

**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:** 1092

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject No:** 10921123

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Cohort Selection**

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

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

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** MAIN INFORMED CONSENT

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/1/2020
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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:** 1092

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject No:** 10921123

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[10921123]
2.	Birth Date:	(b) (6) /1952
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

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

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**Form Comments**

**Inclusion Criteria Not Met**

1.	Description of Inclusion Criterion Not Met	Not Applicable
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**Exclusion Criteria Met**

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

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** DISPOSITION - SCREENING

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation/Death	Sep/1/2020
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:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hypertension]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[dyslipidemia]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[type 2 diabetes]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[gastro esophageal reflux disease]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[anxiety]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[postmenopausal]
	Start Date:	UNK/UNK/2003
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Gastric Bypass]
	Start Date:	UNK/UNK/2007
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Lap Band procedure]
	Start Date:	UNK/UNK/2012
	Ongoing:	YES
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hernia repair]
	Start Date:	Jun/26/2020
	Ongoing:	NO End Date: Jun/26/2020

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

+	Line/MH Number:	[ ]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[ ]
	Start Date:	//
	Ongoing:	

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - BASELINE

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/1/2020
2.	Weight:	[200.2]
3.	Unit:	LB
4.	Height:	[64.5]
5.	Unit:	in
6.	Body Mass Index:	[33.8]

**Vital Signs Details**

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

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[Form Comments](#)  
[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	Not Applicable _____	<a href="#">Comments</a>
2.	Lab Sub-Panel:	Not Applicable _____	<a href="#">Comments</a>
3.	Collection Date:	Not Applicable _____ //	<a href="#">Comments</a>
4.	Laboratory Name and Address (Derived)	Not Applicable _____ [ ]	<a href="#">Comments</a>
5.	Specimen Type:	Not Applicable _____	<a href="#">Comments</a>

**Lab Result**

6.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** RANDOMIZATION

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Sep/1/2020
2.	Randomization Number:	[248010]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BN5X1S]
5.b	Sample ID	[BL9TXJ]
5.c	Sample ID	[BL9TXK]

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BN5X22]
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090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** VACCINATION

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**eCRF Audit Trail History**

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/1/2020 10:03
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** REACTOGENICITY DIARY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[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:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Oct/19/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Oct-2020 16:01

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - TEMP

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Oct/19/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[97.5]
	Unit:	F
	Temperature Location:	FOREHEAD

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Oct/19/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/19/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BM9L6R]
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090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** VACCINATION

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	YES Date of First Delay: Sep/17/2020  Reason(s) for Temporary Delay of Vaccination FEVER OR ACUTE ILLNESS
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/19/2020 09:12
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

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

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

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Nov/16/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/16/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BSJR70]
5.b	Sample ID	[BM9L9W]
5.c	Sample ID	[BSJR6P]

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit

**Form:** DATE OF VISIT - ILLNESS ONSET

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1092

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject No:** 10921123

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

**Form Version:** 20-Feb-2021 02:17

**Form Status:** Not Started

**Site No:** 1092

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject No:** 10921123

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

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

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1092

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject No:** 10921123

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1092

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject No:** 10921123

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

**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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090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit

**Form:** HEALTH CARE UTILIZATION

**Form Version:** 20-Feb-2021 02:19

**Form Status:** Not Started

**Site No:** 1092

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject No:** 10921123

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

**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?	
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**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:** 1092      **Site Name:** (1092) Sterling Research Group, Ltd.

**Subject No:** 10921123      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 10:31

**Illness Details**

1.	Category of Clinical Event:	
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	
3.	Toxicity Grade:	

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**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:** 1092

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject No:** 10921123

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Visit:** POT\_COVID\_CONVA - New  
Unscheduled Visit

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1092

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject No:** 10921123

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

**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	[ ]
----	-----------	-----

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1092

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject No:** 10921123

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

**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:** 1092

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject No:** 10921123

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

**Unplanned Assessments**

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

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form Version:** 15-Sep-2020 21:55

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** DISPOSITION - TREATMENT

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation/Death :	Nov/16/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

**Form Version:** 15-Sep-2020 21:53

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**Disposition - Follow-Up**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New  
Unscheduled Visit

**Form:** DATE OF VISIT - REPEAT SWAB

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1092

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject No:** 10921123

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

**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:** 1092

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject No:** 10921123

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

**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	[ ]
----	-----------	-----

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1092

Site Name: (1092) Sterling Research Group, Ltd.

Subject No: 10921123

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Swelling of eyes	Sep/17/2020 UNK:UNK	NO End Date Time:  Sep/18/2020 UNK:UNK	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	Swelling of lip	Sep/17/2020 UNK:UNK	NO End Date Time:  Sep/18/2020 UNK:UNK	<a href="#">Repeating Pages</a>
3.	ADVERSE EVENT	3	Hives (Urticaria)	Sep/17/2020 UNK:UNK	NO End Date Time:  Sep/18/2020 UNK:UNK	<a href="#">Repeating Pages</a>
4.	ADVERSE EVENT	4	Epigastric Pain	Oct/7/2020 21:30	NO End Date Time:  Oct/8/2020 17:30	<a href="#">Repeating Pages</a>
5.	ADVERSE EVENT	5	Chronic Focally Active Gastritis	Oct/7/2020 UNK:UNK	YES	<a href="#">Repeating Pages</a>

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Locked, Frozen

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Swelling of eyes]
4.	Start Date Time:	Sep/17/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/18/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: CONCOMITANT DRUG TREATMENT
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Locked, Frozen

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Locked, Frozen

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Swelling of lip]
4.	Start Date Time:	Sep/17/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/18/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: CONCOMITANT DRUG TREATMENT
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Locked, Frozen

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Locked, Frozen

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Hives (Urticaria)]
4.	Start Date Time:	Sep/17/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/18/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: CONCOMITANT DRUG TREATMENT
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Locked, Frozen

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Locked, Frozen

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Epigastric Pain]
4.	Start Date Time:	Oct/7/2020 21:30
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/8/2020 17:30
6.	Toxicity Grade:	3
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES  Is this serious event associated with congenital anomaly or birth defect? NO  Did this serious event result in death? NO  Did this serious event require or prolong hospitalization? YES  Did this serious event result in persistent or significant disability/incapacity? NO  Is this serious event life threatening? NO  Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Locked, Frozen

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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: [Gastric Pouch distention]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020407104]

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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**Adverse Event Report**

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

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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



**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1092

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject No:** 10921123

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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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	[ ]

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - NON STUDY  
VACCINATIONS

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1092

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject No:** 10921123

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1092

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject No:** 10921123

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

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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:	//

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1092

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject No:** 10921123

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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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?	

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1092

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject No:** 10921123

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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**Radiation Treatment**

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



**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1092

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject No:** 10921123

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

#	Transfusion Type	Date of Transfusion	Form Instance
1.			<a href="#">Repeating Pages</a>

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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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:** 1092

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject No:** 10921123

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

**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:** 1092

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject No:** 10921123

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

**Vital Signs**

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

**Vital Signs Details**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Version:** 20-Feb-2021 02:14

**Form Status:** Not Started

**Site No:** 1092

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject No:** 10921123

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

**Lab Urinalysis**

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

**Lab Result**

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

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VACCINATION

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Not Started

**Site No:** 1092

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject No:** 10921123

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

**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?	

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 1

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1092

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject No:** 10921123

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

**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:** 1092

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject No:** 10921123

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

**Contact Outcome**

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



**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1092

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject No:** 10921123

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/21/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** FURTHER VACCINATION CONFIRMATION

**Form Version:** 10-Dec-2020 02:25

**Form Status:** Data Complete, Frozen

**Site No:** 1092

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject No:** 10921123

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per other protocol allowance(s) and confirmed to have received only placebo at Vaccination 1/2
----	---	--

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** TREATMENT UNBLINDED

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Jan/22/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[Form Comments](#)

[eCRF Audit Trail History](#)

**Withdrawal Of Consent**

			<a href="#">Comments</a>
1.	Withdrawal of Consent Date :	Not Applicable <hr/> //	

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** DEATH DETAILS CODED

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[Form Comments](#)  
[eCRF Audit Trail History](#)

**Death Details**

1.	Date of Collection / Notification of Death:	Not Applicable _____ //	<a href="#">Comments</a>
----	---	-------------------------------	--------------------------

**Cause of Death**

2.	Cause of Death Status:	Not Applicable _____
	Cause of Death:	Not Applicable _____ [ ]

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/25/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:31

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** INFORMED CONSENT - FURTHER VACCINATION

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Informed Consent - Further Vaccination**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/25/2021
----	--------------	--

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:30

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[Form Comments](#)

**Inclusion Criteria Not Met**

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

**Exclusion Criteria Met**

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



**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:31

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Disposition - Screening for Further Vaccination**

1.	Date of Completion/Discontinuation/Death :	Jan/25/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[Form Comments](#)  
[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	Not Applicable _____	<a href="#">Comments</a>
2.	Lab Sub-Panel:	Not Applicable _____	<a href="#">Comments</a>
3.	Collection Date:	Not Applicable _____ //	<a href="#">Comments</a>
4.	Laboratory Name and Address (Derived)	Not Applicable _____ [ ]	<a href="#">Comments</a>
5.	Specimen Type:	Not Applicable _____	<a href="#">Comments</a>

**Lab Result**

6.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/25/2021
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	[BNVLMW]
5.b	Sample ID	[BM9LHF]
5.c	Sample ID	[BNVLMK]

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/25/2021
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	[BM9LHM]
-----	-----------	----------

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** VACCINATION

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/25/2021 11:46
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Feb/15/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[Form Comments](#)  
[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	Not Applicable _____	<a href="#">Comments</a>
2.	Lab Sub-Panel:	Not Applicable _____	<a href="#">Comments</a>
3.	Collection Date:	Not Applicable _____ //	<a href="#">Comments</a>
4.	Laboratory Name and Address (Derived)	Not Applicable _____ [ ]	<a href="#">Comments</a>
5.	Specimen Type:	Not Applicable _____	<a href="#">Comments</a>

**Lab Result**

6.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/15/2021
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	[BRBT0N]
-----	-----------	----------

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)



**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** VACCINATION

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/15/2021 10:14
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[Form Comments](#)

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/25/2021
2.	Erroneous Visit	ERRONEOUS VISIT

**Header Text:** c4591001

**Visit:** V103\_MONTH1

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** V104\_MONTH6

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

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V104\_MONTH6

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** V105\_MONTH18

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

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V105\_MONTH18

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** FURTHER\_VACCINATION\_EOT -  
Unscheduled

**Form:** DISPOSITION - TREATMENT

**Form Version:** 20-Feb-2021 02:26

**Form Status:** Not Started

**Site No:** 1092

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject No:** 10921123

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

**Disposition - Treatment**

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



**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Nov/16/2020

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** CASEBOOK SIGNATURE FORM

**Form Status:** Data Complete, Signed, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Casebook Signature Form**

1.	Casebook Signature	<a href="#">Click Here to Enable</a>
----	--------------------	--------------------------------------

**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:** 1092

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject No:** 10921123

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

[Audit Trail](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
(b) (6)	Approved	Mar-03-2021 13:24:03 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

**Affidavit:**

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

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

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

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-01-2020 10:03:18 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	all inclusion and exclusion criteria met Not Applicable

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-01-2020 10:04:12 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	10921123 is postmenopausal Not Applicable

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[Back to Form](#)

Item	Date	User	Comment
1	Sep-01-2020 10:04:12 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	10921123 is postmenopausal Not Applicable

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
2	Sep-01-2020 10:04:12 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	10921123 is postmenopausal
			Not Applicable

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
3	Sep-01-2020 10:04:12 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	10921123 is postmenopausal Not Applicable



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
4	Sep-01-2020 10:04:12 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	10921123 is postmenopausal
			Not Applicable

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
5	Sep-01-2020 10:04:12 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	10921123 is postmenopausal Not Applicable

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
6.a	Sep-01-2020 10:04:12 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	10921123 is postmenopausal
			Not Applicable

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
6.a	Sep-01-2020 10:04:12 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	10921123 is postmenopausal
			Not Applicable

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
6.a	Sep-01-2020 10:04:12 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	10921123 is postmenopausal
			Not Applicable

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** WITHDRAWAL OF CONSENT - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
Form	Jan-22-2021 08:38:18 (UTC-05:00) Eastern Time (US & Canada)	Kofi Amoah (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** Disposition

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** WITHDRAWAL OF CONSENT - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
1	Jan-22-2021 08:38:18 (UTC-05:00) Eastern Time (US & Canada)	Kofi Amoah (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** DEATH DETAILS CODED - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
Form	Jan-22-2021 08:38:32 (UTC-05:00) Eastern Time (US & Canada)	Kofi Amoah (b) (4)	Not Applicable



**Header Text:** c4591001

**Visit:** Disposition

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** DEATH DETAILS CODED - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
1	Jan-22-2021 08:38:32 (UTC-05:00) Eastern Time (US & Canada)	Kofi Amoah (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER  
VACCINATION - Comments

**Form Version:** 10-Dec-2020 02:30

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1092

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject No:** 10921123

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
Form	Jan-25-2021 11:53:49 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	all inclusion and exclusion criteria met Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
Form	Jan-25-2021 15:01:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
1	Jan-25-2021 15:01:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
2	Jan-25-2021 15:01:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
3	Jan-25-2021 15:01:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
4	Jan-25-2021 15:01:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
5	Jan-25-2021 15:01:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
6.a	Jan-25-2021 15:01:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
6.a	Jan-25-2021 15:01:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
6.a	Jan-25-2021 15:01:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
Form	Feb-15-2021 10:21:10 (UTC-05:00) Eastern Time (US & Canada)	Kofi Amoah (b) (4)	Subject is Post Menopausal <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
1	Feb-15-2021 10:21:10 (UTC-05:00) Eastern Time (US & Canada)	Kofi Amoah (b) (4)	Subject is Post Menopausal <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
2	Feb-15-2021 10:21:10 (UTC-05:00) Eastern Time (US & Canada)	Kofi Amoah (b) (4)	Subject is Post Menopausal <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
3	Feb-15-2021 10:21:10 (UTC-05:00) Eastern Time (US & Canada)	Kofi Amoah (b) (4)	Subject is Post Menopausal <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
4	Feb-15-2021 10:21:10 (UTC-05:00) Eastern Time (US & Canada)	Kofi Amoah (b) (4)	Subject is Post Menopausal <hr/> Not Applicable



**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
5	Feb-15-2021 10:21:10 (UTC-05:00) Eastern Time (US & Canada)	Kofi Amoah (b) (4)	Subject is Post Menopausal <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
6.a	Feb-15-2021 10:21:10 (UTC-05:00) Eastern Time (US & Canada)	Kofi Amoah (b) (4)	Subject is Post Menopausal
			Not Applicable

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
6.a	Feb-15-2021 10:21:10 (UTC-05:00) Eastern Time (US & Canada)	Kofi Amoah (b) (4)	Subject is Post Menopausal
			Not Applicable

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
6.a	Feb-15-2021 10:21:10 (UTC-05:00) Eastern Time (US & Canada)	Kofi Amoah (b) (4)	Subject is Post Menopausal
			Not Applicable

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
Form	Feb-15-2021 11:19:15 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	entered in error

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1092

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject No:** 10921123

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
(b) (6)	Approved	Mar-03-2021 13:24:03 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

**Affidavit:**

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

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

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

(b) (6)	N/A	Jan-25-2021 11:53:01 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

(b) (6)	Approved	Jan-22-2021 19:42:26 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

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

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

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

Kofi Amoah	N/A	Jan-22-2021 08:38:08 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1092

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject No:** 10921123

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

(b) (6)	Approved	Nov-16-2020 10:44:30 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

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

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

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

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** COHORT\_SELECTION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Sep-01-2020 10:02:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 10:02:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry



**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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*I. Consent Was:*

Date	Location	User	Value	Reason
Sep-01-2020 10:02:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Sep/1/2020	Initial Entry

Header Text: c4591001

Visit: COHORT\_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1092

Subject No: 10921123

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1092) Sterling Research Group, Ltd.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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**1. Subject ID**

Date	Location	User	Value	Reason
Sep-01-2020 10:02:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10921123	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Sep-01-2020 10:01:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6) /1952	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Sep-01-2020 10:02:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Sep-01-2020 10:02:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT HISPANIC OR LATINO(A ) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 10:02:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

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

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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*I. Date of Visit*

Date	Location	User	Value	Reason
Sep-01-2020 10:02:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/1/2020	Initial Entry

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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**1. Date of Completion/Discontinuation/Death**

Date	Location	User	Value	Reason
Sep-01-2020 10:03:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/1/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Sep-01-2020 10:03:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Sep-01-2020 10:03:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1092

Subject No: 10921123

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1092) Sterling Research Group, Ltd.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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*I.a*

Date	Location	User	Value	Reason
Sep-01-2020 11:18:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number</b> 1 : <b>Medical History T</b> hypertension <b>erm:</b> <b>Start Date:</b> UNK/UNK/2 010 <b>Ongoing:</b> YES	Initial Entry

*I.a Line/MH Number:*

Date	Location	User	Value	Reason
Sep-01-2020 11:18:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 11:18:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> hypertension	Initial Entry

*I.a Start Date:*

Date	Location	User	Value	Reason
Sep-01-2020 11:18:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2010	Initial Entry

*I.a Ongoing:*

Date	Location	User	Value	Reason
Sep-01-2020 11:18:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1092

Subject No: 10921123

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1092) Sterling Research Group, Ltd.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

**I.b**

Date	Location	User	Value	Reason
Sep-01-2020 11:18:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number 2</b> : <b>Medical History T dyslipidemia</b> <b>erm:</b> <b>Start Date:</b> UNK/UNK/2 010 <b>Ongoing:</b> YES	Initial Entry

**I.b Line/MH Number:**

Date	Location	User	Value	Reason
Sep-01-2020 11:18:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 11:18:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> dyslipidemia	Initial Entry

**I.b Start Date:**

Date	Location	User	Value	Reason
Sep-01-2020 11:18:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2010	Initial Entry

**I.b Ongoing:**

Date	Location	User	Value	Reason
Sep-01-2020 11:18:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.c**

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1092

Subject No: 10921123

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1092) Sterling Research Group, Ltd.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

Date	Location	User	Value	Reason
Sep-01-2020 11:20:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number</b> 3 : <b>Medical History T</b> type 2 diabet <b>erm:</b> es <b>Start Date:</b> UNK/UNK/2 010 <b>Ongoing:</b> YES	Initial Entry

*I.c Line/MH Number:*

Date	Location	User	Value	Reason
Sep-01-2020 11:20:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 11:20:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> type 2 diabetes	Initial Entry

*I.c Start Date:*

Date	Location	User	Value	Reason
Sep-01-2020 11:20:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2010	Initial Entry

*I.c Ongoing:*

Date	Location	User	Value	Reason
Sep-01-2020 11:20:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

*I.d*

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

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Sep-01-2020 11:21:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 4 <b>Medical History Term:</b> gastro esophageal reflux disease <b>Start Date:</b> UNK/UNK/2015 <b>Ongoing:</b> YES	Initial Entry
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Header Text: c4591001

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Site No: 1092

Subject No: 10921123

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1092) Sterling Research Group, Ltd.

Subject Initials: ---

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***1.d Line/MH Number:***

Date	Location	User	Value	Reason
Sep-01-2020 11:21:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

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

Date	Location	User	Value	Reason
Nov-09-2020 07:54:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-09-2020 07:27:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	added
Nov-09-2020 02:14:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical - Unfrozen. SAE report states evaluation in Hosp by gastric biopsy revealed chronic gastritis. If a pre-existing condition, please evaluate for relevance to safety, and update Med Hx (AE/SAE) if applicable
Nov-06-2020 10:55:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Candidate	Clinical - Unfrozen. SAE report states evaluation in Hosp by gastric biopsy revealed chronic gastritis. If a pre-existing condition, please evaluate for relevance to safety, and update Med Hx (AE/SAE) if

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Header Text: c4591001

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Subject No: 10921123

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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Subject Initials: ---

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				applicable
Oct-26-2020 15:52:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-26-2020 07:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Thank You
Oct-26-2020 06:51:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Thanks for the response, form has been unfreeze, please update as per below query
Oct-23-2020 08:56:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Please "unfreeze" to update page
Oct-22-2020 13:46:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical SAE report for Epigastric pain reported Gastric Bypass surgery 2007 and Lab band procedure in 2012; based on clinical relevance to serious event, please update medical history with these conditions
Sep-01-2020 11:21:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> gastro esophageal reflux diseas e	Initial Entry

**1.d Start Date:**

Date	Location	User	Value	Reason
Sep-01-2020 11:21:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2015	Initial Entry

**1.d Ongoing:**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

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**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

Sep-01-2020 11:21:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry
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*I.e*

Date	Location	User	Value	Reason
Sep-01-2020 11:22:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number</b> 5 : <b>Medical History Term:</b> anxiety <b>Start Date:</b> UNK/UNK/2018 <b>Ongoing:</b> YES	Initial Entry

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Subject No: 10921123

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1092) Sterling Research Group, Ltd.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

***1.e Line/MH Number:***

Date	Location	User	Value	Reason
Sep-01-2020 11:22:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 11:22:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> anxiety	Initial Entry

***1.e Start Date:***

Date	Location	User	Value	Reason
Sep-01-2020 11:22:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2018	Initial Entry

***1.e Ongoing:***

Date	Location	User	Value	Reason
Sep-01-2020 11:22:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***1.f***

Date	Location	User	Value	Reason
Sep-01-2020 11:22:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number 6 : Medical History Term: postmenopausal Start Date: UNK/UNK/2003 Ongoing: YES	Initial Entry

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

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Subject No: 10921123

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1092) Sterling Research Group, Ltd.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

***1.f Line/MH Number:***

Date	Location	User	Value	Reason
Sep-01-2020 11:22:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 6	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 11:22:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> postmenopausal	Initial Entry

***1.f Start Date:***

Date	Location	User	Value	Reason
Sep-01-2020 11:22:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2003	Initial Entry

***1.f Ongoing:***

Date	Location	User	Value	Reason
Sep-01-2020 11:22:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***1.g***

Date	Location	User	Value	Reason
Oct-26-2020 07:35:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number</b> 7 : <b>Medical History Term:</b> Gastric Bypass <b>Start Date:</b> UNK/UNK/2007 <b>Ongoing:</b> YES	Initial Entry

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: c4591001

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Site No: 1092

Subject No: 10921123

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1092) Sterling Research Group, Ltd.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

**I.g Line/MH Number:**

Date	Location	User	Value	Reason
Oct-26-2020 07:35:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

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

Date	Location	User	Value	Reason
Oct-26-2020 07:35:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Gastric Bypass	Initial Entry

**I.g Start Date:**

Date	Location	User	Value	Reason
Oct-26-2020 07:35:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2007	Initial Entry

**I.g Ongoing:**

Date	Location	User	Value	Reason
Oct-26-2020 07:35:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.h**

Date	Location	User	Value	Reason
Oct-26-2020 07:36:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Numbe 8 r: <b>Medical History</b> Lap Band proc <b>Term:</b> edure <b>Start Date:</b> UNK/UNK/20 12 <b>Ongoing:</b> YES	Initial Entry

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Header Text: c4591001

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Subject No: 10921123

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1092) Sterling Research Group, Ltd.

Subject Initials: ---

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**1.h Line/MH Number:**

Date	Location	User	Value	Reason
Oct-26-2020 07:36:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 8	Initial Entry

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

Date	Location	User	Value	Reason
Oct-26-2020 07:36:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Lap Band procedure	Initial Entry

**1.h Start Date:**

Date	Location	User	Value	Reason
Oct-26-2020 07:36:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2012	Initial Entry

**1.h Ongoing:**

Date	Location	User	Value	Reason
Oct-26-2020 07:36:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.i**

Date	Location	User	Value	Reason
Oct-26-2020 07:36:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 9 <b>Medical History Te</b> Hernia repair <b>rm:</b> <b>Start Date:</b> Jun/26/2020 <b>Ongoing:</b> NO End Date: Jun/26/2020	Initial Entry

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: c4591001

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Site No: 1092

Subject No: 10921123

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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*I.i Line/MH Number:*

Date	Location	User	Value	Reason
Oct-26-2020 07:36:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 9	Initial Entry

*I.i Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:*

Date	Location	User	Value	Reason
Oct-26-2020 07:36:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Hernia repair	Initial Entry

*I.i Start Date:*

Date	Location	User	Value	Reason
Oct-26-2020 07:36:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Jun/26/2020	Initial Entry

*I.i Ongoing:*

Date	Location	User	Value	Reason
Oct-26-2020 07:36:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO End Date:  Jun/26/2020	Initial Entry

*I.j*

Date	Location	User	Value	Reason
Nov-11-2020 08:14:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Line/MH Number:</u> <u>Medical History Term:</u> <u>Start Date:</u> <u>Ongoing:</u>	Changed Information (DELETED)
Nov-10-2020 11:30:55 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

Time (US & Canada)		(b) (4), (b) (6)	<b>Line/MH Number:</b> <b>Medical History Term:</b> <b>Start Date:</b> <b>Ongoing:</b>	
Nov-10-2020 11:30:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Line/MH Number:</b> <b>Medical History Term:</b> <b>Start Date:</b> <b>Ongoing:</b> YES	Transcription Error
Nov-10-2020 11:30:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> : <b>Medical History Term:</b> <b>Start Date:</b> Oct/13/20 20 <b>Ongoing:</b> YES	Transcription Error
Nov-09-2020 07:27:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 10 <b>Medical History Term:</b> Chronic Focally Gastritis <b>Start Date:</b> Oct/13/2020 <b>Ongoing:</b> YES	Initial Entry

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1092

Subject No: 10921123

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1092) Sterling Research Group, Ltd.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

**1.j Line/MH Number:**

Date	Location	User	Value	Reason
Nov-11-2020 08:14:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information <b>(DELETED)</b>
Nov-10-2020 11:30:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Nov-09-2020 07:27:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10	Initial Entry

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

Date	Location	User	Value	Reason
Nov-11-2020 08:14:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information <b>(DELETED)</b>
Nov-10-2020 11:30:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Nov-09-2020 07:27:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Chronic Focally Gastritis	Initial Entry

**1.j Start Date:**

Date	Location	User	Value	Reason
Nov-11-2020 09:29:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	Response satisfies query
Nov-11-2020 08:14:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information <b>(DELETED)</b>

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

Nov-11-2020 08:14:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: An swere d	Answer Auto Query
Nov-11-2020 08:00:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Rei ssued: Opene d	DM: Please consider to delete this logline.
Nov-10-2020 16:16:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Clo sed	Auto closed by Validation Check: VC_MH001_02_AN
Nov-10-2020 11:30:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: An swere d	Transcription Error
Nov-10-2020 11:30:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: An swere d	Answer Auto Query
Nov-10-2020 11:30:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> :	Transcription Error
Nov-09-2020 15:52:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Op ened	DMW5325434;The Medical History condition 'Start Date' is after the first study treatment 'Start Date'. Please

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

				review. If date is correct, consider moving event to the Adverse Event CRF per protocol instructions.
Nov-09-2020 15:30:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM: If condition started after first vaccination, the condition should be on the AE page and not Medical History. Please consider updating the Medical History and AE page as appropriate.
Nov-09-2020 10:28:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	SAE was completed
Nov-09-2020 08:33:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM Q: Per CRF completion Guidelines section 8.7, Newly diagnosed or worsening medical condition noted during the study must immediately be reported as an adverse event. Please review and update as appropriate.
Nov-09-2020 07:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

Nov-09-2020 07:27:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Start Date is after or equal to the first vaccination date 01/Sep/2020. Please review and update as appropriate.
Nov-09-2020 07:27:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : Oct/13/2020	Initial Entry

***Lj Ongoing:***

Date	Location	User	Value	Reason
Nov-11-2020 08:14:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information ( <b>DELETED</b> )
Nov-10-2020 11:30:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Nov-09-2020 07:27:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1092

Subject No: 10921123

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1092) Sterling Research Group, Ltd.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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**1. Date:**

Date	Location	User	Value	Reason
Sep-01-2020 11:23:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sep/1/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Sep-01-2020 11:23:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 200.2	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Sep-01-2020 11:23:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> LB	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Sep-01-2020 11:23:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 64.5	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Sep-01-2020 11:23:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> in	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Sep-01-2020 11:23:09	ACV0PFEINFP6000	auto calc	<u>Data Entry:</u>	Initial Entry

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1092

Subject No: 10921123

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1092) Sterling Research Group, Ltd.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

(UTC-05:00) Eastern Time (US & Canada)		(autocalc)	33.8	
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7.a

Date	Location	User	Value	Reason
Sep-01-2020 11:23:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Record Identifier 1 :: Temperature: 98.4 Temperature Unit: F Temperature Location: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-01-2020 11:23:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-01-2020 11:23:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 98.4	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-01-2020 11:23:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-01-2020 11:23:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1092

Site Name: (1092) Sterling Research Group, Ltd.

Subject No: 10921123

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-01-2020 10:04:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Sep-01-2020 10:04:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Sep-01-2020 10:04:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Sep-01-2020 10:04:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Sep-01-2020 10:04:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a**

Date	Location	User	Value	Reason
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090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1092

Site Name: (1092) Sterling Research Group, Ltd.

Subject No: 10921123

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

Sep-01-2020 10:04:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Id entifier:</b> Not Applic able <b>Test::</b> Not Applic able <b>Result::</b> Not Applic able <b>Not Done::</b> Not Applic able	Initial Entry
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-01-2020 10:04:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-01-2020 10:04:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-01-2020 10:04:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-01-2020 10:04:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** RANDOMIZATION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Sep-01-2020 11:23:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/1/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Sep-01-2020 11:23:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 248010	Initial Entry

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1092

Site Name: (1092) Sterling Research Group, Ltd.

Subject No: 10921123

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-01-2020 10:04:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-01-2020 10:04:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-01-2020 10:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-01-2020 10:04:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-01-2020 10:04:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/1/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-01-2020 10:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BN5X1S	Initial Entry

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1092

Site Name: (1092) Sterling Research Group, Ltd.

Subject No: 10921123

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

5.a Sample ID

Date	Location	User	Value	Reason
Sep-01-2020 10:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BN5X1S	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-01-2020 10:05:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BL9TXJ	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-01-2020 10:05:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BL9TXJ	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-01-2020 10:05:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BL9TXK	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-01-2020 10:05:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BL9TXK	Initial Entry

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1092**Site Name:** (1092) Sterling Research Group, Ltd.**Subject No:** 10921123**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:31[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-01-2020 10:04:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-01-2020 10:04:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-01-2020 10:04:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-01-2020 10:04:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-01-2020 10:04:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/1/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-01-2020 10:04:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BN5X22	Initial Entry

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
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**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1092

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject No:** 10921123

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-01-2020 10:04:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BN5X22	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1092

Subject No: 10921123

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1092) Sterling Research Group, Ltd.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Sep-01-2020 11:23:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-01-2020 11:23:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-01-2020 11:23:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Sep-01-2020 11:23:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sep/1/2020 10:03	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-01-2020 11:23:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Sep-01-2020 11:23:58	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** VACCINATION - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1092

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject No:** 10921123

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	LEFT	
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**7. Route:**

Date	Location	User	Value	Reason
Sep-01-2020 11:23:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Sep-01-2020 11:23:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 11:23:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Sep-01-2020 10:03:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGENICITY E-DI ARY NOT COLLECTED FOR T HIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:02

Site No: 1092

Subject No: 10921123

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1092) Sterling Research Group, Ltd.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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*I. Date of Visit*

Date	Location	User	Value	Reason
Oct-27-2020 04:01:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	As per site confirmation - updated PD tracker
Oct-26-2020 10:00:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	DOV is correct
Oct-26-2020 07:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	PDQ: DOV at this visit is out of window (-25 day) from DOV (01/Sep/2020) at VID1VX1L. Please either update DOV or confirm whether visit is out of window due to temporary delay of vaccination/ else provide details as appropriate.
Oct-23-2020 09:21:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Oct-22-2020 10:45:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	corrected
Oct-21-2020 14:49:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Erroneous Visit is marked however there is data in all of the forms within this visit. Please remove the Erroneous visit

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:02

Site No: 1092

Subject No: 10921123

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1092) Sterling Research Group, Ltd.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

				field OR remove all data in the forms within this visit or clarify.
Oct-21-2020 14:48:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Reword query
Oct-21-2020 14:47:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this visit.
Oct-20-2020 08:31:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this visit.
Oct-20-2020 08:31:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/19/2020	Initial Entry
Sep-29-2020 02:43:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-28-2020 09:35:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Forms will be updated on date the visit will occur.
Sep-26-2020 08:24:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM1: Previous response noted. Please update the forms once visit has occurred and respond to the query only after updating the data

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

				OR once confirmed that visit will never occur.
Sep-25-2020 09:31:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	visit not completed yet, date erroneously entered
Sep-25-2020 06:08:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly review and complete 'Date of Visit, Nasal Swab, Pregnancy Test, Vaccination, Vital Signs' forms at this visit. Thank you.

**2. Erroneous Visit**

Date	Location	User	Value	Reason
Oct-22-2020 10:44:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Sep-25-2020 08:47:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ERRONEOUS VISIT	Initial Entry

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 10-Oct-2020 16:01

Site No: 1092

Subject No: 10921123

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1092) Sterling Research Group, Ltd.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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**1. Date:**

Date	Location	User	Value	Reason
Oct-20-2020 08:31:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/19/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Oct-20-2020 08:31:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 97.5 <b>Temperature Unit:</b> F <b>Temperature Location:</b> FOREHE AD	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Oct-20-2020 08:31:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Oct-20-2020 08:31:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 97.5	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Oct-20-2020 08:31:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

**2.a Temperature Location:**

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Oct-2020 16:01

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

Date	Location	User	Value	Reason
Oct-20-2020 08:31:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FOREHEAD	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1092

Site Name: (1092) Sterling Research Group, Ltd.

Subject No: 10921123

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Oct-20-2020 08:31:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Oct-20-2020 08:31:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Oct-20-2020 08:31:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/19/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Oct-20-2020 08:31:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Oct-20-2020 08:31:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
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090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1092

Site Name: (1092) Sterling Research Group, Ltd.

Subject No: 10921123

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

Oct-20-2020 08:31:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 113 <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> <b>Not Done::</b> NOT DONE	Initial Entry
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**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Oct-20-2020 08:31:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Oct-20-2020 08:31:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Not Done:**

Date	Location	User	Value	Reason
Oct-20-2020 08:31:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)



Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1092

Site Name: (1092) Sterling Research Group, Ltd.

Subject No: 10921123

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-20-2020 08:32:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-20-2020 08:32:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-20-2020 11:46:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-20-2020 10:46:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-20-2020 08:32:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-20-2020 08:32:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/19/2020	Initial Entry

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1092

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject No:** 10921123

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

**5.a**

Date	Location	User	Value	Reason
Oct-20-2020 11:46:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BM9L6R	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-20-2020 11:46:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM9L6R	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1092

Subject No: 10921123

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1092) Sterling Research Group, Ltd.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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**I. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Nov-05-2020 14:00:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Nov-05-2020 14:00:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of First Delay:  Sep/17/2020  Reason(s) for Temporary Del ay of Vaccination  FEVER OR ACUTE ILLN ESS	New Information
Nov-05-2020 13:39:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-05-2020 11:55:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	'Was there a temporary delay of vaccination?' is marked as Yes and 'Date of First Delay' is not entered. Please review and update as appropriate.
Nov-05-2020 11:55:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-05-2020 11:55:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Reason(s) for Temporary Del ay of Vaccination  FEVER OR ACUTE ILLN ESS	Changed Information

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1092

Subject No: 10921123

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1092) Sterling Research Group, Ltd.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

Nov-05-2020 10:54:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Clinical: CRF has been unlocked so data can be updated.
Nov-05-2020 07:22:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Please allow for data to be updated
Nov-04-2020 15:15:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Please update the temporary delay of vaccination from No to Yes since was delayed due to AE/SAE.
Nov-04-2020 10:54:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	subject's visit was delayed due to illness and hospitalization as previously reported in AE/SAE
Nov-03-2020 13:41:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Clin: Please provide reason Visit 2 was delayed.
Nov-03-2020 09:42:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Date correct as is. Original Visit 2 was delayed.
Nov-02-2020 12:31:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPDClin:Per projected visit date this patients Visit 2 was delayed and was outside of window. Please confirm if there was a temporary delay of vaccination and if confirmed update from No to Yes. If there was not provide reason outside of visit window.
Oct-20-2020 08:32:34 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1092

Subject No: 10921123

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1092) Sterling Research Group, Ltd.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

Time (US & Canada)	(b) (4), (b) (6)
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2. Treatment Name

Date	Location	User	Value	Reason
Oct-20-2020 08:32:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-20-2020 08:32:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Oct-20-2020 08:32:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Oct/19/2020 09:12	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-20-2020 08:32:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Oct-20-2020 08:32:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Oct-20-2020 08:32:34 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

Time (US & Canada)				
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**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Oct-20-2020 08:32:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Oct-20-2020 08:32:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

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

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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*I. Date of Visit*

Date	Location	User	Value	Reason
Nov-16-2020 09:22:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/16/2020	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:** 1092**Site Name:** (1092) Sterling Research Group, Ltd.**Subject No:** 10921123**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:31[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Nov-16-2020 09:22:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-16-2020 09:22:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-16-2020 09:48:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-16-2020 09:22:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-16-2020 09:22:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Nov/16/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-16-2020 09:48:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BSJR70	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: 1092

Site Name: (1092) Sterling Research Group, Ltd.

Subject No: 10921123

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

5.a Sample ID

Date	Location	User	Value	Reason
Nov-16-2020 09:48:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BSJR70	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-16-2020 09:49:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BM9L9W	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-16-2020 09:49:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BM9L9W	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-16-2020 09:49:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BSJR6P	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-16-2020 09:49:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BSJR6P	Initial Entry

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form Version:** 15-Sep-2020 21:55

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Nov-16-2020 09:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/16/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Nov-16-2020 09:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Nov-16-2020 09:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Date	Location	User	Value	Reason
Sep-18-2020 09:48:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1092) Sterling Research Group, Ltd.

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Date	Location	User	Value	Reason
Sep-18-2020 09:51:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Date	Location	User	Value	Reason
Sep-18-2020 09:58:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Date	Location	User	Value	Reason
Oct-20-2020 08:48:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Date	Location	User	Value	Reason
Nov-10-2020 11:32:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1092

Subject No: 10921123

Generated By: (b) (4)

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Form Status: Data Complete, Locked, Frozen

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Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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**1. Category:**

Date	Location	User	Value	Reason
Sep-18-2020 09:48:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Sep-18-2020 09:48:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Sep-18-2020 09:48:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> Swelling of eyes	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Sep-18-2020 09:48:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> Sep/17/2020 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Sep-18-2020 09:48:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> NO End Date Time: Sep/18/2020 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
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090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)



Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1092

Subject No: 10921123

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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Sep-18-2020 09:48:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> 2	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Sep-18-2020 09:48:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Sep-18-2020 09:48:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-23-2020 10:10:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 1: Closed	Response satisfies query
Sep-23-2020 08:31:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	Query 1: Answered	Benadryl , Pepsid and Deltasone are the meds listed for the treatment of AE. Benazepril was the cause of all AE.
Sep-23-2020 08:21:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 1: Reissued:Opened	Clin: Thank you for your response, can I please confirm that this reaction was due to the con meds listed (Benadryl,

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**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1092**Subject No:** 10921123**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1092) Sterling Research Group, Ltd.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:31

				Pepcid and Deltasone)and not Benazepril (which caused the hives), or are the meds listed the treatment for the AE?
Sep-22-2020 07:37:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	Query 1: Answered	Benadryl 25 MG QD Pepcid 20 MG QD Deltasone 40 MG QD
Sep-21-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 1: Opened	Clin: Please clarify what concomitant drug treatment was received that caused this AE
Sep-18-2020 10:05:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  CONCOMITANT DRUG TREATMENT	New Information
Sep-18-2020 09:48:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  Unknown reason	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Sep-18-2020 09:48:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

**Header Text:** c4591001

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

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen

**Site Name:** (1092) Sterling Research Group, Ltd.

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Date	Location	User	Value	Reason
Sep-18-2020 09:48:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> YES	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Sep-18-2020 10:06:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 09:48:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 09:48:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> NO	Initial Entry

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Header Text: c4591001

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Site No: 1092

Site Name: (1092) Sterling Research Group, Ltd.

Subject No: 10921123

Subject Initials: ---

Generated By: (b) (4)

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**1. Category:**

Date	Location	User	Value	Reason
Sep-18-2020 09:51:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Sep-18-2020 09:51:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Sep-18-2020 09:51:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> Swelling of lip	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Sep-18-2020 09:51:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> Sep/17/2020 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Sep-18-2020 09:51:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> NO End Date Time: Sep/18/2020 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1092

Subject No: 10921123

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1092) Sterling Research Group, Ltd.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

Date	Location	User	Value	Reason
Sep-18-2020 09:51:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> 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
Sep-18-2020 09:51:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Sep-18-2020 09:51:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-23-2020 10:09:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 1: Closed	Response satisfies query
Sep-23-2020 08:32:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	Query 1: Answered	Benadryl , Pepcid and Deltasone are the meds listed for the treatment of AE. Benazepril was the cause of all AE.
Sep-23-2020 08:20:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 1: Reissued:Opened	Clin: Thank you for your response, can I please confirm that this reaction was

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

				due to the con meds listed (Benadryl, Pepcid and Deltasone)and not Benazepril (which caused the hives), or are the meds listed the treatment for the AE?
Sep-22-2020 07:40:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	Query 1: Answered	Benadryl 25 MG QD Pepcid 20 MG QD Deltasone 40 MG QD
Sep-21-2020 11:40:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 1: Opened	Clin: Please clarify what concomitant drug treatment was received that caused this AE
Sep-18-2020 10:06:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  CONCOMITANT DRUG TREATMENT	New Information
Sep-18-2020 09:51:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  Unknown reason	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Sep-18-2020 09:51:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1092

Subject No: 10921123

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1092) Sterling Research Group, Ltd.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-18-2020 09:51:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<u>Data Entry:</u> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-18-2020 10:06:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 09:51:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<u>Data Entry:</u> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 09:51:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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Form Status: Data Complete, Locked, Frozen

Site No: 1092

Site Name: (1092) Sterling Research Group, Ltd.

Subject No: 10921123

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

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**1. Category:**

Date	Location	User	Value	Reason
Sep-18-2020 09:58:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Sep-18-2020 09:58:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Sep-18-2020 09:58:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> Hives (Urticaria)	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Sep-18-2020 09:58:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> Sep/17/2020 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Sep-18-2020 09:58:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> NO End Date Time: Sep/18/2020 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)



Header Text: c4591001

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Date	Location	User	Value	Reason
Sep-18-2020 09:58:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> 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
Sep-18-2020 09:58:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Sep-18-2020 09:58:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-23-2020 06:10:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 1: Closed	Response satisfies query
Sep-22-2020 07:52:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	Query 1: Answered	Benazepril 25 MG QD
Sep-21-2020 11:40:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 1: Opened	Clin: Please clarify what concomitant drug treatment was received that caused this AE
Sep-18-2020 10:07:11	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	New Information

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(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	NOT RELATED If Not Related to study treatment(s), this event is due to:  CONCOMITANT DRUG TREATMENT	
Sep-18-2020 09:58:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  Unknown reason	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Sep-18-2020 09:58:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Sep-18-2020 09:58:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> YES	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Sep-18-2020 09:58:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 09:58:57 (UTC-05:00) Eastern	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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**Generated By:** (b) (4)

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**Generated Time (GMT):** 29-Mar-2021 10:31

Time (US & Canada)				
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**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Sep-18-2020 09:58:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> NO	Initial Entry

Header Text: c4591001

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**1. Category:**

Date	Location	User	Value	Reason
Oct-20-2020 08:48:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Oct-20-2020 08:48:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Nov-04-2020 12:31:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-03-2020 09:40:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Recorded in AE no need to unfreeze med history
Oct-30-2020 22:03:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Clinical - please clarify if this diagnosis was previously known prior to study entry (will unfreeze Med Hx); however, if a new diagnosis please record as an AE.
Oct-30-2020 09:16:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Added to medical history please unfreeze med history in Visit 1

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Oct-29-2020 10:40:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical - SAE report states evaluation in Hosp by gastric biopsy revealed chronic gastritis. Please evaluate for safety impact, and record on AE CRF log, if applicable.
Oct-20-2020 08:48:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Epigastric Pain	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-20-2020 08:48:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/7/2020 21:30	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-20-2020 08:48:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Oct/8/2020 17:30	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-20-2020 09:12:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Transcription Error
Oct-20-2020 08:48:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 4	Initial Entry

7. Is the adverse event serious?

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***If Yes, NOTIFY PFIZER IMMEDIATELY.***

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

Date	Location	User	Value	Reason
Nov-03-2020 00:19:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Query closed; will follow for SAE update with the requested COVID test info
Nov-02-2020 17:03:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Follow-Up SAE being submitted
Oct-26-2020 15:58:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	Clinical Please report the COVID test result and date performed on a follow-up SAE form [lab test section; AER#] as a pertinent negative test result for this trial.
Oct-23-2020 08:54:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	No test performed
Oct-22-2020 13:57:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical COVID testing has not been reported in the SAE submitted to safety. Please submit a follow-up SAE form [#2020407104] to provide whether COVID testing was performed (yes/no) and if yes, the results.

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Oct-22-2020 13:54:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Candidate	Clinical COVID testing has not been reported in the SAE submitted to safety. Please submit a follow-up SAE form [#2020407104] to provide whether COVID testing was performed (yes/no) and if yes, the results.
Oct-21-2020 05:27:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-20-2020 08:48:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Epigastric Pain: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Oct-20-2020 08:48:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Is this serious event associated with congenital anomaly or birth defect?  NO Did this serious event result in death?  NO Did this serious event require or prolong hospitalization?  YES Did this serious event result in persistent or significant d	Initial Entry

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			isability/incapacity?  NO  Is this serious event life threatening?  NO  Other medically important serious event  NO
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**8. Is this adverse event the result of a study Medication Error?**  
**If Yes, record the type of medication error on the Medication Error Log.**

Date	Location	User	Value	Reason
Oct-20-2020 08:48:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Nov-06-2020 10:56:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-06-2020 07:28:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Nov-06-2020 07:28:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  Gastric Pouch distention	New Information
Nov-05-2020 11:46:42	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL Abd pain

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(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		'Other' reason is Unk; however SAE report states CT showed elongated fluid collection suggestive of obstruction at gastrojejunostomy; treated by NG tube drainage. Please review and update to a more specific 'Other' reason for pain
Oct-26-2020 15:58:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-23-2020 08:49:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Still ongoing
Oct-22-2020 13:49:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical SAE report includes Con Med Benazepril (Lotensin) started Aug 2005 and ongoing; however, recent events of hives/swelling were attributed to Benazepril. Please confirm if Benazepril was ongoing or had been stopped in a SAE safety followup report
Oct-20-2020 08:48:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>	Initial Entry

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			Unknown	
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-20-2020 08:48:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-20-2020 08:48:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-20-2020 08:48:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-20-2020 08:48:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-20-2020 08:48:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Oct-21-2020 05:27:59 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2020407104	Initial Entry

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Time (US & Canada)	(b) (4), (b) (6)
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**1. Category:**

Date	Location	User	Value	Reason
Nov-10-2020 11:32:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Nov-10-2020 11:32:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Nov-12-2020 17:21:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-12-2020 15:32:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Confirmed, No prior known history
Nov-12-2020 15:08:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Thanks. Pls confirm had no prior known hx or update MedHx CRF as appropriate.
Nov-12-2020 14:24:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Per Medical records report- finding in biopsy
Nov-12-2020 11:08:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical: AE term indicates 'chronic' gastritis but gastritis is not listed in the MedHx CRF. Pls clarify if

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				this is an old or new dx and update MedHx CRF if appropriate. If new dx, how determined to be 'chronic'?
Nov-10-2020 11:32:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Chronic Focally Active Gastritis	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-10-2020 11:32:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/7/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-10-2020 11:32:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-10-2020 11:32:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Nov-10-2020 11:32:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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

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

Date	Location	User	Value	Reason
Nov-10-2020 11:32:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-10-2020 11:32:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  If Other, specify:  Unknown	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-10-2020 11:32:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-10-2020 11:32:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-10-2020 11:32:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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

Date	Location	User	Value	Reason
Nov-10-2020 11:32:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RECOVERED/NOT RES OLVED	Initial Entry

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

Date	Location	User	Value	Reason
Nov-10-2020 11:32:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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:** 1092

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject No:** 10921123

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

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*I. Date of Visit*

Date	Location	User	Value	Reason
Jan-22-2021 08:38:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> Jan/21/2021	Initial Entry



**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form Version:** 10-Dec-2020 02:25

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit  
Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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

Date	Location	User	Value	Reason
Jan-22-2021 08:39:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> Participant is willing to return for Vaccination 3 Participant is:  eligible per other protocol allo wance(s) and confirmed to ha ve received only placebo at V accination 1/2	Initial Entry

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Jan-22-2021 08:38:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> Jan/22/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Jan-22-2021 08:38:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR A DDITIONAL VACCINATION	Initial Entry

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** WITHDRAWAL OF CONSENT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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***1. Withdrawal of Consent Date :***

Date	Location	User	Value	Reason
Jan-22-2021 08:38:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** DEATH DETAILS CODED - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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

Date	Location	User	Value	Reason
Jan-22-2021 08:38:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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*I. Date of Visit*

Date	Location	User	Value	Reason
Jan-25-2021 11:53:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/25/2021	Initial Entry

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:31

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** INFORMED CONSENT - FURTHER VACCINATION - eCRF  
Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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*I. Consent Was:*

Date	Location	User	Value	Reason
Jan-25-2021 11:54:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Jan/25/2021	Initial Entry

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION  
- eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:31

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1092

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject No:** 10921123

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Jan-25-2021 11:54:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/25/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Jan-25-2021 11:54:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> REPEAT SCREENING 1	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Jan-25-2021 11:54:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1092

Site Name: (1092) Sterling Research Group, Ltd.

Subject No: 10921123

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Jan-25-2021 15:01:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Jan-25-2021 15:01:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Jan-25-2021 15:01:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Jan-25-2021 15:01:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Jan-25-2021 15:01:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a**

Date	Location	User	Value	Reason
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090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)



Header Text: c4591001

Visit: V101\_VAX3

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1092

Site Name: (1092) Sterling Research Group, Ltd.

Subject No: 10921123

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

Jan-25-2021 15:01:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test:</b> <b>Result:</b> <b>Not Done:</b>	Initial Entry Not Applicable Not Applicable Not Applicable Not Applicable
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-25-2021 15:01:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jan-25-2021 15:01:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Jan-25-2021 15:01:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Jan-25-2021 15:01:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001**Visit:** V101\_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1092**Site Name:** (1092) Sterling Research Group, Ltd.**Subject No:** 10921123**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:31[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-25-2021 11:55:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-25-2021 11:55:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-25-2021 11:55:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-25-2021 11:55:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-25-2021 11:55:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jan/25/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-25-2021 11:55:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BNVLMW	Initial Entry

Header Text: c4591001

Visit: V101\_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1092

Site Name: (1092) Sterling Research Group, Ltd.

Subject No: 10921123

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

5.a Sample ID

Date	Location	User	Value	Reason
Jan-25-2021 11:55:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BNVLMW	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-25-2021 11:56:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BM9LHF	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-25-2021 11:56:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM9LHF	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-25-2021 11:56:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BNVLMM	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-25-2021 11:56:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BNVLMM	Initial Entry

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001**Visit:** V101\_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1092**Site Name:** (1092) Sterling Research Group, Ltd.**Subject No:** 10921123**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:31[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-25-2021 11:54:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-25-2021 11:54:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-25-2021 11:54:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-25-2021 11:54:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-25-2021 11:54:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jan/25/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-25-2021 11:54:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BM9LHM	Initial Entry

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1092

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject No:** 10921123

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

**5.a Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Jan-25-2021 11:54:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM9LHM	Initial Entry

Header Text: c4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1092

Subject No: 10921123

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1092) Sterling Research Group, Ltd.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Jan-25-2021 15:02:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Jan-25-2021 15:02:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Jan-25-2021 15:02:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Jan-25-2021 15:02:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/25/2021 11:46	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Jan-25-2021 15:02:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Jan-25-2021 15:02:20	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1092

Site Name: (1092) Sterling Research Group, Ltd.

Subject No: 10921123

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	LEFT	
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7. Route:

Date	Location	User	Value	Reason
Jan-25-2021 15:02:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-25-2021 15:02:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-25-2021 15:02:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-25-2021 15:02:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-25-2021 15:02:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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*I. Date of Visit*

Date	Location	User	Value	Reason
Feb-15-2021 10:19:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> Feb/15/2021	Initial Entry



Header Text: c4591001

Visit: V102\_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1092

Site Name: (1092) Sterling Research Group, Ltd.

Subject No: 10921123

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Feb-15-2021 10:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Feb-15-2021 10:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Feb-15-2021 10:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Feb-15-2021 10:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Feb-15-2021 10:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a**

Date	Location	User	Value	Reason
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090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: c4591001

Visit: V102\_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1092

Site Name: (1092) Sterling Research Group, Ltd.

Subject No: 10921123

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

Feb-15-2021 10:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable	Initial Entry
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Feb-15-2021 10:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Feb-15-2021 10:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Feb-15-2021 10:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Feb-15-2021 10:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001**Visit:** V102\_VAX4**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1092**Site Name:** (1092) Sterling Research Group, Ltd.**Subject No:** 10921123**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:31[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-15-2021 11:18:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-15-2021 11:18:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-15-2021 11:18:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-15-2021 11:18:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-15-2021 11:18:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/15/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-15-2021 11:18:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRBT0N	Initial Entry

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1092

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject No:** 10921123

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-15-2021 11:18:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRBT0N	Initial Entry

Header Text: c4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1092

Subject No: 10921123

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1092) Sterling Research Group, Ltd.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Feb-15-2021 10:21:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<u>Data Entry:</u> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Feb-15-2021 10:21:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Feb-15-2021 10:21:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Feb-15-2021 10:21:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<u>Data Entry:</u> Feb/15/2021 10:14	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Feb-15-2021 10:21:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Feb-15-2021 10:21:46	ACV0PFEINFP6000	Kofi Amoah	<u>Data Entry:</u>	Initial Entry

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: c4591001

Visit: V102\_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1092

Site Name: (1092) Sterling Research Group, Ltd.

Subject No: 10921123

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

(UTC-05:00) Eastern Time (US & Canada)		(b) (4)	LEFT	
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7. Route:

Date	Location	User	Value	Reason
Feb-15-2021 10:21:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-15-2021 10:21:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-15-2021 10:21:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-15-2021 10:21:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-15-2021 10:21:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kofi Amoah (b) (4)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: c4591001

Visit: V103\_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1092

Subject No: 10921123

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1092) Sterling Research Group, Ltd.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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**1. Date of Visit**

Date	Location	User	Value	Reason
Feb-16-2021 00:07:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query is invalid or does not apply
Feb-15-2021 11:18:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark any forms containing data within this visit as Not Done/Not Applicable at the form level.
Feb-15-2021 11:17:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/25/2021	Initial Entry

**2. Erroneous Visit**

Date	Location	User	Value	Reason
Feb-15-2021 11:18:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ERRONEOUS VISIT	Initial Entry

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1092

**Subject No:** 10921123

**Generated By:** (b) (4)

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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**1. Subject Status**

Date	Location	User	Value	Reason
Nov-16-2020 09:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Sep-01-2020 11:23:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Sep-01-2020 10:03:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Nov-16-2020 09:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Nov/16/2020	Initial Entry
Sep-01-2020 11:23:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/1/2020	Initial Entry
Sep-01-2020 10:03:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/1/2020	Initial Entry

090177e196ae306c\Final\Final On: 01-Apr-2021 04:06 (GMT)



**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1092

**Site Name:** (1092) Sterling Research Group, Ltd.

**Subject No:** 10921123

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

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*I. Casebook Signature*

Date	Location	User	Value	Reason
Oct-29-2020 11:41:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry