Site No: 1019	**Site Name:** (1019) Diagnostics Research Group
Subject No: 10191229	**Subject Initials:** ---
Generated By: (b) (4)	**Generated Time (GMT):** 29-Mar-2021 04:44

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

8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	~~NO~~
9.	Is this event related to study treatment:	~~NOT RELATED~~ ~~If Not Related to study treatment(s), this event is due to:~~ ~~OTHER~~ ~~If Other, specify:~~ [~~Vehicle Collision~~]
10.	Latest Action Taken with Study Treatment:	~~NOT APPLICABLE~~
11.	Was a Concomitant Medication given?	~~NO~~
12.	Was a Non-Drug Treatment given?	~~NO~~
13.	What was the outcome of this adverse event?:	~~RECOVERED/RESOLVED WITH SEQUELAE~~
14.	Did the adverse event cause the subject to be discontinued from the study?	~~NO~~
15.	Serious Adverse Event Number: For Pfizer Use Only	[~~2020431728~~]

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

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Form Audit Trail

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Small Parafalcine Subdural hematoma]
4.	Start Date Time:	Nov/4/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/3/2020 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
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: [Injury Secondary to Pedestrian-Car Accident.]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED WITH SEQUELAE
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020431728]

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Severe T2 Distraction Injury]
4.	Start Date Time:	Nov/4/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? YES Is this serious event life threatening? NO Other medically important serious event NO

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **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.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Injury Secondary to Pedestrian-Car Accident]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020431728]

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

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Adverse Event Report

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

8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
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: [Injury Secondary to Pedestrian-Car Accident]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED WITH SEQUELAE
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020431728]

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

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Adverse Event Report

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

8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
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: [Injury Secondary to Pedestrian-Car Accident]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED WITH SEQUELAE
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020431728]

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

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eCRF Audit Trail History
Form Audit Trail

Adverse Event Report

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

8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Injury Secondary to Pedestrian-Car Accident]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020431728]

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Queries

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

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eCRF Audit Trail History
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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[7]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Left Pulmonary Emboli]
4.	Start Date Time:	Nov/4/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/4/2020 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
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: [injury Secondary to Pedestrian-Car Accident]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED WITH SEQUELAE
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020431728]

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[8]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Left Superficial Femoral Vein Deep Vein Thrombosis]
4.	Start Date Time:	Nov/4/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/4/2020 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
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: [Injury Secondary to Pedestrian-Car Accident]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED WITH SEQUELAE
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020431728]

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[9]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Sigmoid Volvulus]
4.	Start Date Time:	Nov/4/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/5/2020 UNK:UNK
6.	Toxicity Grade:	4
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? YES Other medically important serious event NO

8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
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: [Hyperemic Bowel]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED WITH SEQUELAE
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020431728]

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

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eCRF Audit Trail History
Form Audit Trail

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[10]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Injury Secondary to Pedestrian-Car Accident]
4.	Start Date Time:	Nov/4/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	4
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? YES Other medically important serious event NO

8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
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: [Pedestrian-Car Accident]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020431728]

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Answered Queries
Site No: 1019
Site Name: (1019) Diagnostics Research Group
Subject No: 10191229
Subject Initials: ---
Generated By: (b) (4)
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:	[11]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Spinal Cord Compression]
4.	Start Date Time:	Nov/4/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	4
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? YES Is this serious event life threatening? YES Other medically important serious event NO

8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [T2 distraction injury]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020431728]

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

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eCRF Audit Trail History
Form Audit Trail

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[12]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Hyperemic Bowel]
4.	Start Date Time:	Nov/4/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/5/2020 UNK:UNK
6.	Toxicity Grade:	4
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? NO Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? YES Other medically important serious event NO

8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Injury Secondary to Pedestrian-Car Accident]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED WITH SEQUELAE
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020431728]

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **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:	[13]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Cardiac Arrest]
4.	Start Date Time:	Nov/21/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/21/2020 UNK:UNK
6.	Toxicity Grade:	4
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? YES Other medically important serious event NO

8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
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: [Injury secondary to pedestrian-car accident]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED WITH SEQUELAE
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020431728]

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **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:	[14]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Cardiac Arrest]
4.	Start Date Time:	Nov/23/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/23/2020 UNK:UNK
6.	Toxicity Grade:	4
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? YES Other medically important serious event NO

8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
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: [Injury secondary to pedestrian-vehicle accident]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED WITH SEQUELAE
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020431728]

Header Text: c4591001

Visit: Logs **Form:** MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1019 **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 **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:** MEDICATION ERROR

Form Version: 17-Jul-2020 21:54 | **Form Status:** Not Started

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **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	[ ]

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191229

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: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191229

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: 1019 **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 **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

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03 | **Form Status:** Not Started

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

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

Header Text: c4591001

Visit: Logs **Form:** RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1019 **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 **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

Header Text: c4591001

Visit: Logs - Unscheduled	**Form:** RADIATION TREATMENT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1019	**Site Name:** (1019) Diagnostics Research Group
Subject No: 10191229	**Subject Initials:** ---
Generated By: (b) (4)	**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: 1019 **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 04:44

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

Header Text: c4591001

Visit: Logs - Unscheduled	**Form:** TRANSFUSIONS
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1019	**Site Name:** (1019) Diagnostics Research Group
Subject No: 10191229	**Subject Initials:** ---
Generated By: (b) (4)	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

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

Header Text: c4591001	
Visit: End of Treatment - Unscheduled	**Form:** DISPOSITION - TREATMENT
Form Version: 20-Feb-2021 02:26	**Form Status:** Data Complete, Verified
Site No: 1019	**Site Name:** (1019) Diagnostics Research Group
Subject No: 10191229	**Subject Initials:** ---
Generated By: (b) (4)	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition - Treatment		
1.	Date of Completion/Discontinuation /Death :	Nov/12/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	ADVERSE EVENT
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: 1019 **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 **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: 1019 **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 **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:** LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14 **Form Status:** Not Started

Site No: 1019 **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 04:44

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

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

Header Text: c4591001
Visit: Unplanned Vaccination - Unscheduled **Form:** VACCINATION
Form Version: 10-Dec-2020 02:26 **Form Status:** Not Started
Site No: 1019 **Site Name:** (1019) Diagnostics Research Group
Subject No: 10191229 **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: 1019 **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 **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: 1019 **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 **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: 1019	**Site Name:** (1019) Diagnostics Research Group
Subject No: 10191229	**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: 1019	**Site Name:** (1019) Diagnostics Research Group
Subject No: 10191229	**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: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191229

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: V201_SURVEIL_CONSENT - Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191229

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:** DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53 | **Form Status:** Not Started

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **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:** Not Started
Site No: 1019	**Site Name:** (1019) Diagnostics Research Group
Subject No: 10191229	**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: Potential ReVax Initial Contact - Unscheduled	**Form:** FURTHER VACCINATION CONFIRMATION
Form Version: 10-Dec-2020 02:25	**Form Status:** Not Started
Site No: 1019	**Site Name:** (1019) Diagnostics Research Group
Subject No: 10191229	**Subject Initials:** ---
Generated By: (b) (4)	**Generated Time (GMT):** 29-Mar-2021 04:44

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

Header Text: c4591001

Visit: Disposition - Unscheduled	**Form:** TREATMENT UNBLINDED
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1019	**Site Name:** (1019) Diagnostics Research Group
Subject No: 10191229	**Subject Initials:** ---
Generated By: (b) (4)	**Generated Time (GMT):** 29-Mar-2021 04:44

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

Header Text: c4591001	
Visit: Disposition - Unscheduled	**Form:** WITHDRAWAL OF CONSENT
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1019	**Site Name:** (1019) Diagnostics Research Group
Subject No: 10191229	**Subject Initials:** ---
Generated By: (b) (4)	**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: 1019	**Site Name:** (1019) Diagnostics Research Group
Subject No: 10191229	**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:** SUBJECT STATUS

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Subject Status		
1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Nov/12/2020

Header Text: c4591001	
Visit: Investigator Signature - Unscheduled	**Form:** CASEBOOK SIGNATURE FORM
Form Version: 22-Apr-2020 21:04	**Form Status:** Data Complete, Verified
Site No: 1019	**Site Name:** (1019) Diagnostics Research Group
Subject No: 10191229	**Subject Initials:** ---
Generated By: (b) (4)	**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: 1019 **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 **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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** INCLUSION/EXCLUSION CRITERIA - Comments

Form Version: 15-Sep-2020 21:53 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
Form	Sep-24-2020 15:29:31 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	N/A 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: 1019 **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 **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	Dec-07-2020 09:36:25 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
Affidavit: N/A				
(b) (6)	Approved	Dec-03-2020 14:07:30 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
Affidavit: By my dated signature below, I, (b) (6), verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject. Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature. To this I do attest by supplying my user name and password and clicking the button marked Submit below.				
(b) (6)	N/A	Nov-26-2020 17:18:11 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
Affidavit: N/A				
(b) (6)	Approved	Nov-16-2020 16:09:55 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

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: 1019	**Site Name:** (1019) Diagnostics Research Group
Subject No: 10191229	**Subject Initials:** ---
Generated By: (b) (4)	**Generated Time (GMT):** 29-Mar-2021 04:44

Affidavit:

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

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

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

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** COHORT SELECTION - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-24-2020 15:27:53 (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
Sep-24-2020 15:27:53 (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:** MAIN INFORMED CONSENT - eCRF Audit Trail History

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Consent Was:

Date	Location	User	Value	Reason
Sep-24-2020 15:28:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** OBTAINED Date Written Consent Obtained Sep/24/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** DEMOGRAPHY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Subject ID

Date	Location	User	Value	Reason
Nov-07-2020 08:41:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-06-2020 11:35:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	data entered
Nov-06-2020 05:58:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020431728 motor vehicle collision(onset date:05Nov2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Sep-24-2020 15:27:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 10191229	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-24-2020 15:27:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** (b) (6)/1957	Enrollment Entry

Header Text: c4591001
Visit: COHORT_SELECTION **Form:** DEMOGRAPHY - eCRF Audit Trail History
Form Version: 15-Sep-2020 21:54 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1019 **Site Name:** (1019) Diagnostics Research Group
Subject No: 10191229 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 04:44

3. Sex:

Date	Location	User	Value	Reason
Sep-24-2020 15:28:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-24-2020 15:28:41 (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
Sep-24-2020 15:28:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** BLACK OR AFRICAN AMERICAN	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-24-2020 15:29:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Sep/24/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:52 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **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
Sep-24-2020 15:29:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Sep/24/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-24-2020 15:29:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-24-2020 15:29:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** COMPLETED	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191229

Subject Initials: ---

Generated By: (b) (4)

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

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1.a

Date	Location	User	Value	Reason
Sep-24-2020 15:30:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 1 **Medical History Term:** Myopia **Start Date:** UNK/UNK/1988 **Ongoing:** YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-24-2020 15:30:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-24-2020 15:30:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Myopia	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Sep-24-2020 15:30:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** UNK/UNK/1988	Initial Entry

1.a Ongoing:

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191229

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-24-2020 15:30:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Sep-24-2020 15:31:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 2 **Medical History Term:** Septal deviation - nasal **Start Date:** Aug/UNK/2018 **Ongoing:** YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

1.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-24-2020 15:31:07 (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
Sep-24-2020 15:31:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Septal deviation - nasal	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Sep-24-2020 15:31:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Aug/UNK/2018	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Sep-24-2020 15:31:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Sep-24-2020 15:31:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 3 **Medical History Term:** Asthma	Initial Entry

			Start Date: UNK/UNK/2013 **Ongoing:** YES	

1.c Line/MH Number:

Date	Location	User	Value	Reason
Sep-24-2020 15:31:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 3	Initial Entry

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

Date	Location	User	Value	Reason
Sep-24-2020 15:31:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Asthma	Initial Entry

1.c Start Date:

Date	Location	User	Value	Reason
Sep-24-2020 15:31:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** UNK/UNK/2013	Initial Entry

1.c Ongoing:

Date	Location	User	Value	Reason
Sep-24-2020 15:31:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES	Initial Entry

1.d

Date	Location	User	Value	Reason
Sep-24-2020 15:31:56 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:**	Initial Entry

Time (US & Canada)			**Line/MH Number:** 4 **Medical History Term:** Recurrent abdominal pain **Start Date:** UNK/UNK/2012 **Ongoing:** YES	

1.d Line/MH Number:

Date	Location	User	Value	Reason
Sep-24-2020 15:31:56 (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
Sep-24-2020 15:31:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Recurrent abdominal pain	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Sep-24-2020 15:31:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** UNK/UNK/2012	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Sep-24-2020 15:31:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES	Initial Entry

1.e

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191229

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-24-2020 15:32:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 5 **Medical History Term:** Chronic constipation **Start Date:** UNK/UNK/2012 **Ongoing:** NO End Date: UNK/UNK/2015	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

1.e Line/MH Number:

Date	Location	User	Value	Reason
Sep-24-2020 15:32:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 5	Initial Entry

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

Date	Location	User	Value	Reason
Sep-24-2020 15:32:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Chronic constipation	Initial Entry

1.e Start Date:

Date	Location	User	Value	Reason
Sep-24-2020 15:32:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** UNK/UNK/2012	Initial Entry

1.e Ongoing:

Date	Location	User	Value	Reason
Sep-24-2020 15:32:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NO End Date: UNK/UNK/2015	Initial Entry

1.f

Date	Location	User	Value	Reason
Sep-24-2020 15:32:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 6	Initial Entry

			Medical History Term: Hemorrhoids **Start Date:** UNK/UNK/1998 **Ongoing:** YES	

1.f Line/MH Number:

Date	Location	User	Value	Reason
Sep-24-2020 15:32:57 (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
Sep-24-2020 15:32:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Hemorrhoids	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Sep-24-2020 15:32:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** UNK/UNK/1998	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Sep-24-2020 15:32:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES	Initial Entry

1.g

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: V1_DAY1_VAX1_L	**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1019	**Site Name:** (1019) Diagnostics Research Group
Subject No: 10191229	**Subject Initials:** ---
Generated By: (b) (4)	**Generated Time (GMT):** 29-Mar-2021 04:44

Sep-24-2020 15:33:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 7 **Medical History Term:** Cyst - bilateral breasts **Start Date:** UNK/UNK/2001 **Ongoing:** NO End Date: UNK/UNK/2001	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

1.g Line/MH Number:

Date	Location	User	Value	Reason
Sep-24-2020 15:33:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 7	Initial Entry

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

Date	Location	User	Value	Reason
Sep-24-2020 15:33:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Cyst - bilateral breasts	Initial Entry

1.g Start Date:

Date	Location	User	Value	Reason
Sep-24-2020 15:33:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** UNK/UNK/2001	Initial Entry

1.g Ongoing:

Date	Location	User	Value	Reason
Sep-24-2020 15:33:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NO End Date: UNK/UNK/2001	Initial Entry

1.h

Date	Location	User	Value	Reason
Sep-24-2020 15:34:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 8	Initial Entry

			Medical History Term: Insomnia **Start Date:** UNK/UNK/2005 **Ongoing:** YES	

1.h Line/MH Number:

Date	Location	User	Value	Reason
Sep-24-2020 15:34:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 8	Initial Entry

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

Date	Location	User	Value	Reason
Sep-24-2020 15:34:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Insomnia	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Sep-24-2020 15:34:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** UNK/UNK/2005	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Sep-24-2020 15:34:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES	Initial Entry

1.i

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

Sep-24-2020 15:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 9 **Medical History Term:** Bilateral carpal tunnel syndrome **Start Date:** UNK/UNK/2006 **Ongoing:** YES	Initial Entry

1.i Line/MH Number:

Date	Location	User	Value	Reason
Sep-24-2020 15:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 9	Initial Entry

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

Date	Location	User	Value	Reason
Sep-24-2020 15:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Bilateral carpal tunnel syndrome	Initial Entry

1.i Start Date:

Date	Location	User	Value	Reason
Sep-24-2020 15:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** UNK/UNK/2006	Initial Entry

1.i Ongoing:

Date	Location	User	Value	Reason
Sep-24-2020 15:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191229

Subject Initials: ---

Generated By: (b) (4)

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

1.j

Date	Location	User	Value	Reason
Sep-24-2020 15:35:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 10 **Medical History Term:** Osteoarthritis - knees **Start Date:** UNK/UNK/1995 **Ongoing:** YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

1.j Line/MH Number:

Date	Location	User	Value	Reason
Sep-24-2020 15:35:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 10	Initial Entry

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

Date	Location	User	Value	Reason
Sep-24-2020 15:35:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Osteoarthritis - knees	Initial Entry

1.j Start Date:

Date	Location	User	Value	Reason
Sep-24-2020 15:35:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** UNK/UNK/1995	Initial Entry

1.j Ongoing:

Date	Location	User	Value	Reason
Sep-24-2020 15:35:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191229

Subject Initials: ---

Generated By: (b) (4)

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

Back to Form

1.k

Date	Location	User	Value	Reason
Sep-24-2020 15:35:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 11 **Medical History Term:** Osteoporosis **Start Date:** UNK/UNK/2013 **Ongoing:** YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

1.k Line/MH Number:

Date	Location	User	Value	Reason
Sep-24-2020 15:35:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 11	Initial Entry

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

Date	Location	User	Value	Reason
Sep-24-2020 15:35:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Osteoporosis	Initial Entry

1.k Start Date:

Date	Location	User	Value	Reason
Sep-24-2020 15:35:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** UNK/UNK/2013	Initial Entry

1.k Ongoing:

Date	Location	User	Value	Reason
Sep-24-2020 15:35:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES	Initial Entry

1.l

Date	Location	User	Value	Reason
Sep-24-2020 15:36:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 12 **Medical History Term:** Recurrent lumbar pain	Initial Entry

			Start Date: UNK/UNK/2010 **Ongoing:** YES	

1.l Line/MH Number:

Date	Location	User	Value	Reason
Sep-24-2020 15:36:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 12	Initial Entry

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

Date	Location	User	Value	Reason
Sep-24-2020 15:36:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Recurrent lumbar pain	Initial Entry

1.l Start Date:

Date	Location	User	Value	Reason
Sep-24-2020 15:36:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** UNK/UNK/2010	Initial Entry

1.l Ongoing:

Date	Location	User	Value	Reason
Sep-24-2020 15:36:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES	Initial Entry

1.m

Date	Location	User	Value	Reason
Sep-24-2020 15:36:29	ACV0PFEINFP6000	auto calc	**Data Entry:**	Initial Entry

(UTC-06:00) Central Time (US & Canada)		(autocalc)	**Line/MH Number:** 13 **Medical History Term:** Anxiety **Start Date:** UNK/UNK/2001 **Ongoing:** YES	

1.m Line/MH Number:

Date	Location	User	Value	Reason
Sep-24-2020 15:36:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 13	Initial Entry

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

Date	Location	User	Value	Reason
Sep-24-2020 15:36:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Anxiety	Initial Entry

1.m Start Date:

Date	Location	User	Value	Reason
Sep-24-2020 15:36:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** UNK/UNK/2001	Initial Entry

1.m Ongoing:

Date	Location	User	Value	Reason
Sep-24-2020 15:36:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191229

Subject Initials: ---

Generated By: (b) (4)

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

1.n

Date	Location	User	Value	Reason
Sep-24-2020 15:36:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 14 **Medical History Term:** Allergic rhinitis **Start Date:** UNK/UNK/1995 **Ongoing:** YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

1.n Line/MH Number:

Date	Location	User	Value	Reason
Sep-24-2020 15:36:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 14	Initial Entry

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

Date	Location	User	Value	Reason
Sep-24-2020 15:36:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Allergic rhinitis	Initial Entry

1.n Start Date:

Date	Location	User	Value	Reason
Sep-24-2020 15:36:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** UNK/UNK/1995	Initial Entry

1.n Ongoing:

Date	Location	User	Value	Reason
Sep-24-2020 15:36:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES	Initial Entry

1.o

Date	Location	User	Value	Reason
Sep-24-2020 15:37:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 15 **Medical History Term:** Cystectomy - bi lateral breasts	Initial Entry

			Start Date: UNK/UNK/2001 **Ongoing:** NO End Date: UNK/UNK/2001	

1.o Line/MH Number:

Date	Location	User	Value	Reason
Sep-24-2020 15:37:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 15	Initial Entry

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

Date	Location	User	Value	Reason
Sep-24-2020 15:37:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Cystectomy - bilateral breasts	Initial Entry

1.o Start Date:

Date	Location	User	Value	Reason
Sep-24-2020 15:37:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** UNK/UNK/2001	Initial Entry

1.o Ongoing:

Date	Location	User	Value	Reason
Sep-24-2020 15:37:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NO End Date: UNK/UNK/2001	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** HIV STATUS - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:57 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

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

Date	Location	User	Value	Reason
Sep-24-2020 15:37:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** The subject is NOT known t o be HIV POSITIVE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date:

Date	Location	User	Value	Reason
Sep-24-2020 15:38:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Sep/24/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-24-2020 15:38:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** 117.7	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-24-2020 15:38:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-24-2020 15:38:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** 62.5	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-24-2020 15:38:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-24-2020 15:38:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 21.2	Initial Entry

7.a

Date	Location	User	Value	Reason
Sep-24-2020 15:38:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** **Record Identifier::** 1 **Temperature:** 97.9 **Temperature Unit:** F **Temperature Location::** EAR	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-24-2020 15:38:36 (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
Sep-24-2020 15:38:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** 97.9	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-24-2020 15:38:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** F	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-24-2020 15:38:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** EAR	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191229

Subject Initials: ---

Generated By: (b) (4)

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

Back to Form

1. Lab Panel:

Date	Location	User	Value	Reason
Sep-24-2020 15:39:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-24-2020 15:39:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-24-2020 15:39:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Sep/24/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-24-2020 15:39:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-24-2020 15:39:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** URINE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191229

Subject Initials: ---

Generated By: (b) (4)

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

6.a

Date	Location	User	Value	Reason
Sep-24-2020 15:39:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Sponsor-Defined Identifier:** 113 **Test::** Choriogonadotropin Beta_PX113 **Result::** **Not Done::** NOT DONE	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-24-2020 15:39:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-24-2020 15:39:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-24-2020 15:39:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NOT DONE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** RANDOMIZATION - eCRF Audit Trail History

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Randomization Date :

Date	Location	User	Value	Reason
Sep-24-2020 15:39:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Sep/24/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-24-2020 15:39:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** 264155	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191229

Subject Initials: ---

Generated By: (b) (4)

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

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Sep-24-2020 15:37:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-24-2020 15:37:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-24-2020 15:38:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-24-2020 15:37:22 (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.
Sep-24-2020 15:37:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES Date of Collection: Sep/24/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191229

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Sep-29-2020 02:14:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query.
Sep-28-2020 08:05:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-28-2020 08:05:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:**	Transcription Error
Sep-25-2020 09:11:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: A carriage is identified. To avoid processing errors, please remove the identified character by deleting the entry and re-entering the data (without using copy and paste).
Sep-24-2020 15:38:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:**	Initial Entry

5.a

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: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191229

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-24-2020 15:38:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** **Sample ID:** BP98GT	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-24-2020 15:38:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** BP98GT	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-24-2020 15:38:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** **Sample ID:** BPRWV5	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-24-2020 15:38:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** BPRWV5	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-24-2020 15:38:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** **Sample ID:** BPRWV6	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191229

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sample ID

Date	Location	User	Value	Reason
Sep-24-2020 15:38:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** BPRWV6	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-24-2020 15:39:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** **Sample ID:** BPRWV7	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Sep-24-2020 15:39:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** BPRWV7	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191229

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
Sep-24-2020 15:39:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-24-2020 15:39:21 (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
Sep-24-2020 15:39:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-24-2020 15:39:21 (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.
Sep-24-2020 15:39:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES Date of Collection: Sep/24/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191229

Subject Initials: ---

Generated By: (b) (4)

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

5.a

Date	Location	User	Value	Reason
Sep-24-2020 15:39:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** **Sample ID:** BP98N1	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-24-2020 15:39:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** BP98N1	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-24-2020 15:40:35 (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
Sep-24-2020 15:40:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-24-2020 15:40:35 (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
Sep-24-2020 15:40:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Sep/24/2020 13:40	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-24-2020 15:40:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

6. Body Side:

Date	Location	User	Value	Reason
Sep-24-2020 15:40:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-24-2020 15:40:35 (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
Sep-24-2020 15:40:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-24-2020 15:40:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-29-2020 01:25:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed by DM: (b) (6)
Sep-28-2020 08:53:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-28-2020 08:53:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Transcription Error
Sep-25-2020 08:35:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	eDiary: Per Trial Max, Subject is not the subset of 'Reactogenicity Diary collection'. Please review and consider to update response for 'Reactogenicity diary collection' as 'No', else clarify in query response. Thanks
Sep-24-2020 15:40:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Oct-15-2020 14:04:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Oct/15/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:01 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date:

Date	Location	User	Value	Reason
Oct-15-2020 14:05:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Oct/15/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-15-2020 14:05:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** **Record Identifier::** 1 **Temperature:** 97.1 **Temperature Unit:** F **Temperature Location::** EAR	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-15-2020 14:05:33 (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-15-2020 14:05:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** 97.1	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:01 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

Oct-15-2020 14:05:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Oct-15-2020 14:05:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** EAR	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191229

Subject Initials: ---

Generated By: (b) (4)

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

Back to Form

1. Lab Panel:

Date	Location	User	Value	Reason
Oct-15-2020 14:05:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Oct-15-2020 14:05:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-15-2020 14:05:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Oct/15/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Oct-15-2020 14:05:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Oct-15-2020 14:05:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** URINE	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191229

Subject Initials: ---

Generated By: (b) (4)

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

6.a

Date	Location	User	Value	Reason
Oct-15-2020 14:05:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Sponsor-Defined Identifier:** 113 **Test::** Choriogonadotropin Beta_PX113 **Result::** **Not Done::** NOT DONE	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-15-2020 14:05:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Oct-15-2020 14:05:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Oct-15-2020 14:05:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NOT DONE	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: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191229

Subject Initials: ---

Generated By: (b) (4)

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

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Oct-15-2020 16:55:23 (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-15-2020 16:55:23 (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-15-2020 16:55:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-15-2020 16:55:23 (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-15-2020 16:55:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES Date of Collection: Oct/15/2020	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: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191229

Subject Initials: ---

Generated By: (b) (4)

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

5.a

Date	Location	User	Value	Reason
Oct-15-2020 16:55:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** **Sample ID:** BP98T2	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 16:55:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** BP98T2	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-15-2020 14:06:02 (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-15-2020 14:06:02 (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-15-2020 14:06:02 (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-15-2020 14:06:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Oct/15/2020 11:09	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-15-2020 14:06:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

6. Body Side:

Date	Location	User	Value	Reason
Oct-15-2020 14:06:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Oct-15-2020 14:06:02 (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-15-2020 14:06:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Oct-15-2020 14:06:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

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

Back to Form

Date	Location	User	Value	Reason
Dec-23-2020 08:45:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	New Information
Dec-11-2020 08:47:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Undeleted	Changed Information
Dec-10-2020 10:56:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Changed Information
Nov-06-2020 10:44:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Dec-07-2020 13:16:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Dec-07-2020 13:18:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Dec-07-2020 13:24:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Dec-07-2020 13:25:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Dec-07-2020 13:26:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Dec-07-2020 13:28:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Dec-07-2020 13:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Dec-07-2020 13:36:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Dec-07-2020 13:37:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Dec-08-2020 09:49:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Dec-08-2020 09:51:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Dec-14-2020 07:23:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

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Date	Location	User	Value	Reason
Dec-14-2020 07:39:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Deleted

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

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Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Category:

Date	Location	User	Value	Reason
Nov-06-2020 10:44:43 (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
Nov-06-2020 10:44:43 (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
Dec-23-2020 19:02:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	closing an answered query on a closed AE
Dec-23-2020 08:45:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Since subject was not the driver, the AE will be closed.
Dec-17-2020 09:20:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	CLINICAL SAE event is Motor Vehicle Collision; however, SAE report does not have this; only Injury due to Pedestrian-car accident. Subject

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Deleted

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

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				was not the driver. Please confirm if this is an additional AE/SAE.
Dec-15-2020 11:47:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Dec-14-2020 08:04:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Will remove Motor Vehicle Collision AE
Dec-11-2020 14:01:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	CLINICAL - As subject was not a driver, a separate report of Motor Vehicle Collision is not required. Serious Adverse Event of Pedestrian-car accident is reported.
Dec-11-2020 08:47:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	opened AE
Dec-11-2020 07:34:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	queries on a closed AE
Dec-10-2020 10:56:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Changed Information

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Deleted

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

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Dec-09-2020 10:26:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	CLINICAL SAE event term is Motor Vehicle Collision; however, SAE report term is Injury due to Pedestrian-car accident. Please review, harmonize reporting, and update in the appropriate location.
Nov-11-2020 05:18:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	safety notified and will continue the FU.
Nov-10-2020 07:46:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	pending medical records
Nov-10-2020 06:09:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	GPDCLIN: Per CRF completion guidelines, MVA should be recorded as an AE when the Participant is the operator of the vehicle. Please confirm subject was the driver and clarify if additional AEs needs to be reported as a result of the

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Visit: Logs - Unscheduled
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Site Name: (1019) Diagnostics Research Group
Subject No: 10191229
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				accident.
Nov-09-2020 11:58:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Query closed; will follow for requested info on driver status
Nov-09-2020 09:51:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Information unknown at the moment. Will update CRF once info is known.
Nov-08-2020 12:33:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical If the subject driving and a MVA occurred, MVA needs to be reported recorded as AEs as well (see specific CRF completion guidelines 8.50.2.1 - MVA should be recorded as an AE when the Participant is the operator of the vehicle)
Nov-06-2020 10:44:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Motor Vehicle Collision	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-07-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:**	Transcription

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Deleted

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

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09:36:52 (UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	Nov/4/2020 UNK:UNK	Error
Nov-06-2020 10:44:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Nov/5/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-17-2020 09:21:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	other query issued
Dec-11-2020 14:19:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-11-2020 08:47:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Opened AE
Dec-11-2020 08:47:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Opened AE
Dec-11-2020 07:34:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Reissued:Opened	queries on a closed AE
Dec-11-2020 07:34:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	queries on a closed AE

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

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Dec-10-2020 10:56:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	Changed Information
Dec-10-2020 10:56:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Dec-09-2020 10:24:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	CLINICAL If subject has been discharged from Hosp to home or other facility, please update Hospital end date in SAE report; also report if ventilator dependency still persists
Dec-09-2020 10:15:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	CLINICAL Thank you. Please submit the SAE end date of 04Nov2020 in a SAE safety update report.
Dec-08-2020 19:18:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-07-2020 09:36:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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Dec-07-2020 09:36:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	For Motor Vehicle Collision End Date & Time 04/Nov/2020 UNK:UNK is before the Start Date & Time 05/Nov/2020 UNK:UNK.
Dec-07-2020 09:36:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Dec-07-2020 09:36:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Dec-07-2020 09:36:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NO End Date Time: Nov/4/2020 UNK:UNK	New Information
Dec-06-2020 13:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL SAE report states as of 24Nov20, subject did not appear on the hospital roster. Can it be confirmed that subject was discharged, in contrast with a possible death
Dec-01-2020 20:21:22	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Please record an

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(UTC-06:00) Central Time (US & Canada)				end date for the motor vehicle collision and, as per CRF completion guidelines, record any associated injuries as separate AE entries
Nov-06-2020 10:44:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-06-2020 10:44:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** 4	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Dec-17-2020 10:07:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Closed	closing old query
Dec-17-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Closed	closing old query

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Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

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10:07:34 (UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)		
Dec-11-2020 08:48:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Answered	Opened AE
Dec-11-2020 08:48:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	Opened AE
Dec-11-2020 07:34:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Reissued:Opened	queries on a closed AE
Dec-11-2020 07:34:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Reissued:Opened	queries on a closed AE
Dec-10-2020 08:55:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 6: Answered	AE form has been updated to harmonize both AE and SAE forms.
Dec-10-2020 08:55:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Answered	AE form has been updated to harmonize both AE and SAE forms.
Dec-10-2020 08:55:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES Is this serious event associated with congenital anomaly or birth defect?	AE form has been updated to harmonize both AE and SAE forms.

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			NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? YES Other medically important serious event NO	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Dec-09-2020 10:17:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Reissued: Opened	Clinical Thank you. Please enter a test date in the SAE lab section for the COVID test during hospitalization, if date is known
Dec-09-2020 10:14:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Reissued: Opened	CLINICAL Thank you. The 08Dec SAE update continues to report 2 serious criteria for event of pedestrian/car accident (Hospitalization and Life-threatening). Please update either AE or SAE to harmonize.
Dec-09-2020 04:59:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Dec-07-2020 14:09:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Answered	Test status has been included on form submitted today.
Dec-07-2020 14:09:14	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	Follow up SAE form has been submitted

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(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)		harmonizing the report. Thank You.
Dec-07-2020 13:39:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Follow up AE form has been updated to reflect 'injury secondary to pedestrian-car accident'
Dec-06-2020 13:53:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Opened	CLINICAL Followup - Covid test status (Yes/No or not performed) was not included in the 24Nov20 update; please submit if available.
Dec-06-2020 13:50:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Opened	CLINICAL Serious criteria for event of Motor Vehicle Accident is Hospitalization; however, SAE criteria include Hosp and Life-threatening. Please review, harmonize reporting, and update in the appropriate location.
Dec-02-2020 06:34:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	new query issued
Dec-02-2020 06:33:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	SAE RECON:AER#2020431728 motor vehicle collision was recorded in both database however, Injury secondary to pedestrian-car accident was recorded as a separate event in Safety

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				database.Please submit a follow up AEM form to clarify event term.
Dec-02-2020 06:29:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued: Opened	For PSSR review
Dec-01-2020 15:08:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	This is an updated term for 'motor vehicle collision'.
Dec-01-2020 05:51:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued: Opened	SAE RECON 1:In safety database,another SAE with term 'Injury secondary to pedestrian-car accident'was recorded. Please confirm if this is an updated term for motor vehicle collision or it should be recorded as separate SAE in CRF.
Nov-30-2020 09:14:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	please clarify. Marked as serious in AE CRF
Nov-25-2020 05:32:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	SAE RECON:AER#2020431728 Injury secondary to pedestrian-car accident(onset date:05Nov2020)was reported as serious in Safety database but missing in AE CRF. Please confirm

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				and update CRF. If safety update is required, submit a follow-up SAE Form.
Nov-10-2020 22:29:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Query closed; will follow for SAE update with the requested COVID test info
Nov-10-2020 11:04:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	sae submitted to state negative covid test
Nov-10-2020 10:35:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical COVID test status (yes/no) during Hospitalization has not been reported in the SAE submitted to safety. Please submit a follow-up SAE form [#2020431728] to document if COVID testing was performed (YES/NO) and if yes, the date and results.
Nov-07-2020 08:41:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-07-2020 04:16:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	For AE Motor Vehicle Collision: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

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Nov-06-2020 10:44:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Motor Vehicle Collision: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-06-2020 10:44:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening?	Initial Entry

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			NO Other medically i mportant serious event NO	

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Nov-06-2020 10:44:43 (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
Nov-06-2020 10:44:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NOT RELATED If Not Related to study tre atment(s), this event is due to: OTHER *If Other, specify:* Vehicle Collision	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-06-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:**	Initial Entry

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10:44:43 (UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	NOT APPLICABLE	

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-06-2020 10:44:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-06-2020 10:44:43 (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
Dec-07-2020 10:15:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Closed	Close Auto Query
Dec-07-2020 10:15:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** RECOVERED/RESOLVED WITH SEQUELAE	New Information
Dec-07-2020	ACV0PFEINFP6000	auto query	Query 5: Op	For AE Motor Vehicle Collision:

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

09:36:25 (UTC-06:00) Central Time (US & Canada)		(autoquery)	ened	Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Nov-27-2020 01:58:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Cl osed	Response satisfies query
Nov-26-2020 19:35:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Cl osed	Response satisfies query
Nov-26-2020 17:18:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: An swered	New Information
Nov-26-2020 17:18:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: An swered	Answer Auto Query
Nov-26-2020 17:18:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry :** NOT RECO VERED/NO T RESOLV ED	New Information
Nov-26-2020 04:15:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Op ened	SAE RECON:AER#2020431728 ,outcome was updated to Not Recovered/Not Resolved on Safety database while reported as 'UNKNOWN' in AE CRF . Please confirm correct outcome. If safety

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

				update is required, please submit a follow-up form.
Nov-24-2020 02:40:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	DM: Response to "What was the outcome of this adverse event?" is 'Unknown', However "Is the adverse event still ongoing?" is marked "Yes", as per previous response medical records will be available by 23 NOV 2020, please review and update, else clarify.
Nov-17-2020 11:55:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Candidate	Possibly receiving medical records 23 NOV 2020. Will update then
Nov-17-2020 07:42:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Possibly receiving medical records 23 NOV 2020. Will update then
Nov-15-2020 12:20:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	In order to put this issue on hold we need an date (or estimated date) as to when the missing information is available. Please provide a DATE as to when we can expect the information. Thank you!
Nov-13-2020 14:12:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-13-2020 14:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Candidate	Awaiting medical records to update Outcome.

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Deleted

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

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

Nov-13-2020 08:56:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Medical records are pending. Unbale to reach subject at this time.
Nov-13-2020 08:45:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	For AE Motor Vehicle Collision: Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Nov-13-2020 08:45:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Nov-13-2020 08:45:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** UNKNOWN	Transcription Error
Nov-12-2020 04:01:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2020431728,outcome was reported as UNKNOWN to Safety DB however, recorded as NOT RECOVERED/NOT RESOLVED on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Nov-10-2020 16:13:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Deleted

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

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

Nov-10-2020 07:47:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Answer Auto Query
Nov-10-2020 07:47:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NOT RECOVERED/NOT RESOLVED	Transcription Error

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Deleted

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

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

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

Date	Location	User	Value	Reason
Nov-10-2020 02:32:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	AE is still ongoing and AE Outcome is not recorded as Unresolved or Resolving. Please reconcile and update data; else clarify
Nov-09-2020 09:52:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Medical records have been requested. Will update once information is known.
Nov-07-2020 08:52:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	RQ#1: AE is till ongoing and AE Outcome is not recorded as Unresolved or Resolving. Please reconcile and update data; else clarify.
Nov-06-2020 11:42:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	ongoing
Nov-06-2020 10:44:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Motor Vehicle Collision: Response to

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

				"What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Nov-06-2020 10:44:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** UNKNOWN	Initial Entry

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

Date	Location	User	Value	Reason
Nov-06-2020 10:44:43 (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
Nov-07-2020 08:41:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** 2020431728	Initial Entry

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Frozen
Site No: 1019
Site Name: (1019) Diagnostics Research Group
Subject No: 10191229
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Category:

Date	Location	User	Value	Reason
Dec-07-2020 13:16:54 (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
Dec-07-2020 13:16:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 2	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-20-2021 05:26:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-19-2021 13:44:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jan-19-2021 13:44:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Small Parafalcine S ubdural hematoma	Transcription Error
Jan-11-2021 05:52:02	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020431728,

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)		the term in Safety was updated to 'Small parafalcine SUBDURAL hematoma' while retained as Small Parafalcine Subdermal hematoma in CRF. Please confirm correct term. If safety update is required, please submit a follow-up form
Dec-07-2020 13:16:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Small Parafalcine S ubdermal hematoma	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-18-2021 18:14:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-10-2021 11:03:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Event updated in SAE safety update.
Feb-10-2021 10:51:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Clinical Thank you; please submit event end date in a SAE safety update
Feb-04-2021 09:36:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Form updated.
Feb-01-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical Please

18:25:52 (UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)		review for end date of this event, which is still listed at Grade 3
Dec-07-2020 13:16:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Nov/4/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-04-2021 09:37:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NO End Date Time: Dec/3/2020 UNK:UNK	Transcription Error
Dec-07-2020 13:16:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-07-2020 13:16:54 (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.

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).

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Frozen
Site No: 1019
Site Name: (1019) Diagnostics Research Group
Subject No: 10191229
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Dec-17-2020 08:45:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Dec-11-2020 08:26:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	SAE form updated.
Dec-11-2020 07:04:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	CLINICAL - Event serious criteria is Hosp; however, SAE event report has serious criteria of Hosp and Life-threatening. Please review, harmonize reporting, and update in the appropriate location.
Dec-11-2020 07:03:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Dec-11-2020 03:57:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-10-2020 15:14:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	SAE report submitted 10Dec2020
Dec-09-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	CLINICAL

10:36:17 (UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)		Subdural hematoma event should be independently be considered for Serious criteria. If Serious, please add to SAE report #2020431728 in the SAE section as a SAE (event is already in the narrative; thank you), otherwise modify Serious criteria
Dec-09-2020 10:34:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	rewording
Dec-09-2020 10:12:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL Event of subdural hematoma is Serious; please add to current SAE report #2020431728 in the SAE section as SAE #2 (hematoma is already in the narrative; thank you).
Dec-07-2020 13:16:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Small Parafalcine Subdermal hematoma: Response to "Is the adverse event

				serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-07-2020 13:16:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Dec-07-2020 13:16:54 (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
Dec-07-2020 13:16:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER *If Other, specify:* Injury Secondary to Pedestrian-Car Accident.	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-07-2020 13:16:54 (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
Dec-07-2020 13:16:54 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NO	Initial Entry

Time (US & Canada)				

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-07-2020 13:16:54 (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
Feb-16-2021 01:48:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	issue resolved
Feb-11-2021 12:22:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Candidate	Pending SDB update
Feb-10-2021 09:25:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Submitted to SDB
Feb-10-2021 00:07:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2020431728,outcome was updated to RECOVERED/RESOLVED WITH SEQUELAE on AE CRF while reported as Not Recovered/Not Resolved in SDB. Please confirm outcome.If safety update is required, please submit a follow-up form.

Feb-04-2021 09:42:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-04-2021 09:42:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** RECOVERED/RESOLVED WITH SEQUELAE	New Information
Feb-04-2021 09:37:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Small Parafalcine Subdural hematoma: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Dec-07-2020 13:16:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Dec-07-2020 13:16:54 (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
Dec-11-2020 03:57:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** 2020431728	Initial Entry

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete
Site No: 1019
Site Name: (1019) Diagnostics Research Group
Subject No: 10191229
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 04:44

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1. Category:

Date	Location	User	Value	Reason
Dec-07-2020 13:18:42 (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
Dec-07-2020 13:18:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 3	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-17-2020 08:47:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Query closed; will follow for SAE update with the requested fracture info
Dec-15-2020 08:39:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Cannot confirm, awaiting more medical records.
Dec-11-2020 08:10:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	CLINICAL - please confirm if the subject has a T2 fracture; update AE and SAE if fracture is

				present
Dec-11-2020 07:22:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	term was split
Dec-11-2020 07:07:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	CLINICAL - Event term is Severe T2 Distraction Injury; however, SAE event term is T2 Distraction with Spinal Chord Compression. Please review, harmonize reporting, and update in the appropriate location
Dec-11-2020 07:07:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	typo
Dec-11-2020 07:06:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL - Event term is Severe T2 Distraction Injury; however, SAE event term is Sever T2 Distraction with Spinal Chord Compression.

				Please review, harmonize reporting, and update in the appropriate location
Dec-08-2020 11:48:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Dec-08-2020 09:47:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Dec-08-2020 09:47:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Severe T2 Distraction Injury	Changed Information
Dec-07-2020 15:05:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Multiple concepts in the term SEVERE T2 DISTRACTION INJURY WITH SPINAL CORD COMPRESSION. Split the term into SEVERE T2 DISTRACTION INJURY and SPINAL CORD COMPRESSION

				and submit separately. Thank you.
Dec-07-2020 13:18:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Severe T2 Distraction Injury With Spinal Cord Compression	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-07-2020 13:18:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Nov/4/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-07-2020 13:18:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-07-2020 13:18:42	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** 3	Initial Entry

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)		

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Dec-17-2020 08:45:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Dec-11-2020 08:25:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Changed Information
Dec-11-2020 08:25:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES Is this serious event ass ociated with congenital anomaly or birth defect? NO Did this serious event re sult in death? NO Did this serious event re quire or prolong hospita lization? YES	Changed Information

			Did this serious event result in persistent or significant disability/incapacity? YES Is this serious event life threatening? NO Other medically important serious event NO	
Dec-11-2020 07:05:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-11-2020 07:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	CLINICAL - Event serious criteria is Hosp; however, SAE event report has serious criteria of Hosp and Life-threatening. Please review, harmonize reporting, and update in the appropriate location.
Dec-11-2020 03:59:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete
Site No: 1019
Site Name: (1019) Diagnostics Research Group
Subject No: 10191229
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 04:44

Dec-10-2020 15:15:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	SEA report submitted 10Dec2020
Dec-09-2020 10:37:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL T2 distraction event should be independently be considered for Serious criteria. If Serious, please add to SAE report #2020431728 in the SAE section as a SAE (event is already in the narrative; thank you), otherwise modify Serious criteria
Dec-08-2020 09:47:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Severe T2 Distraction Injury: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-07-2020 13:24:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES Is this serious event ass ociated with congenital anomaly or birth defect? NO Did this serious event re sult in death?	Transcription Error

			NO Did this serious event require or prolong hospitalization? NO Did this serious event result in persistent or significant disability/incapacity? YES Is this serious event life threatening? NO Other medically important serious event NO	
Dec-07-2020 13:18:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Severe T2 Distraction Injury With Spinal Cord Compression: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-07-2020 13:18:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES Is this serious event associated with congenital anomaly or birth defect?	Initial Entry

			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.

Date	Location	User	Value	Reason
Dec-07-2020 13:18:42 (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:

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete
Site No: 1019
Site Name: (1019) Diagnostics Research Group
Subject No: 10191229
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Dec-07-2020 13:18:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER *If Other, specify:* Injury Secondary to Pedestrian-Car Accident	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-07-2020 13:18:42 (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
Dec-07-2020 13:18:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-07-2020 13:18:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Dec-07-2020 13:18:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Dec-07-2020 13:18:42 (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
Dec-11-2020 03:59:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** 2020431728	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Category:

Date	Location	User	Value	Reason
Dec-07-2020 13:24:14 (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
Dec-07-2020 13:24:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 4	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-07-2020 13:24:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Right Hemopneumothorax	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-07-2020 13:24:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Nov/4/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-18-2021 18:15:19	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)		
Feb-10-2021 11:04:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Event updated in SAE safety.
Feb-10-2021 10:50:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Clinical Thank you; please submit event end date in a SAE safety update
Feb-04-2021 09:35:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-04-2021 09:35:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NO End Date Time: Dec/4/2020 UNK:UNK	New Information
Feb-01-2021 18:21:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical Please review for end date of this event, which is still listed at Grade 4
Dec-07-2020 13:24:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-07-2020 13:24:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** 4	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Dec-11-2020 08:29:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Dec-11-2020 08:27:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	Changed Information
Dec-11-2020 08:27:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES Is this serious event as sociated with congenit al anomaly or birth de fect? NO Did this serious event result in death? NO Did this serious event require or prolong hos pitalization? YES Did this serious event	Changed Information

			result in persistent or s ignificant disability/in capacity? NO Is this serious event lif e threatening? YES Other medically impor tant serious event NO	
Dec-11-2020 07:14:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	CLINICAL - Event serious criteria is Life-threatening; however, SAE event report has serious criteria of Hosp and Life-threatening. Please review, harmonize reporting, and update in the appropriate location.
Dec-11-2020 07:13:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	typo
Dec-11-2020 07:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-11-2020 07:08:40 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	CLINICAL - Event term is Severe T2 Distraction Injury;

Central Time (US & Canada)				however, SAE event term is Sever T2 Distraction with Spinal Chord Compression. Please review, harmonize reporting, and update in the appropriate location
Dec-11-2020 03:26:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-10-2020 15:15:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	SAE report submitted 10Dec2020
Dec-09-2020 10:38:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL Hemopneuomothorax event should be independently be considered for Serious criteria. If Serious, please add to SAE report #2020431728 in the SAE section as a SAE (event is already in the narrative; thank you), otherwise modify Serious criteria
Dec-07-2020 13:24:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Right Hemopneumothorax: Response to "Is the adverse event serious?" is 'Yes' but

				"Serious Adverse Event Number" is blank.
Dec-07-2020 13:24:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES Is this serious event as sociated with congenit al anomaly or birth de fect? NO Did this serious event result in death? NO Did this serious event require or prolong hos pitalization? NO Did this serious event result in persistent or s ignificant disability/in capacity? NO Is this serious event lif e threatening? YES Other medically impor tant serious event NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Dec-07-2020 13:24:14 (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
Dec-07-2020 13:24:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER *If Other, specify:* Injury Secondary to Pedestrian-Car Accident	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-07-2020 13:24:14 (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
Dec-07-2020 13:24:14 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NO	Initial Entry

Time (US & Canada)				

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-07-2020 13:24:14 (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
Feb-16-2021 01:48:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	issue resolved
Feb-11-2021 12:23:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Candidate	Pending SDB update
Feb-10-2021 09:25:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Submitted to SDB
Feb-10-2021 00:06:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2020431728,outcome was updated to RECOVERED/RESOLVED WITH SEQUELAE on AE CRF while reported as Not Recovered/Not Resolved in SDB. Please confirm outcome.If safety update is required, please submit a follow-up form.

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Frozen
Site No: 1019
Site Name: (1019) Diagnostics Research Group
Subject No: 10191229
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 04:44

Feb-04-2021 09:44:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-04-2021 09:44:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** RECOVERED/RESOLVED WITH SEQUELAE	Transcription Error
Feb-04-2021 09:35:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Right Hemopneumothorax: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Dec-07-2020 13:24:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Dec-07-2020 13:24:14 (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
Dec-11-2020 03:26:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** 2020431728	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Category:

Date	Location	User	Value	Reason
Dec-07-2020 13:25:43 (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
Dec-07-2020 13:25:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 5	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-07-2020 13:25:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Left Pneumothorax	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-07-2020 13:25:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Nov/4/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-18-2021 18:15:38	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)		
Feb-10-2021 11:04:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Event updated in SAE safety update.
Feb-10-2021 10:50:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Clinical Thank you; please submit event end date in a SAE safety update
Feb-04-2021 09:35:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-04-2021 09:35:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NO End Date Time: Dec/4/2020 UNK:UNK	New Information
Feb-01-2021 18:22:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical Please review for end date of this event, which is still listed at Grade 4
Dec-07-2020 13:25:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-07-2020 13:25:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** 4	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Dec-11-2020 13:45:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Dec-11-2020 08:28:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	Changed Information
Dec-11-2020 08:28:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity?	Changed Information

			NO Is this serious event life threatening? YES Other medically importa nt serious event NO	
Dec-11-2020 07:15:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	CLINICAL - Event serious criteria is Life-threatening; however, SAE event report has serious criteria of Hosp and Life-threatening. Please review, harmonize reporting, and update in the appropriate location.
Dec-11-2020 07:14:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	typo
Dec-11-2020 07:09:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-11-2020 07:09:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	CLINICAL - Event term is Severe T2 Distraction Injury;

				however, SAE event term is Sever T2 Distraction with Spinal Chord Compression. Please review, harmonize reporting, and update in the appropriate location
Dec-11-2020 03:29:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-10-2020 15:15:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	SAE report submitted 10Dec2020
Dec-09-2020 10:39:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL Pneumothorax event should be independently be considered for Serious criteria. If Serious, please add to SAE report #2020431728 in the SAE section as a SAE (event is already in the narrative; thank you), otherwise modify Serious criteria
Dec-07-2020 13:25:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Left Pneumothorax: Response to "Is the adverse event

				serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-07-2020 13:25:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? NO Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? YES Other medically important serious event NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Dec-07-2020 13:25:43 (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
Dec-07-2020 13:25:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER *If Other, specify:* Injury Secondary to Pedestrian-Car Accident	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-07-2020 13:25:43 (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
Dec-07-2020 13:25:43 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NO	Initial Entry

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Frozen
Site No: 1019
Site Name: (1019) Diagnostics Research Group
Subject No: 10191229
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)				

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-07-2020 13:25:43 (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
Feb-16-2021 01:48:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	issue resolved
Feb-11-2021 12:23:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Candidate	Pending SDB update
Feb-10-2021 09:26:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Submitted to SDB.
Feb-10-2021 00:08:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2020431728,outcome was updated to RECOVERED/RESOLVED WITH SEQUELAE on AE CRF while reported as Not Recovered/Not Resolved in SDB. Please confirm outcome.If safety update is required, please submit a follow-up form.

Feb-04-2021 09:45:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-04-2021 09:45:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** RECOVERED/RESOLVED WITH SEQUELAE	New Information
Feb-04-2021 09:35:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Left Pneumothorax: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Dec-07-2020 13:25:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Dec-07-2020 13:25:43 (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
Dec-11-2020 03:29:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** 2020431728	Initial Entry

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete
Site No: 1019
Site Name: (1019) Diagnostics Research Group
Subject No: 10191229
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Category:

Date	Location	User	Value	Reason
Dec-07-2020 13:26:58 (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
Dec-07-2020 13:26:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 6	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-07-2020 13:26:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Bilateral Rib Fractures	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-07-2020 13:26:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Nov/4/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-10-2021 10:48:15	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)		
Feb-04-2021 09:42:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Per latest medical records, event is still ongoing
Feb-01-2021 18:24:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical Please review for end date of this event, which is still listed at Grade 3
Dec-07-2020 13:26:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-07-2020 13:26:58 (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.

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

Date	Location	User	Value	Reason
Dec-17-2020 08:30:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query

Dec-11-2020 08:28:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	SAE form has been updated.
Dec-11-2020 07:17:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	CLINICAL - Event serious criteria is Hosp; however, SAE event report has serious criteria of Hosp and Life-threatening. Please review, harmonize reporting, and update in the appropriate location.
Dec-11-2020 07:17:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Deleted	typo
Dec-11-2020 07:17:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-11-2020 07:16:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Candidate	CLINICAL - Event serious criteria is Life-threatening; however, SAE event report has serious criteria of Hosp and Life-threatening. Please review, harmonize reporting, and update in the

				appropriate location.
Dec-11-2020 03:36:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-10-2020 15:16:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	SAE report submitted 10Dec2020
Dec-09-2020 10:39:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL Bilat Rib fractures event should be independently be considered for Serious criteria. If Serious, please add to SAE report #2020431728 in the SAE section as a SAE (event is already in the narrative; thank you), otherwise modify Serious criteria
Dec-07-2020 13:26:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Bilateral Rib Fractures: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-07-2020 13:26:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES Is this serious event ass ociated with congenital	Initial Entry

			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.

Date	Location	User	Value	Reason
Dec-07-2020 13:26:58 (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
Dec-07-2020 13:26:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER *If Other, specify:* Injury Secondary to Pedestrian-Car Accident	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-07-2020 13:26:58 (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
Dec-07-2020 13:26:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-07-2020 13:26:58 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NO	Initial Entry

Time (US & Canada)				

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

Date	Location	User	Value	Reason
Dec-07-2020 13:26:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Dec-07-2020 13:26:58 (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
Dec-11-2020 03:36:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** 2020431728	Initial Entry

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Queries
Site No: 1019
Site Name: (1019) Diagnostics Research Group
Subject No: 10191229
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Category:

Date	Location	User	Value	Reason
Dec-07-2020 13:28:14 (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
Dec-07-2020 13:28:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 7	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-07-2020 13:28:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Left Pulmonary Emboli	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-01-2021 18:25:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	incorrect field queried
Feb-01-2021 18:23:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical Please review for end date of this event, which is still listed at Grade 3

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Queries
Site No: 1019
Site Name: (1019) Diagnostics Research Group
Subject No: 10191229
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 04:44

Dec-07-2020 13:28:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Nov/4/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-18-2021 18:16:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-10-2021 11:05:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Event updated in SAE safety.
Feb-10-2021 10:52:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Clinical Thank you; please submit event end date in a SAE safety update
Feb-04-2021 14:53:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-04-2021 14:53:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NO End Date Time: Dec/4/2020 UNK:UNK	New Information
Feb-01-2021 18:25:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical Please review for end date of this event, which is still listed at Grade 3
Dec-07-2020 13:28:14	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES	Initial Entry

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)		

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-07-2020 13:28:14 (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.

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

Date	Location	User	Value	Reason
Dec-17-2020 08:32:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Dec-11-2020 08:32:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	SAE form updated.
Dec-11-2020 07:03:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-11-2020 07:02:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	CLINICAL - Event serious criteria is Hosp; however, SAE event report has serious criteria of

				Hosp and Life-threatening. Please review, harmonize reporting, and update in the appropriate location.
Dec-11-2020 03:39:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-10-2020 15:16:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	SAE report submitted 10Dec2020
Dec-09-2020 10:40:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL PE event should be independently be considered for Serious criteria. If Serious, please add to SAE report #2020431728 in the SAE section as a SAE (event is already in the narrative; thank you), otherwise modify Serious criteria
Dec-07-2020 13:28:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Left Pulmonary Emboli: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Queries

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

Dec-07-2020 13:28:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Queries
Site No: 1019
Site Name: (1019) Diagnostics Research Group
Subject No: 10191229
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 04:44

Dec-07-2020 13:28:14 (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
Dec-07-2020 13:35:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER *If Other, specify:* injury Secondary to Pedestrian-Car Accident	Transcription Error
Dec-07-2020 13:28:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER *If Other, specify:* injury Secondary to Pedestrian-Car Injury	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-07-2020 13:28:14 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NOT APPLICABLE	Initial Entry

Time (US & Canada)				

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-07-2021 15:49:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPDCLIN: Pulmonary embolism- drug therapy is listed as NO. please confirm or update CRF and send a FU SAE report. please review all the associated AEs reported for this subject to ensure therapy is recorded correctly. thank you.
Dec-07-2020 13:28:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-07-2020 13:28:14 (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
Feb-16-2021 01:48:33	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	issue resolved

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)		
Feb-11-2021 12:23:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Candidate	Pending SDB update
Feb-10-2021 09:26:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Submitted to SDB.
Feb-10-2021 00:09:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2020431728,outcome was updated to RECOVERED/RESOLVED WITH SEQUELAE on AE CRF while reported as Not Recovered/Not Resolved in SDB. Please confirm outcome.If safety update is required, please submit a follow-up form.
Feb-04-2021 14:54:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-04-2021 14:54:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** RECOVERED/RESOLVED WITH SEQUELAE	New Information
Feb-04-2021 14:53:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Left Pulmonary Emboli: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Queries
Site No: 1019
Site Name: (1019) Diagnostics Research Group
Subject No: 10191229
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 04:44

Dec-07-2020 13:28:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Dec-07-2020 13:28:14 (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
Dec-11-2020 03:41:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** 2020431728	corrected AER number
Dec-11-2020 03:39:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** 10191229	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Category:

Date	Location	User	Value	Reason
Dec-07-2020 13:34:52 (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
Dec-07-2020 13:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 8	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-07-2020 13:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Left Superficial Femoral Vei n Deep Vein Thrombosis	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-07-2020 13:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Nov/4/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-18-2021 18:16:28	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)		
Feb-10-2021 11:03:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	End date has been updated in SAE safety update.
Feb-10-2021 10:52:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Clinical Thank you; please submit event end date in a SAE safety update
Feb-04-2021 14:56:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-04-2021 14:56:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NO End Date Time: Dec/4/2020 UNK:UNK	New Information
Feb-01-2021 18:23:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical Please review for end date of this event, which is still listed at Grade 3
Dec-07-2020 13:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-07-2020 13:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** 3	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Dec-17-2020 08:48:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Dec-17-2020 04:58:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-14-2020 08:03:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	SAE form has been updated.
Dec-11-2020 13:54:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	CLINICAL Thank you for event reporting; please consider if DVT event individually would meet serious criteria. If serious, please submit DVT in the SAE event section for SAE #2020431728
Dec-11-2020 13:52:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	PE is serious

Dec-11-2020 08:34:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Dec-11-2020 08:34:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO	Transcription Error
Dec-11-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL PE

07:19:00 (UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)		event should be independently be considered for Serious criteria. If Serious, please add to SAE report #2020431728 in the SAE section as a SAE (event is already in the narrative; thank you), otherwise modify Serious criteria
Dec-07-2020 13:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Left Superficial Femoral Vein Deep Vein Thrombosis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-07-2020 13:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospital	Initial Entry

			ization? YES Did this serious event re sult in persistent or signi ficant disability/incapaci ty? YES Is this serious event life t hreatening? NO Other medically importa nt serious event NO	

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Dec-07-2020 13:34:52 (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
Dec-07-2020 13:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NOT RELATED If Not Related to study trea tment(s), this event is due t o: OTHER	Initial Entry

			If Other, specify: Injury Secondary to P edestrian-Car Acciden t	

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-07-2020 13:34:52 (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
Dec-07-2020 13:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-07-2020 13:34:52 (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
Feb-16-2021 01:48:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Clos ed	issue resolved

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

Feb-11-2021 12:24:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Candidate	Pending SDB update
Feb-10-2021 09:26:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Submitted to SDB.
Feb-10-2021 00:12:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2020431728,outcome was updated to RECOVERED/RESOLVED WITH SEQUELAE on AE CRF while reported as Not Recovered/Not Resolved in SDB. Please confirm outcome.If safety update is required, please submit a follow-up form.
Feb-04-2021 14:56:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-04-2021 14:56:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** RECOVERED/RESOLVED WITH SEQUELAE	New Information
Feb-04-2021 14:56:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Left Superficial Femoral Vein Deep Vein Thrombosis: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Dec-07-2020 13:34:52	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NOT RECOV	Initial Entry

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	ERED/NOT RESOLVED	

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

Date	Location	User	Value	Reason
Dec-07-2020 13:34:52 (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
Dec-17-2020 04:58:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** 2020431728	Initial Entry

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Frozen
Site No: 1019
Site Name: (1019) Diagnostics Research Group
Subject No: 10191229
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Category:

Date	Location	User	Value	Reason
Dec-07-2020 13:36:40 (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
Dec-07-2020 13:36:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 9	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-11-2020 07:21:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2 : Closed	term was split
Dec-11-2020 07:11:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2 : Opened	CLINICAL - Event term is Sigmoid Volvulus; however, SAE event term is Sigmoid volvulus with hyperemic bowel. Please review, harmonize reporting, and

				update in the appropriate location
Dec-08-2020 11:49:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1 : Closed	Discrepancy has been closed.
Dec-08-2020 09:47:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1 : Answered	Changed Information
Dec-08-2020 09:47:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Sigmoid Volvulus	Changed Information
Dec-07-2020 16:54:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1 : Opened	Multiple concepts in the term SIGMOID VOLVULUS WITH HYPEREMIC BOWEL. Split the term into SIGMOID VOLVULUS and HYPEREMIC BOWEL and submit separately. Thank you.

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Frozen
Site No: 1019
Site Name: (1019) Diagnostics Research Group
Subject No: 10191229
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 04:44

Dec-07-2020 13:36:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Sigmoid Volvulus With Hyperemic Bowel	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-07-2020 13:36:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Nov/4/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-08-2020 09:48:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NO End Date Time: Nov/5/2020 UNK:UNK	Changed Information
Dec-07-2020 13:36:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-07-2020 13:36:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** 4	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Dec-11-2020 13:49:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-11-2020 08:35:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Dec-11-2020 08:35:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES Is this serious event ass ociated with congenital anomaly or birth defect? NO Did this serious event re sult in death? NO Did this serious event re quire or prolong hospita lization? YES Did this serious event re sult in persistent or signi ficant disability/incapac ity?	Changed Information

			NO Is this serious event life threatening? YES Other medically important serious event NO	
Dec-11-2020 07:13:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL - Event serious criteria is Life-theatening; however, SAE event report has serious criteria of Hosp and Life-threatening. Please review, harmonize reporting, and update in the appropriate location.
Dec-11-2020 03:46:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-08-2020 09:47:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Sigmoid Volvulus: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.

Dec-07-2020 13:36:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Sigmoid Volvulus With Hyperemic Bowel: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-07-2020 13:36:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES Is this serious event ass ociated with congenital anomaly or birth defect? NO Did this serious event re sult in death? NO Did this serious event re quire or prolong hospita lization? NO Did this serious event re sult in persistent or signi ficant disability/incapac ity? NO Is this serious event life threatening? YES Other medically importa	Initial Entry

			nt serious event NO	

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Dec-07-2020 13:36:40 (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
Dec-11-2020 13:46:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-11-2020 08:38:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Dec-11-2020 08:38:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NOT RELATED If Not Related to study tr eatment(s), this event is d ue to: OTHER *If Other, specify:* Hyperemic Bowel	Changed Information
Dec-11-2020 07:26:03 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL For Other reason, SAE report

Time (US & Canada)				specifies the Hyperemic bowel as the specific cause. Please review and update Other reason if appropriate.
Dec-07-2020 13:36:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER *If Other, specify:* Injury Secondary to Pedestrian-Car Accident	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-07-2020 13:36:40 (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
Dec-07-2020 13:36:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Frozen
Site No: 1019
Site Name: (1019) Diagnostics Research Group
Subject No: 10191229
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Dec-07-2020 13:36:40 (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
Dec-08-2020 09:51:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-08-2020 09:51:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** RECOVERED/RESOLVED WITH SEQUELAE	Transcription Error
Dec-08-2020 09:48:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Sigmoid Volvulus: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Dec-07-2020 13:36:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Dec-07-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:**	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

13:36:40 (UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	NO	

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Dec-11-2020 03:46:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** 2020431728	Initial Entry

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete
Site No: 1019
Site Name: (1019) Diagnostics Research Group
Subject No: 10191229
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Category:

Date	Location	User	Value	Reason
Dec-07-2020 13:37:41 (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
Dec-07-2020 13:37:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 10	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-04-2021 11:01:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Mar-04-2021 09:17:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	As of now, no patient discharge has been reported to the site.
Feb-18-2021 18:18:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Clinical - please confirm subject remains in Brooke Army Med Ctr San Antonio; no discharge to rehab has been reported. Thank you
Dec-17-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies

09:16:54 (UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)		query
Dec-14-2020 08:02:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	AE CRF has been updated.
Dec-11-2020 07:32:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL On review of SAE report (2020431728), an event of cardiac arrest due to unspecified cardiac arrhythmia, requiring pacer insertion, is noted; however no AE is reported. Please review and update AE CRF if appropriate
Dec-11-2020 07:26:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-10-2020 10:27:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	This is the same as the reported MVA.
Dec-09-2020 10:29:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL - please clarify if this is the same SAE as the original report of MVA, which was modified in the

				SAE report (as subject was NOT driving) to Injury due to Pedestrian-car accident?
Dec-07-2020 13:37:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Injury Secondary to Pedestrian-Car Accident	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-07-2020 13:37:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Nov/4/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-18-2021 18:17:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-10-2021 11:06:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Other secondary injuries still ongoing.
Feb-10-2021 10:54:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical Please review for potential End date of general INJURY event, which is still grade 4, with specific injuries

				now documenting resolving or not resolved
Dec-11-2020 13:51:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-11-2020 08:44:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	This AE is in reference to the injuries sustained because of the pedestrian-car accident.
Dec-11-2020 07:29:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL please consider End date for this SAE reporting the accident occurrence itself; please update AE and SAE if appropriate
Dec-07-2020 13:37:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-07-2020 13:37:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** 4	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **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
Dec-17-2020 09:17:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-11-2020 08:45:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Dec-11-2020 08:45:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO	Transcription Error

			Is this serious event life threatening? YES Other medically importa nt serious event NO	
Dec-11-2020 07:27:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL - Event serious criteria is Life-threatening; however, SAE event report has serious criteria of Hosp and Life-threatening. Please review, harmonize reporting, and update in the appropriate location.
Dec-09-2020 05:02:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-07-2020 13:37:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Injury Secondary to Pedestrian-Car Accident: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

Dec-07-2020 13:37:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? NO Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? YES Other medically important serious event NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason

Dec-07-2020 13:37:41 (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
Dec-07-2020 13:37:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER *If Other, specify:* Pedestrian-Car Accident	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-07-2020 13:37:41 (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
Dec-07-2020 13:37:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

Dec-07-2020 13:37:41 (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
Dec-07-2020 13:37:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Dec-07-2020 13:37:41 (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
Dec-09-2020 05:02:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** 2020431728	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Answered Queries

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Category:

Date	Location	User	Value	Reason
Dec-08-2020 09:49:49 (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
Dec-08-2020 09:49:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 11	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-08-2020 09:49:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Spinal Cord Compression	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-08-2020 09:49:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Nov/4/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-08-2020 09:49:49	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES	Initial Entry

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)		

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-08-2020 09:49:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** 4	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Mar-12-2021 13:25:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	FU SAE report will be sent.
Mar-08-2021 14:21:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Reissued:Opened	GPDCLIN: Please ensure a FU SAE report is submitted with this added criteria if not included in previous SAE report.
Mar-08-2021 07:38:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	New Information
Mar-08-2021 07:38:31	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES	New Information

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	Is this serious event ass ociated with congenital anomaly or birth defect? NO Did this serious event re sult in death? NO Did this serious event re quire or prolong hospita lization? YES Did this serious event re sult in persistent or signi ficant disability/incapac ity? YES Is this serious event life threatening? YES Other medically importa nt serious event NO	
Mar-05-2021 06:53:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	GPDCLIN: Grade 4 event is a life threatening event however, answer to question: Is this serious event life threatening? is NO. Please review

				and clarify.
Dec-25-2020 11:01:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Dec-23-2020 08:40:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Form updated.
Dec-23-2020 08:40:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES Is this serious event ass ociated with congenital anomaly or birth defect? NO Did this serious event re sult in death? NO Did this serious event re quire or prolong hospita lization? YES Did this serious event re sult in persistent or signi ficant disability/incapac ity? YES Is this serious event life threatening? NO	Form updated.

			Other medically importa nt serious event NO	
Dec-17-2020 09:07:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Clinical - With T2 distraction inj & spinal chord compression reported as 1 term in SAE, there is a single Serious criteria (Hosp, Disability). This does not match the single event Chord Compression (Hosp, Life Threat). Please update with split SAE terms
Dec-11-2020 13:50:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-11-2020 08:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Dec-11-2020 08:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES Is this serious event ass ociated with congenital anomaly or birth defect? NO Did this serious event re sult in death?	Transcription Error

			NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? YES Other medically important serious event NO	
Dec-11-2020 07:23:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL - Event serious criteria is Life Threatening; however, SAE event report for T2 distraction with spinal chord injury has serious criteria of Hosp and Life-threatening. Please review, harmonize reporting, and update in the appropriate

				location.
Dec-11-2020 04:14:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-08-2020 09:49:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Spinal Cord Compression: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-08-2020 09:49:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES Is this serious event ass ociated with congenital anomaly or birth defect? NO Did this serious event re sult in death? NO Did this serious event re quire or prolong hospita lization? NO Did this serious event re sult in persistent or signi ficant disability/incapac ity? NO	Initial Entry

			Is this serious event life threatening? YES Other medically importa nt serious event NO	

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Dec-08-2020 09:49:49 (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
Dec-11-2020 13:50:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-11-2020 08:46:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Dec-11-2020 08:46:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NOT RELATED If Not Related to study tr eatment(s), this event is d ue to: OTHER	Changed Information

			If Other, specify: T2 distraction injury	
Dec-11-2020 07:25:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL For Other reason, SAE report specifies the T2 distraction injury as the specific cause. Please review and update Other reason if appropriate.
Dec-08-2020 09:49:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NOT RELATED If Not Related to study tr eatment(s), this event is d ue to: OTHER *If Other, specify:* Injury Secondary to Pedestrian-Car Acci dent	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-08-2020 09:49:49 (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

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Answered Queries
Site No: 1019
Site Name: (1019) Diagnostics Research Group
Subject No: 10191229
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 04:44

Dec-08-2020 09:49:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-08-2020 09:49:49 (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
Dec-08-2020 09:49:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Dec-08-2020 09:49:49 (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
Dec-11-2020 04:14:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** 2020431728	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Category:

Date	Location	User	Value	Reason
Dec-08-2020 09:51:11 (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
Dec-08-2020 09:51:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 12	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-08-2020 09:51:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Hyperemic Bowel	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-08-2020 09:51:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Nov/4/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-08-2020 09:51:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NO End Date Time:	Initial Entry

			Nov/5/2020 UNK:UNK	

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-08-2020 09:51:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** 4	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Dec-11-2020 03:46:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-08-2020 09:51:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Hyperemic Bowel: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-08-2020 09:51:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES Is this serious event associated with congenital anomaly or birth defect? NO	Initial Entry

			Did this serious event result in death? NO Did this serious event require or prolong hospitalization? NO Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? YES Other medically important serious event NO	

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Dec-08-2020 09:51:11 (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
Dec-08-2020 09:51:11	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NOT RELATED	Initial Entry

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	If Not Related to study treatment(s), this event is due to: OTHER *If Other, specify:* Injury Secondary to Pedestrian-Car Accident	

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-08-2020 09:51:11 (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
Dec-08-2020 09:51:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-08-2020 09:51:11 (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
Dec-08-2020 09:51:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** RECOVERED/RESOLVED WITH SEQUELAE	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Dec-08-2020 09:51:11 (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
Dec-11-2020 03:46:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** 2020431728	Initial Entry

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Frozen
Site No: 1019
Site Name: (1019) Diagnostics Research Group
Subject No: 10191229
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Category:

Date	Location	User	Value	Reason
Dec-14-2020 07:23:52 (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
Dec-14-2020 07:23:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 13	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-24-2020 22:54:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-23-2020 08:57:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Please see detailed narrative stating the pacemaker was implanted after the cardiac arrests.
Dec-17-2020 09:24:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL SAE report pacemaker was implanted on 24Nov2020. Please clarify if this was before or after cardiac

				arrest, & cardiac rhythm that required a pacer, in a SAE safety update
Dec-14-2020 07:23:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Cardiac Arrest	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-14-2020 07:23:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Nov/21/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-17-2020 08:56:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	events reported as separate events
Dec-17-2020 08:55:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL SAE narrative reports that subject codes on 21Nov and 23Nov20; please review stop date. Please submit the Cardiac Arrest to the SAE event section, in a SAE Safety update
Dec-14-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:**	Initial Entry

07:23:52 (UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	NO End Date Time: Nov/21/2020 UNK:UNK	

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-14-2020 07:23:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** 4	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Jan-02-2021 01:33:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Deleted	Close Auto Query
Dec-31-2020 12:19:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Dec-28-2020 15:17:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Candidate	For AE Cardiac Arrest: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

Dec-28-2020 15:17:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Transcription Error
Dec-28-2020 15:17:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? YES	Transcription Error

			Other medically important serious event NO	
Dec-25-2020 11:06:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Clinical Serious criterion for event Cardiac arrest is Life-threatening; however, AE report criteria are life-threatening and Hospitalization/prolonged Hosp. Please review, harmonize reporting, and update in the appropriate location.
Dec-24-2020 10:04:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-23-2020 09:14:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	has been submitted.
Dec-17-2020 05:35:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:Cardiac Arrest(Onset date:21Nov2020) is not reported to Safety database but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

Dec-17-2020 05:33:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query can be addressed internally
Dec-14-2020 07:23:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Cardiac Arrest: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-14-2020 07:23:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? NO Did this serious event result in persistent or significant disability/incapacity?	Initial Entry

			NO Is this serious ev ent life threatenin g? YES Other medically i mportant serious event NO	

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Dec-14-2020 07:23:52 (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
Dec-14-2020 07:23:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NOT RELATED If Not Related to study trea tment(s), this event is due t o: OTHER *If Other, specify:* Injury secondary to pe destrian-car accident	Initial Entry

10. Latest Action Taken with Study Treatment:

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Frozen
Site No: 1019
Site Name: (1019) Diagnostics Research Group
Subject No: 10191229
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Dec-14-2020 07:23:52 (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
Dec-14-2020 07:23:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-14-2020 07:23:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-20-2021 05:28:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-19-2021 13:45:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jan-19-2021 13:45:49	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** RECOVERED/RES	Transcription Error

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	OLVED WITH SE QUELAE	
Jan-05-2021 05:24:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020431728 ,outcome was updated to RECOVERED/RESOLVED WITH SEQUELAE on AE CRF while reported as RECOVERED/RESOLVED in Safety database. Please confirm correct outcome. If safety update is required, please submit a ffup form.
Dec-14-2020 07:23:52 (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
Dec-14-2020 07:23:52 (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-02-2021 01:33:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** 2020431728	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Category:

Date	Location	User	Value	Reason
Dec-14-2020 07:39:51 (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
Dec-14-2020 07:39:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 14	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-14-2020 07:39:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Cardiac Arrest	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-14-2020 07:39:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Nov/23/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-14-2020 07:39:51	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NO	Initial Entry

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	End Date Time: Nov/23/2020 UNK:UNK	

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-14-2020 07:39:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** 4	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Jan-02-2021 01:34:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Deleted	Close Auto Query
Dec-31-2020 12:19:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Dec-28-2020 15:18:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Candidate	For AE Cardiac Arrest: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-28-2020	ACV0PFEINFP6000	auto query	Query 3: Answere	Transcription Error

15:18:31 (UTC-06:00) Central Time (US & Canada)		(autoquery)	d	
Dec-28-2020 15:18:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? YES	Transcription Error

			Other medically i mportant serious event NO	
Dec-25-2020 11:06:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Clinical Serious criterion for event Cardiac arrest is Life-threatening; however, AE report criteria are life-threatening and Hospitalization/prolonged Hosp. Please review, harmonize reporting, and update in the appropriate location.
Dec-24-2020 10:07:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-23-2020 09:15:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answere d	form submitted.
Dec-17-2020 05:37:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:Cardiac Arrest(Onset date:23Nov2020) is not reported to Safety database but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

Dec-17-2020 05:35:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query can be addressed internally
Dec-14-2020 07:39:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Cardiac Arrest: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-14-2020 07:39:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? NO Did this serious event result in persistent or significant disability/incapacity?	Initial Entry

			NO Is this serious ev ent life threatenin g? YES Other medically i mportant serious event NO	

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Dec-14-2020 07:39:51 (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
Dec-14-2020 07:39:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NOT RELATED If Not Related to study trea tment(s), this event is due t o: OTHER *If Other, specify:* Injury secondary to pe destrian-vehicle accid ent	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-14-2020 07:39:51 (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
Dec-14-2020 07:39:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-14-2020 07:39:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** YES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-20-2021 05:29:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-19-2021 13:46:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Frozen
Site No: 1019
Site Name: (1019) Diagnostics Research Group
Subject No: 10191229
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 04:44

Jan-19-2021 13:46:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** RECOVERED/RESOLVED WITH SEQUELAE	Transcription Error
Jan-05-2021 05:24:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020431728 ,outcome was updated to RECOVERED/RESOLVED WITH SEQUELAE on AE CRF while reported as RECOVERED/RESOLVED in Safety database. Please confirm correct outcome. If safety update is required, please submit a ffup form.
Dec-14-2020 07:39:51 (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
Dec-14-2020 07:39:51 (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-02-2021 01:34:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** 2020431728	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled | **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:26 | **Form Status:** Data Complete, Verified

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **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
Mar-12-2021 13:35:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Nov/12/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-12-2021 13:35:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Mar-12-2021 15:48:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Mar-12-2021 15:14:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Mar-12-2021 15:13:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Response to "Status" is ADVERSE EVENT but "Specify Status" is Provided.
Mar-12-2021 15:13:56 (UTC-06:00) Central	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error

Time (US & Canada)				
Mar-12-2021 15:13:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** ADVERSE EVENT	Transcription Error
Mar-12-2021 15:01:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: Since visit 3 is reported to have been missed due to hospitalisation linked to adverse events, please consider updating status to match
Mar-12-2021 13:35:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** OTHER	Initial Entry

4. Specify Status:

Date	Location	User	Value	Reason
Mar-12-2021 15:14:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:**	Transcription Error
Mar-12-2021 13:35:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Subject has been hospitalized since.	Initial Entry

Header Text: c4591001
Visit: Subject Status - Unscheduled
Form: SUBJECT STATUS - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Verified
Site No: 1019
Site Name: (1019) Diagnostics Research Group
Subject No: 10191229
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Subject Status

Date	Location	User	Value	Reason
Mar-12-2021 15:13:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DISCONTINUED	Transcription Error
Mar-12-2021 15:02:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 3: Closed	Response satisfies query
Mar-12-2021 13:36:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	EOT CRF updated.
Mar-12-2021 13:35:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DISCONTINUED	Initial Entry
Mar-09-2021 08:41:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 3: Opened	CLINQUERY: V3 was not done and timepoint has passed - please update EOT page to reflect end of treatment phase (vax1/vax2/V3). Date and status should reflect reason for lack of V3 - per CRF subject was hospitalised
Mar-04-2021 14:35:23 (UTC-06:00) Central Time	ACV0PFEINFP6000	Rivkah Rosen (b) (4)	Query 2: Reissued:Candidate	Check on this data week of 3/15.

(US & Canada)				
Mar-04-2021 09:16:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Subject is still hospitalized.
Mar-02-2021 00:42:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: Visit 3 is overdue based on expected visit window. Please enter data or, if visit will never occur, mark Date of Visit as 'Not Done' with form level comment. If subject is no longer in the trial, complete the Disposition FUP form.
Mar-02-2021 00:42:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Query raised for the same in SUBJSTAT form #1
Feb-22-2021 13:25:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rivkah Rosen (b) (4)	Query 1: Opened	DM: Visit "V3_MONTH1_POSTVAX2_L" was expected to occur on 19-NOV-2020. Please enter data or confirm reason why visit has not yet occurred. If subject is no longer in the trial, please complete the Disposition Follow Up form.
Sep-24-2020 15:39:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ENROLLED/RANDOMIZED	Initial Entry
Sep-24-2020 15:29:47 (UTC-06:00) Central Time	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SCREENED	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled | **Form:** SUBJECT STATUS - eCRF Audit Trail History

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

Site No: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

(US & Canada)				

2. Subject Status Date

Date	Location	User	Value	Reason
Mar-12-2021 15:13:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Nov/12/2020	Transcription Error
Mar-12-2021 13:35:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Nov/12/2020	Initial Entry
Sep-24-2020 15:39:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Sep/24/2020	Initial Entry
Sep-24-2020 15:29:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Sep/24/2020	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: 1019 | **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191229 | **Subject Initials:** ---

Generated By: (b) (4) | **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Casebook Signature

Date	Location	User	Value	Reason
Nov-16-2020 16:01:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	**Data Entry:** Click Here to Enable	Initial Entry