

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: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

[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: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/11/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: DEMOGRAPHY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[12481120]
2.	Birth Date:	(b) (6)/1945
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	BLACK OR AFRICAN AMERICAN
6.	Racial Designation:	

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation/Death	Sep/11/2020
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: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

[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/2017
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Stroke]
	Start Date:	UNK/UNK/2014
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Arthritis]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Penicillin/Sulfa Hives]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/11/2020
2.	Weight:	[119.3]
3.	Unit:	kg
4.	Height:	[180.0]
5.	Unit:	cm
6.	Body Mass Index:	[36.8]

Vital Signs Details

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

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/11/2020
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

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Sep/11/2020
2.	Randomization Number:	[256789]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/11/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP8LC4]
5.b	Sample ID	[BMNXY1]
5.c	Sample ID	[BMNXY2]
5.d	Sample ID	[BMNXY3]

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/11/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP8LC0]
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090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/11/2020 15:41
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/21/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Oct/21/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.7]
	Unit:	C
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Oct/21/2020
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

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/21/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPW1GB]
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	YES Date of First Delay: Oct/1/2020 Reason(s) for Temporary Delay of Vaccination FEVER OR ACUTE ILLNESS
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/21/2020 13:13
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Nov/18/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/18/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRFZ45]
5.b	Sample ID	[BS7YY3]
5.c	Sample ID	[BS7YY4]
5.d	Sample ID	[BS7YY5]

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET
on Oct/02/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

[eCRF Audit Trail History](#)

Date of Visit

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

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
on Oct/02/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Oct/2/2020	
2.	Date of First Symptom Started:	Not Applicable //	Comments
3.	Symptoms Ongoing?	Not Applicable	Comments

Symptoms

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

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
on Oct/02/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

4.i	Symptoms:	VOMITING
	Was symptom present?	NO

Symptoms - Other

5.	Symptoms - Other Text:	[]
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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Sep/27/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN
on Oct/02/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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

Microbiology Specimen

1.	Actual Date of Collection:	Sep/27/2020
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	OTHER
7.	Test Result:	POSITIVE
8.	Comments/Findings/Details:	[Subject was tested while in hospital for SAE; subject denies ever having COVID symptoms]
9.	Trade Name Other, Specify:	[NALT unknown]

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Oct/02/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Subject was hospitalized for SAE; COVID test performed there.]

Aliquot

Please enter barcode for each aliquot.

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

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
on Oct/02/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Subject was hospitalized for SAE; COVID test performed there.]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION
on Oct/02/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

[eCRF Audit Trail History](#)

Health Care Utilization

1.a	Physician or Healthcare Professional:	SPECIALIST
	Occurrence of Visits or Contacts:	NO
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM
	Occurrence of Visits or Contacts:	NO
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	NO
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	NO
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	NO
1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[]
----	-------------------------------------	-----

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	NO
----	--	----

090177e196f28347Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT
on Oct/02/2020

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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Respiratory Treatment

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

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS
on Oct/02/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	NO
3.	Toxicity Grade:	0

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

#	Category of Clinical Event	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.					Repeating Pages

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE
on Oct/02/2020

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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Illness Details

1.	Category of Clinical Event:	
2.	Subcategory of Clinical Event:	
3.	Was a diagnosis obtained?	
4.	Toxicity Grade:	

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	Repeating Pages

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Oct/02/2020

Form Version: 21-Aug-2020 02:49

Form Status: Not Started

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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Lab Chemistry Details

1.	Lab Panel:	
2.	Laboratory Name and Address	[]
3.	Collection Date:	//
4.	Specimen Type:	

Lab Result

5.	Sponsor ID:	[]
	Test:	
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

#	Category for Lab Test	Vendor Name (DE RIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	Repeating Pages

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
on Oct/02/2020

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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Laboratory Data Hematology

1.	Lab Panel:	
2.	Laboratory Name and Address	[]
3.	Collection Date:	//
4.	Specimen Type:	

Lab Result

5.	Sponsor ID:	[]
	Test:	
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Oct/02/2020

Form Version: 21-Aug-2020 02:50

Form Status: Not Started

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	Systolic:	[]
	Diastolic:	[]
	Respiratory Rate in respirations/minute:	[]
	Heart Rate in beats/minute:	[]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

#	Date:	Vital Signs Details		Form Instance
1.		Record Identifier:	Oxygen Saturation	Repeating Pages

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Oct/02/2020

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.				Repeating Pages

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS
on Oct/02/2020

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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Oxygenation Parameters

1.	Date Time of Assessment:	//
2.	Arterial Blood Gases PaO2 (mmHg):	[]
3.	FiO2 (Fraction of Inhaled Oxygen):	[]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
on Oct/02/2020

Form Version: 06-Jul-2020 21:55

Form Status: Not Started

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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Concomitant Medications

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

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					Repeating Pages

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING
on Oct/02/2020

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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Imaging

1.	Date of Assessment:	//
2.	Location of Assessment:	
3.	Type of Imaging Exam:	
4.	Assessment:	

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET
on Jan/21/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

[eCRF Audit Trail History](#)

Date of Visit

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

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_B
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090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
on Jan/21/2021

Form Version: 20-Feb-2021 02:17

Form Status: Data Complete

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Mar/8/2021
2.	Date of First Symptom Started:	Jan/21/2021
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Jan/21/2021

Symptoms

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

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
on Jan/21/2021

Form Version: 20-Feb-2021 02:17

Form Status: Data Complete

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

Symptoms - Other

5.	Symptoms - Other Text:	[]
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Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN
on Jan/21/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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[eCRF Audit Trail History](#)

Microbiology Specimen

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

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Jan/21/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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

Electronic Sample Tracking

1.	Data Origin	SITE	Comments
2.	Sample Type	NASAL_SWAB_SELF	Comments
3.	Sample Collected?	NO	Comments
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Sxs resolved more than 4 days]	Comments

Aliquot

Please enter barcode for each aliquot.

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

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
on Jan/21/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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

Electronic Sample Tracking

1.	Data Origin	SITE	Comments
2.	Sample Type	NASAL_SWAB	Comments
3.	Sample Collected?	NO	Comments
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Sxs resolved more than 4 days]	Comments

Aliquot

Please enter barcode for each aliquot.

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

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT
on Jan/21/2021

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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Respiratory Treatment

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

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

#	Category of Clinical Event	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.					Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE
on Jan/21/2021

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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Illness Details

1.	Category of Clinical Event:	
2.	Subcategory of Clinical Event:	
3.	Was a diagnosis obtained?	
4.	Toxicity Grade:	

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	Repeating Pages

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Jan/21/2021

Form Version: 21-Aug-2020 02:49

Form Status: Not Started

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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Lab Chemistry Details

1.	Lab Panel:	
2.	Laboratory Name and Address	[]
3.	Collection Date:	//
4.	Specimen Type:	

Lab Result

5.	Sponsor ID:	[]
	Test:	
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

#	Category for Lab Test	Vendor Name (DE RIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Jan/21/2021

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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Laboratory Data Hematology

1.	Lab Panel:	
2.	Laboratory Name and Address	[]
3.	Collection Date:	//
4.	Specimen Type:	

Lab Result

5.	Sponsor ID:	[]
	Test:	
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Jan/21/2021

Form Version: 21-Aug-2020 02:50

Form Status: Not Started

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

[Back to Form](#)

Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	Systolic:	[]
	Diastolic:	[]
	Respiratory Rate in respirations/minute:	[]
	Heart Rate in beats/minute:	[]

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

#	Date:	Vital Signs Details		Form Instance
1.		Record Identifier:	Oxygen Saturation	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Jan/21/2021

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.				Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS
on Jan/21/2021

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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Oxygenation Parameters

1.	Date Time of Assessment:	//
2.	Arterial Blood Gases PaO2 (mmHg):	[]
3.	FiO2 (Fraction of Inhaled Oxygen):	[]

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
on Jan/21/2021

Form Version: 06-Jul-2020 21:55

Form Status: Not Started

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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Concomitant Medications

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

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** IMAGING
on Jan/21/2021

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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Imaging

1.	Date of Assessment:	//
2.	Location of Assessment:	
3.	Type of Imaging Exam:	
4.	Assessment:	

090177e196f28347\Final\Final On: 04-May-2021 13:17 (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: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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

090177e196f28347\Final\Final On: 04-May-2021 13:17 (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: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

Unplanned Assessments

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Nov/18/2020
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: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

Disposition - Follow-Up

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

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

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: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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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090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Mild Stroke	Sep/23/2020 UNK:UNK	YES	Repeating Pages
2. DELETED	ADVERSE EVENT	2	Diarrhea	Jan/21/2021 UNK:UNK	NO End Date Time: Jan/21/2021 UNK:UNK	Repeating Pages

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

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[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT	
2.	AE ID:	[1]	Comments
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Mild Stroke]	
4.	Start Date Time:	Sep/23/2020 UNK:UNK	
5.	Is the adverse event still ongoing?	YES	
6.	Toxicity Grade:	3	
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	<p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect? NO</p> <p>Did this serious event result in death? NO</p> <p>Did this serious event require or prolong hospitalization? YES</p> <p>Did this serious event result in persistent or significant disability/incapacity? NO</p> <p>Is this serious event life threatening? NO</p> <p>Other medically important serious event YES</p>	
8.	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	

090177e196f28347Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

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: [Atherosclerotic cardiovascular disease]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020381724]

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Diarrhea]
4.	Start Date Time:	Jan/21/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/21/2021 UNK:UNK
6.	Toxicity Grade:	4
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	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: [Subject stated that diarrhea was due to eating burger and milkshake]

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

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

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

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

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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	[]

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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

090177e196f28347\Final\Final On: 04-May-2021 13:17 (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: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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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:	//

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

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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?	

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

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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: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

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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: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VITAL SIGNS - TEMP

Form Version: 20-Feb-2021 02:16

Form Status: Not Started

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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:	

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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?	

090177e196f28347\Final\Final On: 04-May-2021 13:17 (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: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/6/2021
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: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	---

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/15/2021
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: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/15/2021
----	--------------	--

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation/Death :	Jan/15/2021
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: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Jan/15/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/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	[BRFYP6]
5.b	Sample ID	[BSGZY4]
5.c	Sample ID	[BSGZY5]
5.d	Sample ID	[BSGZY6]

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/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	[BRFYP4]
-----	-----------	----------

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

[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/15/2021 12:02
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/5/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Feb/5/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/5/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRFYSM]
-----	-----------	----------

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

[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/5/2021 13:01
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

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

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: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

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: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

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: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

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: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

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: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Nov/18/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

[Audit Trail](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-13-2020 14:13:55 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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Item	Date	User	Comment
2	Nov-06-2020 11:30:15 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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Item	Date	User	Comment
3	Nov-06-2020 11:30:25 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Jan/21/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-08-2021 12:19:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Jan/21/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

[Back to Form](#)

Item	Date	User	Comment
1	Mar-08-2021 12:19:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Jan/21/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

[Back to Form](#)

Item	Date	User	Comment
2	Mar-08-2021 12:19:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Jan/21/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

[Back to Form](#)

Item	Date	User	Comment
3	Mar-08-2021 12:19:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Jan/21/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

[Back to Form](#)

Item	Date	User	Comment
4	Mar-08-2021 12:19:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Jan/21/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

[Back to Form](#)

Item	Date	User	Comment
5	Mar-08-2021 12:19:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Jan/21/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

[Back to Form](#)

Item	Date	User	Comment
6	Mar-08-2021 12:19:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Jan/21/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

[Back to Form](#)

Item	Date	User	Comment
7	Mar-08-2021 12:19:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Jan/21/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

[Back to Form](#)

Item	Date	User	Comment
8	Mar-08-2021 12:19:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Jan/21/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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Item	Date	User	Comment
9	Mar-08-2021 12:19:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Jan/21/2021

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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Item	Date	User	Comment
Form	Mar-09-2021 10:29:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
Form	Mar-08-2021 12:20:05 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

[Back to Form](#)

Item	Date	User	Comment
1	Mar-09-2021 10:29:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
1	Mar-08-2021 12:20:05 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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Item	Date	User	Comment
2	Mar-09-2021 10:29:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
2	Mar-08-2021 12:20:05 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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Item	Date	User	Comment
3	Mar-09-2021 10:29:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
3	Mar-08-2021 12:20:05 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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Item	Date	User	Comment
4	Mar-09-2021 10:29:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
4	Mar-08-2021 12:20:05 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Jan/21/2021

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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Item	Date	User	Comment
Form	Mar-09-2021 10:28:20 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
Form	Mar-08-2021 12:24:26 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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Item	Date	User	Comment
1	Mar-09-2021 10:28:20 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
1	Mar-08-2021 12:24:26 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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Item	Date	User	Comment
2	Mar-09-2021 10:28:20 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
2	Mar-08-2021 12:24:26 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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Item	Date	User	Comment
3	Mar-09-2021 10:28:20 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
3	Mar-08-2021 12:24:26 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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Item	Date	User	Comment
4	Mar-09-2021 10:28:20 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
4	Mar-08-2021 12:24:26 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Comments

Form Status: Data Complete

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

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Item	Date	User	Comment
2	Oct-07-2020 13:43:32 (UTC-05:00) Eastern Time (US & Canada)	Luis Monsalve (b) (4)	There has been no further information about the hospitalization and some of the fields are unknown at this time

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

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: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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Item	Date	User	Comment
Form	Jan-19-2021 08:25:50 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Jan-27-2021 12:31:39 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

Mohamed Al-ibrahim	Approved	Jan-26-2021 16:30:05 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
--------------------	----------	---	------	--------

Affidavit:

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

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

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

(b) (6)	N/A	Nov-18-2020 16:36:23 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mohamed Al-ibrahim	Approved	Nov-10-2020 12:57:16 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
--------------------	----------	---	------	--------

Affidavit:

By my dated signature below, I, MohamedAl-ibrahim, 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.

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-13-2020 14:13:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-13-2020 14:13:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

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I. Consent Was:

Date	Location	User	Value	Reason
Sep-13-2020 14:13:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Sep/11/2020	Initial Entry

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

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1. Subject ID

Date	Location	User	Value	Reason
Oct-08-2020 02:24:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Event entered in Inform. Issue resolved
Oct-07-2020 20:46:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Oct-05-2020 09:33:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020381724 mild stroke hospitalization(onset date:23Sep2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Sep-13-2020 14:13:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12481120	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Nov-06-2020 06:43:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	DOB year updated to 1945 in Safety. issue resolved
Nov-05-2020 05:38:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candi date	SAE RECON: Pending SDB update
Nov-04-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Updated SAE Formed

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

13:07:18 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		faxed to DSU: 04Nov2020.
Nov-03-2020 06:16:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Open d	SAE RECON 4: Per PSSR Comment 'In checking with the DSU- As per last follow-up received on 05Oct2020, DOB was updated to 1944. In case this needs to be updated to 1945, kindly provide an updated SAE form report.'
Oct-30-2020 07:31:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candi date	For PSSR review.
Oct-29-2020 14:07:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	As per PI, this has been submitted and re-submitted multiple times.
Oct-24-2020 10:15:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Open d	SAE RECON 3:A follow up AEM form is required to update the Date of birth in Safety database.If the correct date is (b) (6) 1945 per previous query response. Please submit follow up AEM form to correct the date of birth in safety database.
Oct-23-2020 09:58:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Oct-21-2020 06:13:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Open d	SAE RECON 2: Per latest SAE listing the year of birth is still 1944. Please submit follow up AEM form to correct the date of birth in safety database.
Oct-21-2020 01:14:56	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candi date	SAE RECON: To check SAE listing if DOB will be

090177e196f28347Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

(UTC-05:00) Eastern Time (US & Canada)				updated
Oct-20-2020 13:46:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Oct-17-2020 08:49:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	SAE RECON 1:Per query response 'Original value is correct' however, based on latest SAE listing, the year of birth reported to Safety database is 1944. Please confirm if follow up AEM form was submitted to update date of birth in SDB.
Oct-16-2020 15:33:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Oct-08-2020 05:37:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020381724 ,the date of birth was reported as (b) (6) 1944 to Safety but was recorded (b) (6) 1945 in AE CRF. Please confirm if date of birth was reported. If safety update is required, please submit a follow-up form
Sep-13-2020 14:12:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1945	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-13-2020 14:13:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-13-2020 14:13:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-13-2020 14:13:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLACK OR AFRICAN AMER ICAN	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

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I. Date of Visit

Date	Location	User	Value	Reason
Oct-30-2020 06:25:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-29-2020 14:28:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Oct-05-2020 10:56:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Details on visit 'V2VX2L' are missing. Kindly consider to update or else clarify. Thank you.
Sep-13-2020 14:13:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/11/2020	Initial Entry

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-13-2020 14:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/11/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-13-2020 14:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-13-2020 14:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

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I.a

Date	Location	User	Value	Reason
Sep-13-2020 14:14:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: Hypertension Start Date: UNK/UNK/2017 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-13-2020 14:14:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 16:10:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	SAE update noted.
Oct-02-2020 17:17:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	Per SDB subject was hospitalized during 8 days, but event and other clinical information has not been detailed yet. Please update AE log with event and submit FU SAE form with relevant information.
Sep-13-2020 14:14:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hypertension	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

1.a Start Date:

Date	Location	User	Value	Reason
Sep-13-2020 14:14:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2017	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Sep-13-2020 14:14:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Sep-13-2020 14:14:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term: Stroke Start Date: UNK/UNK/2014 Ongoing: YES	Initial Entry

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

1.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-13-2020 14:14:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Sep-13-2020 14:14:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Stroke	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Sep-13-2020 14:14:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2014	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Sep-13-2020 14:14:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Sep-13-2020 14:15:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Term: Arthritis Start Date: UNK/UNK/2015 Ongoing: YES	Initial Entry

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

I.c Line/MH Number:

Date	Location	User	Value	Reason
Sep-13-2020 14:15:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Sep-13-2020 14:15:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Arthritis	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Sep-13-2020 14:15:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Sep-13-2020 14:15:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Sep-13-2020 14:16:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: Penicillin/Sulfa Hives Start Date: UNK/UNK/2010 Ongoing: YES	Initial Entry

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

1.d Line/MH Number:

Date	Location	User	Value	Reason
Sep-13-2020 14:16:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Sep-13-2020 14:16:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Penicillin/Sulfa Hives	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Sep-13-2020 14:16:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Sep-13-2020 14:16:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

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1. Date:

Date	Location	User	Value	Reason
Sep-13-2020 14:17:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/11/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-13-2020 14:17:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 119.3	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-13-2020 14:17:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-13-2020 14:17:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 180.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-13-2020 14:17:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-13-2020 14:17:03 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 36.8	Initial Entry

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

Time (US & Canada)

7.a

Date	Location	User	Value	Reason
Sep-13-2020 14:17:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: 1 Temperature: 36.9 Temperature Unit: C Temperature Location: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-13-2020 14:17:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-13-2020 14:17:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.9	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-13-2020 14:17:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-13-2020 14:17:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196f28347FinalFinal On: 04-May-2021 13:17 (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: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-13-2020 14:17:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-13-2020 14:17:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-13-2020 14:17:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/11/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-13-2020 14:17:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-13-2020 14:17:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-13-2020 14:17:18	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196f28347FinalFinal On: 04-May-2021 13:17 (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: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

(UTC-05:00) Eastern Time (US & Canada)		(autocalc)	Sponsor-Defined Identifier: Test:: Choriogonadotropin Beta_PX113 Result:: Not Done:: NOT DONE
--	--	------------	--

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-13-2020 14:17:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-13-2020 14:17:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-13-2020 14:17:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

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1. Randomization Date :

Date	Location	User	Value	Reason
Sep-13-2020 14:17:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/11/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-13-2020 14:17:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 256789	Initial Entry

090177e196f28347FinalFinal On: 04-May-2021 13:17 (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: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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1. Data Origin

Date	Location	User	Value	Reason
Sep-13-2020 14:19:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-13-2020 14:19:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-13-2020 14:19:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-13-2020 14:19:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-13-2020 14:19:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/11/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-13-2020 14:19:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP8LC4	Initial Entry

090177e196f28347FinalFinal On: 04-May-2021 13:17 (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: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

5.a Sample ID

Date	Location	User	Value	Reason
Sep-13-2020 14:19:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP8LC4	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-13-2020 14:20:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BMNXY1	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-13-2020 14:20:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BMNXY1	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-13-2020 14:20:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BMNXY2	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-13-2020 14:20:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BMNXY2	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-13-2020 14:20:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BMNXY3	Initial Entry

090177e196f28347\Final\Final On: 04-May-2021 13:17 (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: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

5.d Sample ID

Date	Location	User	Value	Reason
Sep-13-2020 14:20:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BMNXY3	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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1. Data Origin

Date	Location	User	Value	Reason
Sep-13-2020 14:18:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-13-2020 14:18:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-13-2020 14:18:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-13-2020 14:18:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-13-2020 14:18:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/11/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-13-2020 14:18:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP8LCO	Initial Entry

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

5.a Sample ID

Date	Location	User	Value	Reason
Sep-13-2020 14:18:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP8LC0	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-13-2020 14:17:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-13-2020 14:17:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-13-2020 14:17:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-13-2020 14:17:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/11/2020 15:41	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-13-2020 14:17:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-13-2020 14:17:58 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196f28347Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

Time (US & Canada)				
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7. Route:

Date	Location	User	Value	Reason
Sep-13-2020 14:17:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-13-2020 14:17:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-13-2020 14:17:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-13-2020 14:18:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENICITY E- DIARY NOT COLLECTED F OR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

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I. Date of Visit

Date	Location	User	Value	Reason
Nov-02-2020 03:37:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	TDV details updated
Oct-30-2020 11:15:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Updated
Oct-30-2020 04:49:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	PDQ: DOV at this visit is out of window (17 day) from DOV (11/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-29-2020 14:16:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/21/2020	Initial Entry

090177e196f28347Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

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I. Date:

Date	Location	User	Value	Reason
Oct-29-2020 14:18:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-29-2020 14:18:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/21/2020	Transcription Error
Oct-29-2020 14:17:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Vital Signs Date is not same as Vaccination Date in the same visit. Please review and update as appropriate or clarify.
Oct-29-2020 14:17:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/28/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-29-2020 14:18:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier 1 : Temperature: 36.7 Temperature Unit C : Temperature Loc ORAL CAV ation:: ITY	Transcription Error
Oct-29-2020 14:17:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier 1 : Temperature: 36.7 Temperature Unit F :	Initial Entry

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

			Temperature Location:	ORAL CAVITY
--	--	--	-----------------------	-------------

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-29-2020 14:17:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Oct-29-2020 14:18:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-29-2020 14:17:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Temperature 36.7 F is outside of Normal Range 97 - 99.5 F.
Oct-29-2020 14:17:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 36.7	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Oct-29-2020 14:18:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> C	Transcription Error
Oct-29-2020 14:17:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Oct-29-2020 14:17:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> ORAL CAVITY	Initial Entry

090177e196f28347FinalFinal On: 04-May-2021 13:17 (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: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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1. Lab Panel:

Date	Location	User	Value	Reason
Oct-29-2020 14:17:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Oct-29-2020 14:17:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-29-2020 14:17:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/21/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Oct-29-2020 14:17:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Oct-29-2020 14:17:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Oct-29-2020 14:17:39	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

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Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

(UTC-05:00) Eastern Time (US & Canada)		(autocalc)	Sponsor-Defined Identifier: Test:: Choriogonadotropin Beta_PX113 Result:: Not Done:: NOT DONE
--	--	------------	--

6.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-29-2020 14:17:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Oct-29-2020 14:17:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Oct-29-2020 14:17:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

090177e196f28347FinalFinal On: 04-May-2021 13:17 (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: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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1. Data Origin

Date	Location	User	Value	Reason
Oct-29-2020 14:19:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-29-2020 14:19:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-29-2020 14:19:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-29-2020 14:19:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-29-2020 14:19:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/21/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-29-2020 14:19:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPW1GB	Initial Entry

090177e196f28347Final\Final On: 04-May-2021 13:17 (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: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

5.a Sample ID

Date	Location	User	Value	Reason
Oct-29-2020 14:19:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPW1GB	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-30-2020 11:15:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of First Delay: Oct/1/2020 Reason(s) for Temporary Delay of Vaccination FEVER OR ACUTE ILLNES S	New Information
Oct-29-2020 14:17:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Oct-29-2020 14:17:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-29-2020 14:17:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Oct-29-2020 14:17:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/21/2020 13:13	Initial Entry

5. Anatomical Location:

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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

Date	Location	User	Value	Reason
Oct-29-2020 14:17:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Oct-29-2020 14:17:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Oct-29-2020 14:17:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-29-2020 14:17:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Oct-29-2020 14:17:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

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1. Date of Visit

Date	Location	User	Value	Reason
Nov-18-2020 16:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/18/2020	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, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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1. Data Origin

Date	Location	User	Value	Reason
Nov-18-2020 16:36:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-18-2020 16:36:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-18-2020 16:36:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-18-2020 16:36:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-18-2020 16:36:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/18/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-18-2020 16:36:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRFZ45	Initial Entry

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

5.a Sample ID

Date	Location	User	Value	Reason
Nov-18-2020 16:36:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRFZ45	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-18-2020 16:37:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BS7YY3	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-18-2020 16:37:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS7YY3	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-18-2020 16:37:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BS7YY4	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-18-2020 16:37:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS7YY4	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-18-2020 16:37:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BS7YY5	Initial Entry

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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

5.d Sample ID

Date	Location	User	Value	Reason
Nov-18-2020 16:37:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS7YY5	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Oct/02/2020**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1248**Site Name:** (1248) SNBL Clinical Pharmacology Center**Subject No:** 12481120**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 04-May-2021 12:42[Back to Form](#)**1. Date of Visit**

Date	Location	User	Value	Reason
Nov-05-2020 04:32:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Closed as per comment on SWAB. updated PD tracker
Nov-04-2020 07:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Nov-04-2020 07:38:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Nov-04-2020 07:38:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Nov-04-2020 07:38:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/2/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Nov-04-2020 07:38:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/02/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1248**Site Name:** (1248) SNBL Clinical Pharmacology Center**Subject No:** 12481120**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 04-May-2021 12:42[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Nov-06-2020 06:37:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed as per site response.
Nov-04-2020 07:39:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject tested positive for Covid during hospitalization for SAE; subject reports they never has any Covid symptoms.
Nov-04-2020 07:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	All symptoms are reported as Not Present and there is no Other Symptom reported. Please review and update as appropriate.
Nov-04-2020 07:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/2/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Nov-06-2020 22:16:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-06-2020 11:30:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Nov-06-2020 09:56:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	As per other CRF Illness visit pages, subject was asymptomatic but tested positive while

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/02/2020

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

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Site No: 1248

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Generated By: (b) (4)

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				in the hospital for an unrelated SAE. No answers for #2 or #3 based on this data.
Nov-06-2020 03:51:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for Data item#2 and 3 are missing. Kindly review and update.

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Nov-06-2020 11:30:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4.a

Date	Location	User	Value	Reason
Nov-04-2020 07:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Nov-04-2020 07:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Nov-04-2020 07:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
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090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/02/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

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Subject Initials: ---

Generated By: (b) (4)

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Nov-04-2020 07:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Present: NO	Initial Entry
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4.b Symptoms:

Date	Location	User	Value	Reason
Nov-04-2020 07:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Nov-04-2020 07:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Nov-04-2020 07:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: NO	Initial Entry

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/02/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

4.c Symptoms:

Date	Location	User	Value	Reason
Nov-04-2020 07:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Nov-04-2020 07:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Nov-04-2020 07:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Nov-04-2020 07:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Nov-04-2020 07:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Nov-04-2020 07:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCREASED MUSCLE PAIN	Initial Entry

090177e196f28347Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/02/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

			Symptom NO Present:	
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4.e Symptoms:

Date	Location	User	Value	Reason
Nov-04-2020 07:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Nov-04-2020 07:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Nov-04-2020 07:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms NEW LOSS OF TASTE OR SMELL Symptom NO Present:	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Nov-04-2020 07:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Nov-04-2020 07:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

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090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/02/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

Date	Location	User	Value	Reason
Nov-04-2020 07:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCREASED SORE THROAT Symptom NO Present:	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Nov-04-2020 07:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Nov-04-2020 07:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Nov-04-2020 07:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHEA Symptom Present: NO	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Nov-04-2020 07:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Nov-04-2020 07:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/02/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

4.i

Date	Location	User	Value	Reason
Nov-04-2020 07:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: VOMITING Symptom Present: NO	Initial Entry

4.i Symptoms:

Date	Location	User	Value	Reason
Nov-04-2020 07:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Nov-04-2020 07:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Audit Trail
on Oct/02/2020

Form Version: 06-Jul-2020 21:54

Form Status:

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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Date	Location	User	Value	Reason
Nov-04-2020 07:41:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Oct/02/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Nov-04-2020 07:41:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/27/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Nov-04-2020 07:41:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWABBED MATERIAL	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Nov-04-2020 07:41:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NASOPHARYNX	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Nov-04-2020 07:41:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYNDRO ME CORONAVIRUS 2	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Nov-04-2020 07:41:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC TES T	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Nov-04-2020 07:41:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

090177e196f28347Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Oct/02/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

7. Test Result:

Date	Location	User	Value	Reason
Nov-04-2020 07:41:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: POSITIVE	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Nov-04-2020 07:41:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Subject was tested while in hospital for SAE; subject denies ever having COVID symptoms	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Nov-04-2020 07:41:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NALT unknown	Initial Entry

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/02/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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1. Data Origin

Date	Location	User	Value	Reason
Nov-04-2020 07:42:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-04-2020 07:42:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-04-2020 07:42:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-04-2020 07:42:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Subject was hospitalized for SAE; COVID test performed there.	Initial Entry

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/02/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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1. Data Origin

Date	Location	User	Value	Reason
Nov-04-2020 07:42:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-04-2020 07:42:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-04-2020 07:42:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-04-2020 07:42:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Subject was hospitalized for SAE; COVID test performed there.	Initial Entry

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Oct/02/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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I.a

Date	Location	User	Value	Reason
Nov-04-2020 07:42:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-04-2020 07:42:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-04-2020 07:42:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Nov-04-2020 07:42:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: NO	Initial Entry

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Oct/02/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-04-2020 07:42:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY ROOM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-04-2020 07:42:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.c

Date	Location	User	Value	Reason
Nov-04-2020 07:42:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry

1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-04-2020 07:42:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-04-2020 07:42:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.d

Date	Location	User	Value	Reason
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090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Oct/02/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

Nov-04-2020 07:42:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner URGENT : CARE Occurrence of Visits NO or Contacts:	Initial Entry
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1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-04-2020 07:42:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-04-2020 07:42:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Nov-04-2020 07:42:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO	Initial Entry

090177e196f28347Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Oct/02/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

1.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-04-2020 07:42:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-04-2020 07:42:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.f

Date	Location	User	Value	Reason
Nov-04-2020 07:42:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTH ER Occurrence of Visits or Contacts: NO	Initial Entry

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-04-2020 07:42:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-04-2020 07:42:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Has the subject been hospitalized due to potential COVID-19 illness?

Date	Location	User	Value	Reason
Nov-04-2020 07:42:58 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
on Oct/02/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

Time (US & Canada)	(b) (4), (b) (6)
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090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: ILLNESS DETAILS - eCRF Audit Trail History on Oct/02/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Nov-04-2020 07:44:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNES S	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Nov-09-2020 13:33:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-09-2020 12:02:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Nov-09-2020 12:02:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Changed Information
Nov-07-2020 22:14:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 2: Opened	CLIQUEY: Since per SOD form, subject is Asymptomatic, diagnosis should be reported as "NO".
Nov-06-2020 14:17:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-05-2020 09:41:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Updated
Nov-05-2020 06:58:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Since per SOD form, subject is Asymptomatic, please review if response to "Was a diagnosis obtained for Potential

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: ILLNESS DETAILS - eCRF Audit Trail History on Oct/02/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

				COVID-19 Illness?" should be No and toxicity Grade as '0". Please update as appropriate or else clarify.
Nov-04-2020 07:44:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Respiratory Illness Diagnoses:</i> COVID-19 Date of Diagnosis: Sep/27/2020	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-09-2020 13:33:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-09-2020 12:03:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Updated
Nov-09-2020 02:47:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical Query: COVID-19 diagnosis should not be entered on this CRF unless there was a local positive test and symptoms recorded. As subject is Asymptomatic, please update.
Nov-06-2020 15:04:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Candidate	Clinical Query: COVID-19 diagnosis should not be entered on this CRF unless there was a local positive

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History
on Oct/02/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

				test and symptoms recorded. As subject is Asymptomatic, please update.
Nov-06-2020 15:03:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	error
Nov-06-2020 14:59:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical Query: COVID-19 diagnosis should not be entered on this CRF unless there was a local positive test and symptoms recorded. As no local positive test recorded in COVID TEST CRF, please update.
Nov-05-2020 09:41:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0	updated
Nov-04-2020 07:44:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Jan/21/2021

Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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I. Date of Visit

Date	Location	User	Value	Reason
Mar-10-2021 04:44:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	as per site comments updated on swab forms
Mar-10-2021 02:01:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	This will be checked post BLA
Mar-09-2021 10:32:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Attempting to schedule COV visit with participant - no date at this time
Mar-09-2021 10:29:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Mar-09-2021 06:21:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	PDQ: Convalescent visit is missing and 35+ days (47) have passed since COVID Illness Visit. If visit occurred record data as a matching CONVA visit; if visit did not occur attempt to schedule visit even if OOW and obtain the CONVA sample else clarify.
Mar-09-2021 03:36:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	PDQ: Date of Visit is completed but Date of Collection

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Jan/21/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

				in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Mar-08-2021 12:19:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Mar-08-2021 12:17:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Mar-08-2021 12:17:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Mar-08-2021 12:17:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/21/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Mar-08-2021 12:17:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_B	Initial Entry

090177e196f28347Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Jan/21/2021**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 20-Feb-2021 02:17**Form Status:** Data Complete**Site No:** 1248**Site Name:** (1248) SNBL Clinical Pharmacology Center**Subject No:** 12481120**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 04-May-2021 12:42[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Mar-09-2021 08:49:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-08-2021 12:24:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Mar-08-2021 12:23:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/8/2021	Transcription Error
Mar-08-2021 12:22:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/21/2021	Transcription Error
Mar-08-2021 12:19:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of assessment is not same as Date Visit. Please check and correct.
Mar-08-2021 12:19:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/8/2021	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Mar-08-2021 12:19:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/21/2021	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Mar-08-2021 12:19:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved :	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Jan/21/2021

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

Form Version: 20-Feb-2021 02:17

Form Status: Data Complete

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

			Jan/21/2021	
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4.a

Date	Location	User	Value	Reason
Mar-08-2021 12:19:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Mar-08-2021 12:19:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Mar-08-2021 12:19:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Mar-08-2021 12:19:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Present: NO	Initial Entry

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Jan/21/2021

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

Form Version: 20-Feb-2021 02:17

Form Status: Data Complete

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

4.b Symptoms:

Date	Location	User	Value	Reason
Mar-08-2021 12:19:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Mar-08-2021 12:19:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Mar-08-2021 12:19:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: NO	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Mar-08-2021 12:19:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Mar-08-2021 12:19:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
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090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Jan/21/2021

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

Form Version: 20-Feb-2021 02:17

Form Status: Data Complete

Site No: 1248

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Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

Mar-08-2021 12:19:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry
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4.d Symptoms:

Date	Location	User	Value	Reason
Mar-08-2021 12:19:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Mar-08-2021 12:19:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Mar-08-2021 12:19:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCREASED MUSCLE PAIN Symptom Present: NO	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Mar-08-2021 12:19:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Mar-08-2021 12:19:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Jan/21/2021

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

Form Version: 20-Feb-2021 02:17

Form Status: Data Complete

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

4.f

Date	Location	User	Value	Reason
Mar-08-2021 12:19:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms NEW LOSS OF TASTE OR SMELL Symptom NO Present:	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Mar-08-2021 12:19:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Mar-08-2021 12:19:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Mar-08-2021 12:19:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCREASED SORE THROAT Symptom NO Present:	Initial Entry

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Jan/21/2021

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

Form Version: 20-Feb-2021 02:17

Form Status: Data Complete

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

4.g Symptoms:

Date	Location	User	Value	Reason
Mar-08-2021 12:19:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SORE T HROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Mar-08-2021 12:19:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Mar-08-2021 12:19:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHEA Symptom Present: YES	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Mar-08-2021 12:19:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Mar-08-2021 12:19:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.i

Date	Location	User	Value	Reason
Mar-08-2021 12:19:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: VOMITING Symptom Present: NO	Initial Entry

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit
on Jan/21/2021

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

Form Version: 20-Feb-2021 02:17

Form Status: Data Complete

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

4.i Symptoms:

Date	Location	User	Value	Reason
Mar-08-2021 12:19:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Mar-08-2021 12:19:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Jan/21/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Mar-08-2021 12:19:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Mar-08-2021 12:19:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Mar-08-2021 12:19:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Mar-08-2021 12:19:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Mar-08-2021 12:19:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Mar-08-2021 12:19:31	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
on Jan/21/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	Not Done	
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7. Test Result:

Date	Location	User	Value	Reason
Mar-08-2021 12:19:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Mar-08-2021 12:19:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Mar-08-2021 12:19:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Jan/21/2021

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

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1. Data Origin

Date	Location	User	Value	Reason
Mar-09-2021 10:30:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry
Mar-09-2021 10:29:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Mar-08-2021 12:20:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-09-2021 10:30:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry
Mar-09-2021 10:29:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Mar-08-2021 12:20:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-09-2021 17:00:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Clo sed	Auto closed by Validation Check: VC_BEETRK001_07
Mar-09-2021 10:30:18 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: An swere	Initial Entry

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Jan/21/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

Eastern Time (US & Canada)			d	
Mar-09-2021 10:30:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : NO	Initial Entry
Mar-09-2021 10:29:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry :	Initial Entry
Mar-08-2021 23:48:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW7636220;Sample Collected is not expected to be Not Done. If the sample was not collected then please mark 'Sample collected' as 'NO' and provide the reason sample was not done in field 'If no sample was collected.....' of this page. Thank you.
Mar-08-2021 12:20:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Not Done	Initial Entry

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

Date	Location	User	Value	Reason
Mar-09-2021 10:30:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sxs resolved more than 4 days	Initial Entry
Mar-09-2021 10:29:53 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196f28347Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Jan/21/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

Time (US & Canada)		(b) (4), (b) (6)		
Mar-08-2021 12:20:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Jan/21/2021

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Mar-09-2021 10:29:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry
Mar-09-2021 10:28:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Mar-08-2021 12:24:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-09-2021 10:29:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry
Mar-09-2021 10:28:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Mar-08-2021 12:24:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-09-2021 17:00:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_BEETRK001_07
Mar-09-2021 10:29:39 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answer	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Jan/21/2021

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

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Form Status: Data Complete, Frozen, Verified

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Subject No: 12481120

Subject Initials: ---

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Eastern Time (US & Canada)			d	
Mar-09-2021 10:29:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : NO	Initial Entry
Mar-09-2021 10:28:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry :	Initial Entry
Mar-08-2021 23:48:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW7636221;Sample Collected is not expected to be Not Done. If the sample was not collected then please mark 'Sample collected' as 'NO' and provide the reason sample was not done in field 'If no sample was collected.....' of this page. Thank you.
Mar-08-2021 12:24:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Not Done	Initial Entry

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

Date	Location	User	Value	Reason
Mar-09-2021 10:29:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sxs resolved more than 4 days	Initial Entry
Mar-09-2021 10:28:20 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Jan/21/2021

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: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

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Generated By: (b) (4)

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Time (US & Canada)		(b) (4), (b) (6)		
Mar-08-2021 12:24:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Nov-18-2020 16:37:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/18/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Nov-18-2020 16:37:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-18-2020 16:37:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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Date	Location	User	Value	Reason
Oct-07-2020 13:24:17 (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: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

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

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Date	Location	User	Value	Reason
Mar-09-2021 10:33:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Feb-08-2021 16:19:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

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Header Text: c4591001

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Generated By: (b) (4)

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Form Status: Data Complete

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

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1. Category:

Date	Location	User	Value	Reason
Oct-07-2020 13:24:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-07-2020 13:24:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-05-2020 12:36:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 3: Closed	Response satisfies query
Nov-04-2020 07:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	COVID test result added to Illness Visit.
Nov-02-2020 01:55:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 3: Reissued:Opened	Clin: A local SARS-COV-2 NAAT test result positive was reported on the SAE report for Mild Stroke. Please complete the potential COVID CRF forms. If the subject experienced any symptom related to COVID-19 please conduct a visit- collect a nasal swab ASAP

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Oct-25-2020 08:43:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-23-2020 13:22:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-23-2020 11:17:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	New Information
Oct-23-2020 11:17:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Oct-23-2020 11:17:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Oct-23-2020 11:17:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mild Stroke	New Information
Oct-20-2020 01:46:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 3: Opened	Clin: A local SARS-COV-2 NAAT test result positive was reported on the SAE report for Mild Stroke. Please complete the potential COVID CRF forms. If the subject experienced any symptom related to COVID-19 please conduct a visit- collect a nasal swab ASAP
Oct-09-2020 08:23:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Information was not changed. Per the paper AE Log, mild stroke is the AE. Please confirm which is correct and update either the

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Visit: Logs - Unscheduled

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				CRF or source document as needed.
Oct-08-2020 16:32:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	AE Stroke was reported but is also listed in Medical History. Clarify if this is a worsening of the baseline condition, if yes, consider adding "worsening" to the AE term. AE as baseline conditions should only be reported as AEs if they worsen. [SDQ]
Oct-07-2020 20:46:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mild Stroke/Hospitalization	New Information
Oct-07-2020 17:09:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-07-2020 17:09:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Luis Monsalve (b) (4)	Data Entry: Mild Stroke	Transcription Error
Oct-07-2020 16:17:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Should hospitalization be considered result of adverse event rather than the adverse event itself? Please confirm and update verbiage if needed.
Oct-07-2020 13:24:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mild Stroke/Hospitalization	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
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Oct-07-2020 13:24:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/23/2020 UNK:UNK	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-07-2020 13:24:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-07-2020 13:40:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Luis Monsalve (b) (4)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-29-2020 16:38:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Oct-29-2020 14:09:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Updated
Oct-29-2020 14:09:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death?	Updated

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			<p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>YES</p>	
Oct-09-2020 09:06:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	Information not changed. Initial and Follow-Up SAE reports indicate hospitalization and important medical event as seriousness criteria. Please confirm if "life threatening" is accurate and update CRF or submit SAE follow-up report.
Oct-08-2020 02:22:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-07-2020 20:46:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Mild Stroke/Hospitalization: Response to "Is the adverse event serious?" is 'Yes' but

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				"Serious Adverse Event Number" is blank.
Oct-07-2020 17:09:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Mild Stroke: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Oct-07-2020 17:09:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Transcription Error
Oct-07-2020 17:09:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Oct-07-2020 17:09:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Luis Monsalve (b) (4)	<p>Data Entry:</p> <p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p>	Transcription Error

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1248**Subject No:** 12481120**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1248) SNBL Clinical Pharmacology Center**Subject Initials:** ---**Generated Time (GMT):** 04-May-2021 12:42

			<p>YES</p> <p>Other medically important serious event</p> <p>NO</p>	
Oct-07-2020 16:06:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Per Initial and Follow-Up SAE reports, seriousness criteria met are hospitalization and important medical event. Please confirm if "life threatening" is accurate and update CRF if needed.
Oct-07-2020 13:41:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Luis Monsalve (b) (4)	<p>Data Entry:</p> <p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Is this serious event life threatening?</p> <p>YES</p>	New Information
Oct-07-2020 13:24:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Is this adverse event serious? is reported 'Yes', but at least one seriousness criteria is missing. Please review and update as

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				appropriate.
Oct-07-2020 13:24:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Mild Stroke/Hospitalization: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Oct-07-2020 13:24:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Did this serious event requi re or prolong hospitalizatio n? YES	Initial Entry

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

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

Date	Location	User	Value	Reason
Oct-07-2020 13:40:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Luis Monsalve (b) (4)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-04-2020 09:06:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Samuel Dychter (b) (4)	Query 2: Closed	Response satisfies query
Nov-04-2020 08:21:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Medical history already includes previous stroke. Additionally, medical history page is frozen.
Nov-01-2020 18:59:16 (UTC-05:00)	ACV0PFEINFP6000	Samuel Dychter (b) (4)	Query 2: Opened	GPD Clin: Per the medical history,

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Eastern Time (US & Canada)				atherosclerotic cardiovascular disease is not listed. Please consider to include this condition.
Oct-31-2020 08:12:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-30-2020 15:22:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-30-2020 15:22:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Atherosclerotic cardiovascular	Changed Information

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Oct-30-2020 14:39:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	Please review "If not related to study treatment other" field, the following text was indicated in the comment field [Atherosclerotic cardiovascular disease,cerebro vascular accident]. Any symptoms, AEs or other key data should be collected on the appropriate page. Please review and update as necessary. (b) (4)
Oct-07-2020 13:40:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Luis Monsalve (b) (4)	Data Entry: 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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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

				Atherosclerotic cardiovascular disease; status post cerebrovascular accident
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-07-2020 13:40:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Luis Monsalve (b) (4)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-07-2020 17:09:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Luis Monsalve (b) (4)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-07-2020 17:09:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Luis Monsalve (b) (4)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

Oct-07-2020 13:24:17 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry
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090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

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

Date	Location	User	Value	Reason
Oct-07-2020 13:40:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Luis Monsalve (b) (4)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Oct-08-2020 02:22:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020381724	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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

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1. Category:

Date	Location	User	Value	Reason
Feb-08-2021 16:19:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-08-2021 16:19:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-10-2021 11:13:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Mar-09-2021 10:33:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Diarrhea has been entered under COVID illness - AE to be deleted
Mar-08-2021 15:46:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Closed	Response satisfies query
Mar-08-2021 15:46:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Reissued:Opened	Clin: Per Prot Section 8.3.7., COVID-19 listed symptoms DIARRHEA does not qualify as AE and please should be documented only on the COVID-19 Illness CRF SOD form (already

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1248**Subject No:** 12481120**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Deleted**Site Name:** (1248) SNBL Clinical Pharmacology Center**Subject Initials:** ---**Generated Time (GMT):** 04-May-2021 12:42***** THIS REPEATING FORM HAS BEEN DELETED *****

				entered) and should not be captured on the AE CRF page
Mar-08-2021 15:22:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	this has been done
Mar-08-2021 15:22:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	This has been done.
Feb-09-2021 17:05:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Opened	Medical monitor: Despite telehealth visit was not done, please complete the potential COVID-19 Illness Visit CRF forms with all information available. Should be captured also on the SOD CRF form and a NASAL SWAB will not be collected
Feb-09-2021 17:02:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: Per Prot Sect 8.1., COVID-19 listed symptom DIARRHEA, should have please triggered a potential COVID-19 Illness Visit irrespective of perceived etiology or clinical significance and captured only on the CRF SOD form
Feb-08-2021 16:19:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Diarrhea	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

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

Feb-08-2021 16:19:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/21/2021 UNK:UNK	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-08-2021 16:19:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/21/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-08-2021 16:19:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-08-2021 16:19:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Feb-08-2021 16:19:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

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Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

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Form Status: Data Complete, Deleted

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

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

Date	Location	User	Value	Reason
Feb-08-2021 16:19:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Subject stated that diarrhea was due to eating burger and milkshake	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-08-2021 16:19:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-08-2021 16:19:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-08-2021 16:19:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-08-2021 16:19:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

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

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

Date	Location	User	Value	Reason
Feb-08-2021 16:19:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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I. Date of Visit

Date	Location	User	Value	Reason
Jan-19-2021 08:25:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/6/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History

Form Status: Data Complete, Frozen

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

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

Date	Location	User	Value	Reason
Jan-28-2021 19:53:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-27-2021 12:31:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jan-27-2021 12:31:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return f or Vaccination 3 Participant is: eligible per local/national re commendations and confirm ed to have received only pla cebo at Vaccination 1/2	Transcription Error
Jan-21-2021 17:32:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Per CRF Completion Requirements this option is to be selected if participant meets protocol allowance(s) to receive vaccination 6 months post-visit 2 which this subject has not. Please confirm eligibility for revaccination.
Jan-19-2021 08:25:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return f or Vaccination 3 Participant is: eligible per other protocol al lowance(s) and confirmed t o have received only placeb	Initial Entry

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History

Form Status: Data Complete, Frozen

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

o at Vaccination 1/2

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-19-2021 08:24:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/15/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-19-2021 08:24:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry

090177e196f28347\Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-19-2021 08:25:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/15/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION - eCRF
Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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I. Consent Was:

Date	Location	User	Value	Reason
Jan-19-2021 08:25:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Jan/15/2021	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: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Jan-19-2021 08:26:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/15/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-19-2021 08:26:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-19-2021 08:26:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196f28347FinalFinal On: 04-May-2021 13:17 (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: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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1. Lab Panel:

Date	Location	User	Value	Reason
Jan-19-2021 08:26:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Jan-19-2021 08:26:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-19-2021 08:26:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/15/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Jan-19-2021 08:26:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Jan-19-2021 08:26:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Jan-19-2021 08:26:37	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

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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: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

(UTC-05:00) Eastern Time (US & Canada)		(autocalc)	Sponsor-Defined Identifier: Test:: Choriogonadotropin Beta_PX113 Result:: Not Done:: NOT DONE
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-19-2021 08:26:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jan-19-2021 08:26:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Jan-19-2021 08:26:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

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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: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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1. Data Origin

Date	Location	User	Value	Reason
Jan-19-2021 08:26:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-19-2021 08:26:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-19-2021 08:26:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-19-2021 08:26:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-19-2021 08:26:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/15/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-19-2021 08:26:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRFYP6	Initial Entry

090177e196f28347FinalFinal On: 04-May-2021 13:17 (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: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

5.a Sample ID

Date	Location	User	Value	Reason
Jan-19-2021 08:26:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRFYP6	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-19-2021 08:27:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSGZY4	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-19-2021 08:27:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSGZY4	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-19-2021 08:27:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSGZY5	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-19-2021 08:27:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSGZY5	Initial Entry

5.d

Date	Location	User	Value	Reason
Jan-19-2021 08:27:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSGZY6	Initial Entry

090177e196f28347Final\Final On: 04-May-2021 13:17 (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: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

5.d Sample ID

Date	Location	User	Value	Reason
Jan-19-2021 08:27:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSGZY6	Initial Entry

090177e196f28347\Final\Final On: 04-May-2021 13:17 (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: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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1. Data Origin

Date	Location	User	Value	Reason
Jan-19-2021 08:27:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-19-2021 08:27:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-19-2021 08:27:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-19-2021 08:27:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-19-2021 08:27:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/15/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-19-2021 08:27:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRFYP4	Initial Entry

090177e196f28347Final\Final On: 04-May-2021 13:17 (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: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

5.a Sample ID

Date	Location	User	Value	Reason
Jan-19-2021 08:27:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRFYP4	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-19-2021 08:28:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-19-2021 08:28:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-19-2021 08:28:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Jan-19-2021 08:28:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/15/2021 12:02	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-19-2021 08:28:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jan-19-2021 08:28:15 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

Time (US & Canada)

(b) (4), (b) (6)

7. Route:

Date	Location	User	Value	Reason
Jan-19-2021 08:28:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-19-2021 08:28:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-19-2021 08:28:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-19-2021 08:28:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-19-2021 08:28:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196f28347Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-05-2021 18:01:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/5/2021	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: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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1. Lab Panel:

Date	Location	User	Value	Reason
Feb-05-2021 18:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Feb-05-2021 18:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Feb-05-2021 18:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/5/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Feb-05-2021 18:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Feb-05-2021 18:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Feb-05-2021 18:01:28	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196f28347FinalFinal On: 04-May-2021 13:17 (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: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

(UTC-05:00) Eastern Time (US & Canada)		(autocalc)	Sponsor-Defined Identifier: Test:: Choriogonadotropin Beta_PX113 Result:: Not Done:: NOT DONE
--	--	------------	--

6.a Sponsor ID:

Date	Location	User	Value	Reason
Feb-05-2021 18:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Feb-05-2021 18:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Feb-05-2021 18:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

090177e196f28347FinalFinal On: 04-May-2021 13:17 (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: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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1. Data Origin

Date	Location	User	Value	Reason
Feb-05-2021 19:49:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-05-2021 19:49:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-05-2021 19:50:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-05-2021 19:49:57 (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.
Feb-05-2021 19:49:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/5/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-05-2021 19:50:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRFYSM	Initial Entry

090177e196f28347FinalFinal On: 04-May-2021 13:17 (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: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

5.a Sample ID

Date	Location	User	Value	Reason
Feb-05-2021 19:50:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRFYSM	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-05-2021 18:01:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-05-2021 18:01:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-05-2021 18:01:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Feb-05-2021 18:01:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/5/2021 13:01	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-05-2021 18:01:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Feb-05-2021 18:01:40 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196f28347FinalFinal On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

Time (US & Canada)

(b) (4), (b) (6)

7. Route:

Date	Location	User	Value	Reason
Feb-05-2021 18:01:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-05-2021 18:01:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-05-2021 18:01:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-05-2021 18:01:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-05-2021 18:01:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196f28347Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481120

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 04-May-2021 12:42

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1. Subject Status

Date	Location	User	Value	Reason
Nov-18-2020 16:37:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-13-2020 14:17:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-13-2020 14:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Nov-18-2020 16:37:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/18/2020	Initial Entry
Sep-13-2020 14:17:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/11/2020	Initial Entry
Sep-13-2020 14:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/11/2020	Initial Entry

090177e196f28347Final\Final On: 04-May-2021 13:17 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481120

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 04-May-2021 12:42

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1. Casebook Signature

Date	Location	User	Value	Reason
Sep-17-2020 14:03:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry