

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

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

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

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 Aug/20/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10281033]
2.	Birth Date:	(b) (6) 1972
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

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: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

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	Aug/20/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1028

Subject No: 10281033

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1028) Lillestol Research LLC

Subject Initials: ---

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

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable
----	--	----------------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1028

Subject No: 10281033

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1028) Lillestol Research LLC

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Screening

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1028

Subject No: 10281033

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1028) Lillestol Research LLC

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Achilles tendon rupture, right]
	Start Date:	Jun/25/2018
	Ongoing:	NO End Date: Nov/7/2018
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Achilles tendon rupture repair, right]
	Start Date:	Nov/7/2018
	Ongoing:	NO End Date: Nov/7/2018

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/20/2020
2.	Weight:	[169.2]
3.	Unit:	LB
4.	Height:	[68.5]
5.	Unit:	in
6.	Body Mass Index:	[25.3]

Vital Signs Details

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

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1028

Subject No: 10281033

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1028) Lillestol Research LLC

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Aug/20/2020
2.	Randomization Number:	[59313]
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: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

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: Aug/20/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BN61C6]
5.b	Sample ID	[BN61C7]
5.c	Sample ID	[BN61C8]
5.d	Sample ID	[BLBBZH]
5.e	Sample ID	[BLBBZJ]

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

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: Aug/20/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BN61BG]
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090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

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: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

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:	Aug/20/2020 15:12
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

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1028

Subject No: 10281033

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1028) Lillestol Research LLC

Subject Initials: ---

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
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1028

Subject No: 10281033

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1028) Lillestol Research LLC

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/11/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/11/2020
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Vital Signs Details

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

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

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/11/2020
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	[BP92JG]
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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: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

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/11/2020 13:04
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

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

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/12/2020
2.	Erroneous Visit	

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

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: Oct/12/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR8ZV7]
5.b	Sample ID	[BR8ZV8]
5.c	Sample ID	[BR8ZV9]
5.d	Sample ID	[BLBCFS]

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1028

Subject No: 10281033

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1028) Lillestol Research LLC

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Mar/8/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

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: Mar/8/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR11H6]
5.b	Sample ID	[BRVT52]
5.c	Sample ID	[BRVT4X]

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1028

Subject No: 10281033

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1028) Lillestol Research LLC

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_MONTH12_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1028

Subject No: 10281033

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1028) Lillestol Research LLC

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

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 Version: 20-Feb-2021 02:17

Site No: 1028

Subject No: 10281033

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Not Started

Site Name: (1028) Lillestol Research LLC

Subject Initials: ---

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

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

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?	
----	--	--

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

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: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

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: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

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

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

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: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

Unplanned Assessments

1.	Assessments	
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Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

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 :	Oct/12/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

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:	[]

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - **Form:** DATE OF VISIT - REPEAT SWAB
New Unscheduled Visit

Form Version: 10-Oct-2020 15:57 **Form Status:** Not Started

Site No: 1028 **Site Name:** (1028) Lillestol Research LLC

Subject No: 10281033 **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: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	elevated body temperature	Aug/21/2020 UNK:UNK	NO End Date Time: Aug/22/2020 U NK:UNK	Repeating Pages
2. DELETED	ADVERSE EVENT	2	pregnancy of partner	Nov/29/2020 UNK:UNK	YES	Repeating Pages
3.	ADVERSE EVENT	3	miscarriage for pregnant partner	Dec/22/2020 UNK:UNK	NO End Date Time: Dec/22/2020 U NK:UNK	Repeating Pages

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1028

Subject No: 10281033

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1028) Lillestol Research LLC

Subject Initials: ---

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:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[elevated body temperature]
4.	Start Date Time:	Aug/21/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/22/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1028

Subject No: 10281033

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1028) Lillestol Research LLC

Subject Initials: ---

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

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

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

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:	[2]	
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[pregnancy of partner]	
4.	Start Date Time:	Nov/29/2020 UNK:UNK	
5.	Is the adverse event still ongoing?	YES	
6.	Toxicity Grade:	Not Applicable	Comments
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO	

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1028

Subject No: 10281033

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted

Site Name: (1028) Lillestol Research LLC

Subject Initials: ---

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: [pregnancy]
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	[]

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1028

Subject No: 10281033

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1028) Lillestol Research LLC

Subject Initials: ---

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:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[miscarriage for pregnant partner]
4.	Start Date Time:	Dec/22/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/22/2020 UNK:UNK
6.	Toxicity Grade:	2

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1028**Subject No:** 10281033**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Frozen**Site Name:** (1028) Lillestol Research LLC**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:44

7.	<p>Is the adverse event serious?</p> <p>If Yes, NOTIFY PFIZER IMMEDIATELY.</p> <p>Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).</p>	<p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect? NO</p> <p>Did this serious event result in death? NO</p> <p>Did this serious event require or prolong hospitalization? NO</p> <p>Did this serious event result in persistent or significant disability/incapacity? NO</p> <p>Is this serious event life threatening? NO</p> <p>Other medically important serious event YES</p>
8.	<p>Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.</p>	NO
9.	<p>Is this event related to study treatment:</p>	<p>NOT RELATED</p> <p>If Not Related to study treatment(s), this event is due to: OTHER</p> <p>If Other, specify: [partner pregnancy]</p>
10.	<p>Latest Action Taken with Study Treatment:</p>	NOT APPLICABLE
11.	<p>Was a Concomitant Medication given?</p>	NO
12.	<p>Was a Non-Drug Treatment given?</p>	NO

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1028

Subject No: 10281033

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1028) Lillestol Research LLC

Subject Initials: ---

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

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

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1028

Subject No: 10281033

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1028) Lillestol Research LLC

Subject Initials: ---

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

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Medication Error

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

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

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: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

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:	//

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

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 Version: 22-Apr-2020 21:03

Site No: 1028

Subject No: 10281033

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1028) Lillestol Research LLC

Subject Initials: ---

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

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Concomitant Medications

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

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

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 Version: 22-Apr-2020 21:02

Site No: 1028

Subject No: 10281033

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1028) Lillestol Research LLC

Subject Initials: ---

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

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Radiation Treatment

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

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

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 Version: 22-Apr-2020 21:03

Site No: 1028

Subject No: 10281033

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1028) Lillestol Research LLC

Subject Initials: ---

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

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

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: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

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?	

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

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: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

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: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

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: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

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: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

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	Feb/12/2021
2.	Erroneous Visit	

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Feb/12/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

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: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

Death Details

1.	Date of Collection / Notification of Death:	//
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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: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/12/2020

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

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
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Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

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

Name	Signature Meaning	Date	Type	Action
Michael Lillestol	Approved	Mar-09-2021 13:00:27 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:

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

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

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1028

Subject No: 10281033

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1028) Lillestol Research LLC

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-21-2020 07:59:58 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1028

Subject No: 10281033

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Comments

Form Status: Data Complete, Locked, Frozen

Site Name: (1028) Lillestol Research LLC

Subject Initials: ---

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

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

[Back to Form](#)

Item	Date	User	Comment
6	Dec-21-2020 17:41:27 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Michael Lillestol	Approved	Mar-09-2021 13:00:27 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, MichaelLillestol, 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	Mar-08-2021 15:37:33 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Michael Lillestol	Approved	Feb-12-2021 12:18:05 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, MichaelLillestol, 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.

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

(b) (6)	N/A	Feb-12-2021 09:33:23 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Michael Lillestol	Approved	Feb-03-2021 12:28:49 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, MichaelLillestol, 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	Jan-29-2021 09:09:24 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Michael Lillestol	Approved	Jan-21-2021 12:13:45 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, MichaelLillestol, 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.

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

(b) (6)	N/A	Jan-20-2021 08:56:30 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Michael Lillestol	Approved	Jan-05-2021 09:59:47 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, MichaelLillestol, 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	Dec-21-2020 17:41:15 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Michael Lillestol	Approved	Oct-22-2020 17:21:02 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, MichaelLillestol, 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.

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-21-2020 07:59:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-21-2020 07:59:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

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I. Consent Was:

Date	Location	User	Value	Reason
Aug-21-2020 07:59:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent O btained Aug/20/2020	Initial Entry

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

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
Aug-21-2020 07:59:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10281033	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-21-2020 07:58:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) 1972	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-21-2020 07:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-21-2020 07:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LA TINO(A) OR OF SPANI SH ORIGIN	Initial Entry

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1028

Subject No: 10281033

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1028) Lillestol Research LLC

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Aug-21-2020 07:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1028

Subject No: 10281033

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1028) Lillestol Research LLC

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Aug-21-2020 07:59:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/20/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

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
Aug-21-2020 08:00:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/20/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-21-2020 08:00:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-21-2020 08:00:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

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I.a

Date	Location	User	Value	Reason
Aug-24-2020 08:00:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 1 Medical History Term: Achilles tendon rupture, right arm Start Date: Jun/25/2018 Ongoing: NO End Date: Nov/7/2018	Changed Information
Aug-21-2020 08:05:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: Achilles rupture, right arm Start Date: Jun/25/2018 Ongoing: NO End Date: Nov/7/2018	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

Aug-21-2020 08:05:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry
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1.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-24-2020 08:00:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Achilles tendon rupture, right	Changed Information
Aug-21-2020 08:05:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Achilles rupture, right	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Aug-21-2020 08:05:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jun/25/2018	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-21-2020 08:05:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Nov/7/2018	Initial Entry

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

I.b

Date	Location	User	Value	Reason
Aug-24-2020 08:00:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/M 2 H Number: Medical History Term: Achilles tendon rupture repair, right Start Date: Nov/7/2018 Ongoing: NO : End Date: Nov/7/2018	Changed Information
Aug-21-2020 08:06:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 2 Number: Medical History Term: Achilles rupture repair, right Start Date: Nov/7/2018 Ongoing: NO End Date: Nov/7/2018	Initial Entry

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-21-2020 08:06:06 (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
Aug-24-2020 08:49:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Aug-24-2020 08:00:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Aug-24-2020 08:00:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Achilles tendon rupture repair, right	Changed Information
Aug-22-2020 17:27:33 (UTC-06:00)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify ACHILLES RUPTURE

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

Central Time (US & Canada)				REPAIR, RIGHT as follows...The term appears incomplete. If reporting ACHILLES TENDON RUPTURE REPAIR, RIGHT, update the verbatim term as such. Otherwise clarify further and update the term as appropriate. Thank you.
Aug-21-2020 08:06:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Achilles rupture repair, right	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-21-2020 08:06:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/7/2018	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: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

Canada)

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-21-2020 08:06:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO End Date: Nov/7/2018	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1028

Subject No: 10281033

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1028) Lillestol Research LLC

Subject Initials: ---

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

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1. Date:

Date	Location	User	Value	Reason
Aug-21-2020 08:01:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Aug/20/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-21-2020 08:01:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 169.2	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-21-2020 08:01:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-21-2020 08:01:30 (UTC-06:00) Central Time (US &	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 68.5	Initial Entry

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

Canada)				
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5. Unit:

Date	Location	User	Value	Reason
Aug-21-2020 08:01:30 (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
Aug-21-2020 08:01:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 25.3	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-21-2020 08:01:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Ident 1 ifier:: Temperature: 98.1 Temperature F Unit: Temperature ORAL C Location:: AVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-21-2020 08:01:30	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Aug-21-2020 08:01:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.1	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-21-2020 08:01:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-21-2020 08:01:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

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: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

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1. Randomization Date :

Date	Location	User	Value	Reason
Aug-21-2020 08:01:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/20/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-21-2020 08:01:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 59313	Initial Entry

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

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
Aug-21-2020 08:01:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-21-2020 08:01:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-21-2020 08:04:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-21-2020 08:01:58 (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.

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

Aug-21-2020 08:01:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/20/2020	Initial Entry
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5.a

Date	Location	User	Value	Reason
Aug-21-2020 08:04:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN61C6	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 08:04:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN61C6	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-21-2020 08:04:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN61C7	Initial Entry

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

5.b Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 08:04:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BN61C7	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-21-2020 08:04:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BN61C8	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 08:04:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BN61C8	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-21-2020 08:04:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BLBBZH	Initial Entry

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 08:04:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLBBZH	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-21-2020 08:04:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BLBBZJ	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 08:04:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLBBZJ	Initial Entry

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

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
Aug-21-2020 08:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-21-2020 08:02:06 (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
Aug-21-2020 08:03:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-21-2020 08:02:06 (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.

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

Aug-21-2020 08:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/20/2020	Initial Entry
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5.a

Date	Location	User	Value	Reason
Aug-21-2020 08:03:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN61BG	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 08:03:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN61BG	Initial Entry

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-21-2020 08:03:30 (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
Aug-21-2020 08:03:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-21-2020 08:03:30 (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
Aug-21-2020 08:03:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/20/2020 15:12	Initial Entry

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1028

Subject No: 10281033

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1028) Lillestol Research LLC

Subject Initials: ---

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

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-21-2020 08:03:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-21-2020 08:03:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-21-2020 08:03:30 (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
Aug-21-2020 08:03:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFI ED OBSERVATION PERI OD	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1028

Subject No: 10281033

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1028) Lillestol Research LLC

Subject Initials: ---

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

Aug-21-2020 08:03:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry
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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: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-21-2020 08:03:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1028

Subject No: 10281033

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1028) Lillestol Research LLC

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-11-2020 18:40:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/11/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date:

Date	Location	User	Value	Reason
Sep-11-2020 18:40:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/11/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-11-2020 18:40:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Temperature: 98.1 Temperature F Unit: Temperature ORAL C Location:: AVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-11-2020 18:40:20 (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
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090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

Sep-11-2020 18:40:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.1	Initial Entry
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2.a Unit:

Date	Location	User	Value	Reason
Sep-11-2020 18:40:20 (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
Sep-11-2020 18:40:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

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-11-2020 18:40:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-11-2020 18:40:28 (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-11-2020 18:40:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-11-2020 18:40:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

Sep-11-2020 18:40:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/11/2020	Initial Entry
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5.a

Date	Location	User	Value	Reason
Sep-11-2020 18:40:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP92JG	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-11-2020 18:40:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP92JG	Initial Entry

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-11-2020 18:41:01 (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-11-2020 18:41:01 (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-11-2020 18:41:01 (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-11-2020 18:41:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/11/2020 13:04	Initial Entry

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-11-2020 18:41:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-11-2020 18:41:01 (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-11-2020 18:41:01 (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-11-2020 18:41:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFI ED OBSERVATION PERI OD	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1028

Subject No: 10281033

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1028) Lillestol Research LLC

Subject Initials: ---

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

Sep-11-2020 18:41:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

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
Oct-12-2020 16:45:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/12/2020	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Oct-12-2020 16:45:34 (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-12-2020 16:45:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-12-2020 16:45:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-12-2020 16:45:34 (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.

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

Oct-12-2020 16:45:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/12/2020	Initial Entry
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5.a

Date	Location	User	Value	Reason
Oct-12-2020 16:45:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR8ZV7	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-12-2020 16:45:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR8ZV7	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-12-2020 16:46:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR8ZV8	Initial Entry

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

5.b Sample ID

Date	Location	User	Value	Reason
Oct-12-2020 16:46:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BR8ZV8	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-12-2020 16:46:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BR8ZV9	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-12-2020 16:46:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BR8ZV9	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-12-2020 16:46:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BLBCFS	Initial Entry

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sample ID

Date	Location	User	Value	Reason
Oct-12-2020 16:46:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLBCFS	Initial Entry

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1028

Subject No: 10281033

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1028) Lillestol Research LLC

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-08-2021 15:37:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/8/2021	Initial Entry

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

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
Mar-08-2021 15:37:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-08-2021 15:37:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-08-2021 15:38:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-08-2021 15:37:44 (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.

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

Mar-08-2021 15:37:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/8/2021	Initial Entry
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5.a

Date	Location	User	Value	Reason
Mar-08-2021 15:38:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR11H6	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-08-2021 15:38:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR11H6	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-08-2021 15:38:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRVT52	Initial Entry

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

5.b Sample ID

Date	Location	User	Value	Reason
Mar-08-2021 15:38:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRVT52	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-08-2021 15:38:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRVT4X	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-08-2021 15:38:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRVT4X	Initial Entry

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

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
Oct-12-2020 16:49:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/12/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-12-2020 16:49:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-12-2020 16:49:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Oct-13-2020 09:47:34 (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: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

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

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Date	Location	User	Value	Reason
Jan-04-2021 10:11:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Changed Information
Dec-21-2020 17:41:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1028

Subject No: 10281033

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1028) Lillestol Research LLC

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Jan-20-2021 08:56:30 (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, Locked, Frozen

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

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
Oct-13-2020 09:47:34 (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
Oct-13-2020 09:47:34 (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
Oct-13-2020 09:47:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: elevated body temperature	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-13-2020 09:47:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/21/2020 UNK:UNK	Initial Entry

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-13-2020 09:47:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Aug/22/2020 UNK:U NK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-13-2020 09:47:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-13-2020 09:47:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-13-2020 09:47:34 (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
Oct-13-2020 09:47:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-13-2020 09:47:34 (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
Oct-13-2020 09:47:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-13-2020 09:47:34 (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
Oct-13-2020 09:47:34 (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
Oct-13-2020 09:47:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Deleted**Site No:** 1028**Site Name:** (1028) Lillestol Research LLC**Subject No:** 10281033**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44***** THIS REPEATING FORM HAS BEEN DELETED *****[Back to Form](#)**1. Category:**

Date	Location	User	Value	Reason
Dec-21-2020 17:41:15 (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-21-2020 17:41:15 (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
Dec-21-2020 17:41:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: pregnancy of partner	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-21-2020 17:41:15 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/29/2020 UNK:UNK	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, Deleted**Site No:** 1028**Site Name:** (1028) Lillestol Research LLC**Subject No:** 10281033**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44***** THIS REPEATING FORM HAS BEEN DELETED *****Time (US &
Canada)**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Dec-21-2020 17:41:15 (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-21-2020 17:41:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

7. Is the adverse event serious?**If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

Date	Location	User	Value	Reason
Jan-05-2021 07:16:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	event inactivated in Inform

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: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

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

Jan-04-2021 10:11:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Changed data per query
Dec-31-2020 18:24:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Closed	Response satisfies query
Dec-31-2020 01:30:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	SAE RECON 1:Per latest listing event was invalidated since it was considered duplicate with maternal case '2020506248' as partner is also in this trial. Please confirm if this should be inactivated to avoid duplication of report.
Dec-29-2020 12:22:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Answered	Changed Information
Dec-29-2020 12:22:34 (UTC-06:00) Central Time (US	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Deleted	Close Auto Query

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Deleted

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

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

& Canada)				
Dec-29-2020 12:22:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Changed Information
Dec-23-2020 09:26:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Opened	CLINICAL Would like to clarify if the pregnant partner is also a study subject (e.g. 10291003); if so, only 1 report per pregnancy is required. Partner- in-study information would be provided in female's Exposure during Pregnancy report.
Dec-22-2020 11:32:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Candidate	For AE pregnancy of partner: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-22-2020 11:32:16 (UTC-06:00) Central Time (US	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Changed Information

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

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

& Canada)				
Dec-22-2020 11:32:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Dec-22-2020 11:32:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry: YES</p> <p>Is this serious event a ssociated with conge nital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong ho spitalization?</p> <p>NO</p> <p>Did this serious event result in persistent or significant disability/i ncapacity?</p> <p>NO</p> <p>Is this serious event li fe threatening?</p>	Changed Information

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

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Site No: 1028

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Generated By: (b) (4)

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

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

			NO	
			Other medically important serious event	
			YES	
Dec-22-2020 08:37:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	SAE RECON: pregnancy of partner(Onset date:29Nov2020) 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
Dec-22-2020 07:24:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query can be addressed internally
Dec-21-2020 17:41:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Is this adverse event serious?' is reported 'Yes', but at least one seriousness criteria is missing. Please review and update as

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Deleted**Site No:** 1028**Site Name:** (1028) Lillestol Research LLC**Subject No:** 10281033**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44***** THIS REPEATING FORM HAS BEEN DELETED *****

				appropriate.
Dec-21-2020 17:41:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE pregnancy of partner: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-21-2020 17:41:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Other medically important serious event YES	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-21-2020 17:41:15 (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-21-2020 17:41:15 (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:	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Deleted

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

			OTHER	
			<i>If Other, specify:</i>	
			pregnancy	

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-21-2020 17:41:15 (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-21-2020 17:41:15 (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-21-2020 17:41:15 (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?:

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Deleted**Site No:** 1028**Site Name:** (1028) Lillestol Research LLC**Subject No:** 10281033**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44***** THIS REPEATING FORM HAS BEEN DELETED *****

Date	Location	User	Value	Reason
Dec-22-2020 11:31:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-22-2020 11:31:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/NOT RESOLVED	Changed Information
Dec-21-2020 17:41:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE pregnancy of partner: 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".
Dec-21-2020 17:41:15 (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
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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted

Site No: 1028

Site Name: (1028) Lillestol Research LLC

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Generated By: (b) (4)

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

Dec-21-2020 17:41:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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1. Category:

Date	Location	User	Value	Reason
Jan-20-2021 08:56:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-20-2021 08:56:30 (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
Feb-16-2021 12:04:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-09-2021 10:00:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	this was already sent in.
Feb-09-2021 01:22:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical Event term is 'Miscarriage for PG partner'; however, SAE

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Frozen**Site No:** 1028**Site Name:** (1028) Lillestol Research LLC**Subject No:** 10281033**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44

				report (2020506220) has event term 'Pregnant Partner'. Please submit a SAE report update with the SAE term 'Miscarriage for PG partner'
Jan-29-2021 11:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-29-2021 09:09:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Jan-29-2021 09:09:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: miscarriage for pregnant partner	Changed Information
Jan-28-2021 17:23:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical - As this reports a SAE 'miscarriage', the exposure to drug is not required in the term (as with pregnancy, reported for 10281002), ie just miscarriage for pregnant

Header Text: c4591001

Visit: Logs - Unscheduled

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Generated By: (b) (4)

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				partner.
Jan-20-2021 08:56:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: partner exposure during pregnancy miscarriage	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-25-2021 08:49:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Safety unit has confirmed updates are on hold as they resolve technical reporting problems
Feb-16-2021 10:40:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	I have a fax confirmation that the EDP was sent on 02Feb2021 and the SAE follow up was sent in on 01Feb2021
Feb-15-2021 22:02:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Open ed	Clinical Thank you/ however there has not been an update to the SAE safety report since the original report on 21Dec20

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Frozen**Site No:** 1028**Site Name:** (1028) Lillestol Research LLC**Subject No:** 10281033**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44

Feb-09-2021 10:00:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Answered	this was already sent in.
Feb-09-2021 01:24:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	Clinical - Event 'Miscarriage in PG partner' start date is 22Dec20; however, SAE report start date is 29Nov20. Please review SAE start date, harmonize reporting, and update in applicable location
Jan-20-2021 08:56:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Dec/22/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-20-2021 08:56:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO End Date Time: Dec/22/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Header Text: c4591001

Visit: Logs - Unscheduled

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Site Name: (1028) Lillestol Research LLC

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Subject Initials: ---

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Jan-20-2021 08:56:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-25-2021 08:50:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Feb-16-2021 02:43:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Deleted	Query can be addressed internally
Feb-09-2021 10:00:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	confirmed as entered per protocol
Feb-09-2021 01:28:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Clinical - Event serious criterion is Medically Important;

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Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

Canada)				however, SAE report does not specify any serious criteria. Please review serious criteria, harmonize reporting, and update in the appropriate location
Feb-09-2021 01:27:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Candidate	Clinical - Event serious criterion is Medically Important; however, SAE report does not specify any serious criteria. Please review serious criteria, harmonize reporting, and update in the appropriate location
Jan-29-2021 09:09:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	For AE miscarriage for pregnant partner: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is

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Visit: Logs - Unscheduled

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Form Status: Data Complete, Frozen

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

				blank.
Jan-21-2021 05:02:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query can be addressed internally
Jan-20-2021 08:56:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE partner exposure during pregnancy miscarriage: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-20-2021 08:56:30 (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 def ect? NO Did this serious event r esult in death? NO Did this serious event r equire or prolong hosp italization?	Initial Entry

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Frozen**Site No:** 1028**Site Name:** (1028) Lillestol Research LLC**Subject No:** 10281033**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44

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

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

Date	Location	User	Value	Reason
Jan-20-2021 08:56:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-20-2021 08:56:30 (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:	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

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Form Status: Data Complete, Frozen

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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			OTHER	
			<i>If Other, specify:</i>	
			partner pregnancy	

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-20-2021 08:56:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-20-2021 08:56:30 (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
Jan-20-2021 08:56:30 (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
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090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

Jan-20-2021 08:56:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLV ED	Initial Entry
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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Jan-20-2021 08:56:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

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
Feb-12-2021 09:35:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/12/2021	Transcription Error
Feb-12-2021 09:33:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/11/2021	Initial Entry

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001**Visit:** Potential ReVax Initial Contact -
Unscheduled**Form:** FURTHER VACCINATION CONFIRMATION - eCRF
Audit Trail History**Form Version:** 10-Dec-2020 02:25**Form Status:** Data Complete, Frozen**Site No:** 1028**Site Name:** (1028) Lillestol Research LLC**Subject No:** 10281033**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**I. Select appropriate response - Is participant willing to return for Vaccination 3?**

Date	Location	User	Value	Reason
Feb-12-2021 09:34:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-12-2021 09:33:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-12-2021 09:33:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible and NOT co nfirmed to have recei ved only placebo at Vaccination 1/2	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-12-2021 09:34:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/12/2021	Transcription Error
Feb-12-2021 09:34:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/11/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-12-2021 09:34:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1028

Site Name: (1028) Lillestol Research LLC

Subject No: 10281033

Subject Initials: ---

Generated By: (b) (4)

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

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1. Subject Status

Date	Location	User	Value	Reason
Oct-12-2020 16:49:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-21-2020 08:01:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZ ED	Initial Entry
Aug-21-2020 08:00:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-12-2020 16:49:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/12/2020	Initial Entry
Aug-21-2020 08:01:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/20/2020	Initial Entry
Aug-21-2020 08:00:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/20/2020	Initial Entry

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1028

Subject No: 10281033

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail
History

Form Status: Data Complete, Signed, Verified

Site Name: (1028) Lillestol Research LLC

Subject Initials: ---

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

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1. Casebook Signature

Date	Location	User	Value	Reason
Oct-22-2020 09:00:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae3e10\Final\Final On: 01-Apr-2021 04:45 (GMT)