

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:55

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: COHORT_SELECTION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Cohort Selection

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

| | | |
|----|---|-----------------|
| 1. | Select appropriate response - Protocol version | 08 SEP 2020 |
| 2. | Select appropriate response - What cohort does the subject belong to? | STAGE 3 COHORTS |

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1248

Subject No: 12481218

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): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Informed Consent

| | | |
|----|--------------|--|
| 1. | Consent Was: | OBTAINED Date Written Consent Obtained Sep/20/2020 |
|----|--------------|--|

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Demography

| | | |
|----|---------------------------------|--|
| 1. | Subject ID | [12481218] |
| 2. | Birth Date: | (b) (6)/1994 |
| 3. | Sex: | MALE |
| 4. | Ethnicity: | NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN |
| 5. | Race: (Check X all that apply): | WHITE |
| 6. | Racial Designation: | |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1248

Subject No: 12481218

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): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Sep/20/2020 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 1248

Subject No: 12481218

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): 29-Mar-2021 18:51

[Form Comments](#)

[eCRF Audit Trail History](#)

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1248

Subject No: 12481218

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): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Disposition - Screening

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481218

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): 29-Mar-2021 18:51

[Form Comments](#)

Medical History Details

| | | |
|----|--|--------------------------------|
| 1. | Line/MH Number: | Not Applicable _____ [] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | Not Applicable _____ [] |
| | Start Date: | Not Applicable _____ // |
| | Ongoing: | Not Applicable _____ |

090177e196ae2f2b\Final\Final On: 01-Apr-2021 03:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: HIV STATUS

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

HIV Status

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1248

Subject No: 12481218

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): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Vital Signs

| | | |
|----|------------------|-------------|
| 1. | Date: | Sep/20/2020 |
| 2. | Weight: | [69.4] |
| 3. | Unit: | kg |
| 4. | Height: | [174.5] |
| 5. | Unit: | cm |
| 6. | Body Mass Index: | [22.8] |

Vital Signs Details

| | | |
|-----|-----------------------|-------------|
| 7.a | Record Identifier: | 1 |
| | Temperature: | [36.7] |
| | Unit: | C |
| | Temperature Location: | ORAL CAVITY |

090177e196ae2f2b\Final\Final On: 01-Apr-2021 03:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481218

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): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Disposition

| | | |
|----|-----------------------|-------------|
| 1. | Randomization Date : | Sep/20/2020 |
| 2. | Randomization Number: | [94580] |
| 3. | Randomization Group: | [] |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481218

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): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | SERUM |
| 3. | Sample Collected? | YES Date of Collection: Sep/20/2020 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|-----|-----------|----------|
| 5.a | Sample ID | [BP8LM8] |
| 5.b | Sample ID | [BMNN93] |
| 5.c | Sample ID | [BMNN94] |
| 5.d | Sample ID | [BMNN95] |

090177e196ae2f2b\Final\Final On: 01-Apr-2021 03:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481218

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): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Sep/20/2020 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|-----|-----------|----------|
| 5.a | Sample ID | [BP8LM1] |
|-----|-----------|----------|

090177e196ae2f2b\Final\Final On: 01-Apr-2021 03:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1248

Subject No: 12481218

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): 29-Mar-2021 18:51

[Form Comments](#)

[eCRF Audit Trail History](#)

Vaccination

| | | | |
|-----|---|--------------------------|--------------------------|
| 1. | Was there a temporary delay of vaccination? | Not Done _____ | Comments |
| 2. | Treatment Name | Not Done _____ [] | Comments |
| 3. | Formulation: | Not Done _____ | Comments |
| 4. | Dose Date Time: | Not Done _____ // | Comments |
| 5. | Anatomical Location: | Not Done _____ | Comments |
| 6. | Body Side: | Not Done _____ | Comments |
| 7. | Route: | Not Done _____ | Comments |
| 8. | Actual Dose: | Not Done _____ [] | Comments |
| 9. | Unit: | Not Done _____ | Comments |
| 10. | Timeframe Subject Was Observed | Not Done _____ | Comments |
| 11. | Was the subject observed for at least the protocol specified observation period after investigational product administration? | Not Done _____ | Comments |

090177e196ae2f2b\Final\Final On: 01-Apr-2021 03:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1248

Subject No: 12481218

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): 29-Mar-2021 18:51

[Form Comments](#)

[eCRF Audit Trail History](#)

Reactogenicity Diary

| | | | Comments |
|----|--|-------------------|--------------------------|
| 1. | Select appropriate response - Reactogenicity diary collection | Not Done _____ | |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Date of Visit

| | | |
|----|-----------------|----|
| 1. | Date of Visit | // |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 20-Feb-2021 02:16

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Not Started

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Not Started

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: VACCINATION

Form Status: Not Started

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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? | |

090177e196ae2f2b\Final\Final On: 01-Apr-2021 03:37 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Date of Visit

| | | |
|----|-----------------|----|
| 1. | Date of Visit | // |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Date of Visit

| | | |
|----|-----------------|----|
| 1. | Date of Visit | // |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Date of Visit

| | | |
|----|-----------------|----|
| 1. | Date of Visit | // |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Date of Visit

| | | |
|----|-----------------|----|
| 1. | Date of Visit | // |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Date of Visit

| | | |
|----|-----------------|----|
| 1. | Date of Visit | // |
| 2. | Erroneous Visit | |

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Signs and Symptoms

| | | |
|----|--------------------------------|----|
| 1. | Date of Assessment: | // |
| 2. | Date of First Symptom Started: | // |
| 3. | Symptoms Ongoing? | |

Symptoms

| | | |
|----|----------------------|--|
| 4. | Symptoms: | |
| | Was symptom present? | |

Symptoms - Other

| | | |
|----|------------------------|-----|
| 5. | Symptoms - Other Text: | [] |
|----|------------------------|-----|

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Health Care Utilization

| | | |
|----|---------------------------------------|--|
| 1. | Physician or Healthcare Professional: | |
| | Occurrence of Visits or Contacts: | |

Health Care Utilization Other

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

Health Care Utilization

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

090177e196ae2f2b\Final\Final On: 01-Apr-2021 03:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Illness Details

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Unplanned Assessments

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

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: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

| # | Category | AE Identifier | Adverse Event | Start Date | Is the Adverse Event Still Ongoing | Form Instance |
|----|---------------|---------------|-------------------|-------------------|---|---------------------------------|
| 1. | ADVERSE EVENT | 1 | vasovagal syncope | Sep/20/2020 13:54 | NO End Date Time: Sep/20/2020 14:52 | Repeating Pages |
| 2. | ADVERSE EVENT | 2 | Vomiting | Sep/20/2020 14:52 | NO End Date Time: Sep/21/2020 14:53 | Repeating Pages |

090177e196ae2f2b\Final\Final On: 01-Apr-2021 03:37 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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[Form Audit Trail](#)

Adverse Event Report

| | | |
|-----|---|---|
| 1. | Category: | ADVERSE EVENT |
| 2. | AE ID: | [1] |
| 3. | Adverse Event: (If possible specify diagnosis, not individual symptoms) | [vasovagal syncope] |
| 4. | Start Date Time: | Sep/20/2020 13:54 |
| 5. | Is the adverse event still ongoing? | NO End Date Time: Sep/20/2020 14:52 |
| 6. | Toxicity Grade: | 2 |
| 7. | Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes). | NO |
| 8. | Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log. | NO |
| 9. | Is this event related to study treatment: | NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Study Procedure (phlebotomy)] |
| 10. | Latest Action Taken with Study Treatment: | NOT APPLICABLE |
| 11. | Was a Concomitant Medication given? | NO |
| 12. | Was a Non-Drug Treatment given? | NO |

090177e196ae2f2b\Final\Final On: 01-Apr-2021 03:37 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| | | |
|-----|--|--------------------|
| 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? | YES |
| 15. | Serious Adverse Event Number: For Pfizer Use Only | [] |

090177e196ae2f2b\Final\Final On: 01-Apr-2021 03:37 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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[Form Audit Trail](#)

Adverse Event Report

| | | |
|-----|---|--|
| 1. | Category: | ADVERSE EVENT |
| 2. | AE ID: | [2] |
| 3. | Adverse Event: (If possible specify diagnosis, not individual symptoms) | [Vomiting] |
| 4. | Start Date Time: | Sep/20/2020 14:52 |
| 5. | Is the adverse event still ongoing? | NO End Date Time: Sep/21/2020 14:53 |
| 6. | Toxicity Grade: | 1 |
| 7. | Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes). | NO |
| 8. | Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log. | NO |
| 9. | Is this event related to study treatment: | NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [unknown] |
| 10. | Latest Action Taken with Study Treatment: | NOT APPLICABLE |
| 11. | Was a Concomitant Medication given? | NO |

090177e196ae2f2b\Final\Final On: 01-Apr-2021 03:37 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| | | |
|-----|--|--------------------|
| 12. | Was a Non-Drug Treatment given? | YES |
| 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 | [] |

090177e196ae2f2b\Final\Final On: 01-Apr-2021 03:37 (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: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

Medication Error

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

090177e196ae2f2b\Final\Final On: 01-Apr-2021 03:37 (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: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Status: Not Started

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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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: | // |

090177e196ae2f2b\Final\Final On: 01-Apr-2021 03:37 (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: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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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? | |

090177e196ae2f2b\Final\Final On: 01-Apr-2021 03:37 (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: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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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? | |

090177e196ae2f2b\Final\Final On: 01-Apr-2021 03:37 (GMT)

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: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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

090177e196ae2f2b\Final\Final On: 01-Apr-2021 03:37 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Disposition - Treatment

| | | |
|----|---|---------------|
| 1. | Date of Completion/Discontinuation /Death : | Sep/21/2020 |
| 2. | Phase of Disposition: | VACCINATION |
| 3. | Status: | ADVERSE EVENT |
| 4. | Specify Status: | [] |

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Date of Visit

| | | |
|----|-----------------|----|
| 1. | Date of Visit | // |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VITAL SIGNS - TEMP

Form Version: 20-Feb-2021 02:16

Form Status: Not Started

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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? | |

090177e196ae2f2b\Final\Final On: 01-Apr-2021 03:37 (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: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Contact Outcome

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Date of Visit

| | | |
|----|-----------------|----|
| 1. | Date of Visit | // |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Informed Consent - Asymptomatic Surveillance

| | | |
|----|--------------|--|
| 1. | Consent Was: | |
|----|--------------|--|

090177e196ae2f2b\Final\Final On: 01-Apr-2021 03:37 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Data Complete, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Disposition - Follow-Up

| | | |
|----|---|---------------|
| 1. | Date of Completion/Discontinuation /Death : | Sep/21/2020 |
| 2. | Phase of Disposition: | FOLLOW-UP |
| 3. | Status: | ADVERSE EVENT |
| 4. | Specify Status: | [] |

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Date of Visit

| | | |
|----|-----------------|----|
| 1. | Date of Visit | // |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled **Form:** FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Not Started

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Further Vaccination Confirmation

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[Form Comments](#)

[eCRF Audit Trail History](#)

Withdrawal Of Consent

| | | | Comments |
|----|------------------------------|----------------------------|--------------------------|
| 1. | Withdrawal of Consent Date : | Not Applicable <hr/> // | |

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Subject Status

| | | |
|----|---------------------|--------------|
| 1. | Subject Status | DISCONTINUED |
| 2. | Subject Status Date | Sep/21/2020 |

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[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, Signed, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[Audit Trail](#)

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

- CRF_Sign

| Name | Signature Meaning | Date | Type | Action |
|--------------------|-------------------|---|------|--------|
| Mohamed Al-ibrahim | Approved | Nov-17-2020 15:08:57 (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.

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 1248

Subject No: 12481218

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): 29-Mar-2021 18:51

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| Item | Date | User | Comment |
|------|---|------------------|----------------------------------|
| Form | Nov-04-2020 11:42:58 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not applicable Not Applicable |
| Form | Nov-04-2020 11:35:45 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not applicable |
| Form | Sep-21-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | |
| Form | Sep-21-2020 12:19:20 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

090177e196ae2f2b\Final\Final On: 01-Apr-2021 03:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| Form | Sep-21-2020 12:19:35 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

090177e196ae2f2b\Final\Final On: 01-Apr-2021 03:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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| Item | Date | User | Comment |
|------|---|------------------|----------|
| Form | Sep-21-2020 13:18:28 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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| Item | Date | User | Comment |
|------|---|------------------|----------|
| 1 | Sep-21-2020 13:18:28 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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| Item | Date | User | Comment |
|------|---|------------------|----------|
| 2 | Sep-21-2020 13:18:28 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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| Item | Date | User | Comment |
|------|---|------------------|----------|
| 3 | Sep-21-2020 13:18:28 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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| Item | Date | User | Comment |
|------|---|------------------|----------|
| 4 | Sep-21-2020 13:18:28 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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| Item | Date | User | Comment |
|------|---|------------------|----------|
| 5 | Sep-21-2020 13:18:28 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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| Item | Date | User | Comment |
|------|---|------------------|----------|
| 6 | Sep-21-2020 13:18:28 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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| Item | Date | User | Comment |
|------|---|------------------|----------|
| 7 | Sep-21-2020 13:18:28 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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| Item | Date | User | Comment |
|------|---|------------------|----------|
| 8 | Sep-21-2020 13:18:28 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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| Item | Date | User | Comment |
|------|---|------------------|----------|
| 9 | Sep-21-2020 13:18:28 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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| Item | Date | User | Comment |
|------|---|------------------|----------|
| 10 | Sep-21-2020 13:18:28 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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| Item | Date | User | Comment |
|------|---|------------------|----------|
| 11 | Sep-21-2020 13:18:28 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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| Item | Date | User | Comment |
|------|---|------------------|----------|
| Form | Sep-21-2020 13:18:17 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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| Item | Date | User | Comment |
|------|---|------------------|----------|
| 1 | Sep-21-2020 13:18:17 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Done |

090177e196ae2f2b\Final\Final On: 01-Apr-2021 03:37 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| Form | Nov-06-2020 10:02:06 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: Disposition

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 1 | Nov-06-2020 10:02:06 (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, Signed, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

- CRF_Sign

| Name | Signature Meaning | Date | Type | Action |
|--------------------|-------------------|---|------|--------|
| Mohamed Al-ibrahim | Approved | Nov-17-2020 15:08:57 (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-16-2020 07:46:56 (UTC-05:00) Eastern Time (US & Canada) | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|--------------------|----------|---|------|--------|
| Mohamed Al-ibrahim | Approved | Nov-11-2020 10:54:33 (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.

090177e196ae2f2b\Final\Final On: 01-Apr-2021 03:37 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:55

Site No: 1248

Subject No: 12481218

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): 29-Mar-2021 18:51

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1. Select appropriate response - Protocol version

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Sep-21-2020 12:18:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 08 SEP 2020 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------------------|---------------|
| Sep-21-2020 12:18:55 (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: 12481218

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): 29-Mar-2021 18:51

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I. Consent Was:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Sep-21-2020 12:19:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: OBTAINED Date Written Consent Obtained Sep/20/2020 | Initial Entry |

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

1. Subject ID

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------|-----------------------------------|
| Sep-21-2020 12:18:49 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 12481218 | Item copied from previous form |

2. Birth Date:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|------------------------------------|------------------|
| Sep-21-2020 12:18:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: (b) (6)/1994 | Enrollment Entry |

3. Sex:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------|---------------|
| Sep-21-2020 12:19:10 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: MALE | Initial Entry |

4. Ethnicity:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Sep-21-2020 12:19:10 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT HISPANIC OR LATINO(A) O R OF SPANISH ORIGIN | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------|---------------|
| Sep-21-2020 12:19:10 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: WHITE | Initial Entry |

090177e196ae2f2b\Final\Final On: 01-Apr-2021 03:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1248

Subject No: 12481218

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): 29-Mar-2021 18:51

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I. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Sep-21-2020 12:19:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sep/20/2020 | Initial Entry |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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2.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---|
| Nov-04-2020 11:42:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Criterion Description: | New Information |
| Nov-04-2020 11:35:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Crit Other medical or psychiatric c erio ondition incl. recent (within p n De ast year) or active suicidal ide scrip ation/behavior/lab abnormalit tion: y that may increase the risk of study participation | Changed Information (DELETED) |
| Sep-21-2020 13:22:40 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Crit Other medical or psychiatric c erio ondition incl. recent (within p n De ast year) or active suicidal ide scrip ation/behavior/lab abnormalit tion: y that may increase the risk of study participation | Initial Entry |

2.a Description of Exclusion Criterion Met

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---|
| Nov-04-2020 11:42:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Itemset row was undeleted in order to clear CRF |
| Nov-04-2020 11:42:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | New Information |
| Nov-04-2020 11:35:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Other medical or psychiatric conditio n incl. recent (within past year) or ac tive suicidal ideation/behavior/lab ab normality that may increase the risk of study participation | Changed Information (DELETED) |
| Sep-21-2020 13:22:40 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Other medical or psychiatric conditio n incl. recent (within past year) or ac tive suicidal ideation/behavior/lab ab normality that may increase the risk of study participation | Initial Entry |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1248

Subject No: 12481218

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): 29-Mar-2021 18:51

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1. Date of Completion/Discontinuation/Death

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Sep-21-2020 12:19:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/20/2020 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Sep-21-2020 12:19:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SCREENING | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---------------------------------|---|
| Nov-04-2020 11:34:40 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 4: Closed | Close Auto Query |
| Nov-04-2020 11:34:22 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 4: Opened | Response to "Status" is COMPLETED but "Specify Status" is Provided. |
| Nov-04-2020 11:34:22 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COMPLETED | New Information |
| Nov-04-2020 00:51:52 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Oct-30-2020 11:53:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Subject was randomized. However, subject had vasovagal syncope and |

090177e196ae2f2b\Final\Final On: 01-Apr-2021 03:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1248

Subject No: 12481218

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): 29-Mar-2021 18:51

| | | | | |
|---|-----------------|---------------------------|-----------------------------|--|
| | | | | vomiting AEs during blood collected. He was then discontinued and did not dose. |
| Oct-29-2020 02:42:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | Response satisfies query |
| Oct-29-2020 01:51:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued:Opened | DM1: Screening Disposition Status is still not "Completed". However, Randomization details present in Impala . Please review and update. |
| Oct-27-2020 14:51:44 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 3: Closed | Close Auto Query |
| Oct-27-2020 14:51:30 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 3: Opened | Response to "Status" is OTHER but "Specify Status" is missing. |
| Oct-27-2020 14:51:30 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Answered | New Information |
| Oct-27-2020 14:51:30 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | New Information |
| Oct-27-2020 14:51:30 (UTC-05:00) Eastern Time | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: OTHER | New Information |

090177e196ae2f2b\Final\Final On: 01-Apr-2021 03:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|---|---|-------------------------|--|--|
| (US & Canada) | | | | |
| Oct-14-2020 18:01:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFE SDQ PROD (b) (4) | Query 2: Open ed | As per Impala, Subject status is Discontinued. Please review and update as appropriate. Thank you. (b) (4) |
| Oct-08-2020 08:26:59 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Open ed | DM: Randomization details present in Impala but Screening Disposition Status is not "Completed". Please correct as appropriate and capture randomization details in CRF. |
| Sep-21-2020 13:21:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: SCREEN FAI LURE | Transcription Error |
| Sep-21-2020 12:19:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COMPLETED | Initial Entry |

4. Specify Status:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------------|-----------------|
| Nov-04-2020 11:34:40 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | New Information |
| Oct-27-2020 14:51:44 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Discontinued | Initial Entry |

090177e196ae2f2b\Final\Final On: 01-Apr-2021 03:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Sep-21-2020 12:19:50 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: The subject is NOT known to be HIV POSITIVE | Initial Entry |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1248

Subject No: 12481218

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): 29-Mar-2021 18:51

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1. Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Sep-21-2020 13:15:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sep/20/2020 | Initial Entry |

2. Weight:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------|---------------|
| Sep-21-2020 13:15:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> 69.4 | Initial Entry |

3. Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Sep-21-2020 13:15:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> kg | Initial Entry |

4. Height:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------|---------------|
| Sep-21-2020 13:15:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> 174.5 | Initial Entry |

5. Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Sep-21-2020 13:15:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> cm | Initial Entry |

6. Body Mass Index:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Sep-21-2020 13:15:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 22.8 | Initial Entry |

7.a

090177e196ae2f2b\Final\Final On: 01-Apr-2021 03:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-21-2020 13:15:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier:: 1 Temperature: 36.7 Temperature Unit: C Temperature Location:: ORAL CAVITY | Initial Entry |

7.a Record Identifier:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Sep-21-2020 13:15:31 (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-21-2020 13:15:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 36.7 | Initial Entry |

7.a Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Sep-21-2020 13:15:31 (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-21-2020 13:15:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: ORAL CAVITY | Initial Entry |

090177e196ae2f2b\Final\Final On: 01-Apr-2021 03:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481218

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): 29-Mar-2021 18:51

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1. Randomization Date :

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Nov-04-2020 14:30:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sep/20/2020 | Initial Entry |

2. Randomization Number:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------|---------------|
| Nov-04-2020 14:30:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> 94580 | Initial Entry |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Sep-21-2020 13:15:59 (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-21-2020 13:15:59 (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-21-2020 13:16:08 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Sep-21-2020 13:15:59 (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-21-2020 13:15:59 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Sep/20/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-21-2020 13:16:08 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BP8LM8 | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|----------------------|-----------------|------------------|--------------------|---------------|
| Sep-21-2020 13:16:08 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |

090177e196ae2f2b\Final\Final On: 01-Apr-2021 03:37 (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: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|---|--|---------------------|--------|--|
| (UTC-05:00) Eastern Time (US & Canada) | | (b) (4), (b) (6) | BP8LM8 | |
|---|--|---------------------|--------|--|

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-21-2020 13:16:22 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sample ID: BMNN93 | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Sep-21-2020 13:16:22 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BMNN93 | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-21-2020 13:16:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sample ID: BMNN94 | Initial Entry |

5.c Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Sep-21-2020 13:16:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BMNN94 | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-21-2020 13:16:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sample ID: BMNN95 | Initial Entry |

5.d Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Sep-21-2020 13:16:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BMNN95 | Initial Entry |

090177e196ae2f2b\Final\Final On: 01-Apr-2021 03:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Sep-21-2020 13:17:23 (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-21-2020 13:17:23 (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-21-2020 13:18:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Sep-21-2020 13:17:23 (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-21-2020 13:17:23 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Sep/20/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-21-2020 13:18:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BP8LM1 | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|----------------------|-----------------|------------------|--------------------|---------------|
| Sep-21-2020 13:18:01 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |

090177e196ae2f2b\Final\Final On: 01-Apr-2021 03:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

(UTC-05:00) Eastern Time
(US & Canada)

(b) (4),
(b) (6)

BP8LM1

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1248

Subject No: 12481218

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): 29-Mar-2021 18:51

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1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Sep-21-2020 13:18:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

2. Treatment Name

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Sep-21-2020 13:18:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Sep-21-2020 13:18:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

4. Dose Date Time:

| Date | Location | User | Value | Reason |
|---|---|----------------------|-------------------|---|
| Nov-09-2020 06:51:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Nov-05-2020 09:49:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | This is correct. Subject was randomized but not dosed due to AE. Disposition list "Adverse Event". |
| Nov-04-2020 17:54:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY (b) (4) | Query 1: Opened | DMW5284857;Randomization number is recorded and the final disposition date is present on the Disposition - Follow-up eCRF, but there is no dosing date present on the Treatment eCRF. Please review and update as |

090177e196ae2f2b\Final\Final On: 01-Apr-2021 03:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1248

Subject No: 12481218

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): 29-Mar-2021 18:51

| | | | | |
|--|-----------------|---------------------|--|---------------|
| | | | | appropriate. |
| Sep-21-2020 13:18:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry : Not D one | Initial Entry |

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Sep-21-2020 13:18:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

6. Body Side:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Sep-21-2020 13:18:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

7. Route:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Sep-21-2020 13:18:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

8. Actual Dose:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Sep-21-2020 13:18:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

9. Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Sep-21-2020 13:18:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae2f2b\Final\Final On: 01-Apr-2021 03:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1248

Subject No: 12481218

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): 29-Mar-2021 18:51

| | | | | |
|---|-----------------|---------------------|--------------------------------|---------------|
| Sep-21-2020 13:18:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | 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-21-2020 13:18:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1248

Subject No: 12481218

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): 29-Mar-2021 18:51

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1. Select appropriate response - Reactogenicity diary collection

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Sep-21-2020 13:18:17 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------|--------|
| Oct-21-2020 10:20:35 (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: 12481218

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------|--------|
| Oct-21-2020 10:21:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Oct-21-2020 10:20:35 (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-21-2020 10:20:35 (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 |
|---|-----------------|------------------|---|---------------|
| Oct-21-2020 10:20:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: vasovagal syncope | Initial Entry |

4. Start Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Oct-21-2020 10:20:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/20/2020 13:54 | Initial Entry |

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Oct-21-2020 10:20:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date Time: Sep/20/2020 14:52 | Initial Entry |

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-------------------------|---------------|
| Oct-21-2020 10:20:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 2 | Initial Entry |

090177e196ae2f2b\Final\Final On: 01-Apr-2021 03:37 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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-21-2020 10:20:35 (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 |
|---|-----------------|------------------|-------------------|---------------|
| Oct-21-2020 10:20:35 (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:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|--|
| Nov-06-2020 11:44:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Nov-06-2020 10:40:11 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | New Information |
| Nov-06-2020 10:40:11 (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 If Other, specify: Study Procedure (phlebotomy) | New Information |
| Nov-06-2020 10:20:21 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued:Opened | clinical: Thanks, the causality then should be UNRELATED; other=study procedure Pls update |

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|---|-----------------|---------------------|-------------------------------|--|
| | | | | CRF. |
| Nov-06-2020 10:02:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Confirmed: related to phlebotomy. |
| Nov-06-2020 09:38:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | clinical-pt appears to have been withdrawn prior to administration of vax 1, was syncopal event before or after any study related procedures such as nasal swab or phlebotomy. Thanks |
| Oct-21-2020 10:20:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RELATED | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-21-2020 10:20:35 (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 |
|---|-----------------|------------------|--------------------------|---------------|
| Oct-21-2020 10:20:35 (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 |
|---|-----------------|------------------|--------------------------|---------------|
| Oct-21-2020 10:20:35 (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 |
|---|-----------------|------------------|--|---------------|
| Oct-21-2020 10:20:35 (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: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---------------------------|--|
| Nov-04-2020 11:40:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | New Information |
| Oct-21-2020 10:24:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Closed | Close Auto Query |
| Oct-21-2020 10:24:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Oct-21-2020 10:24:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | New Information |
| Oct-21-2020 10:22:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Opened | More than 1 AE for this patient has "Did the adverse event cause the subject to be discontinued from the study?" marked as 'Yes'. |
| Oct-21-2020 10:22:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Did the adverse event cause the subject to be discontinued from the study?' is Yes but neither DISPOSITION - TREATMENT form nor DISPOSITION - FOLLOW-UP has Status as "ADVERSE EVENT". Please review and update as appropriate. |
| Oct-21-2020 10:22:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Transcription Error |
| Oct-21-2020 10:20:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Oct-21-2020 10:21:48 (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-21-2020 10:21:48 (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 |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-21-2020 10:21:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Vomiting | Initial Entry |

4. Start Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Oct-21-2020 10:21:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/20/2020 14:52 | Initial Entry |

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------|---|
| Nov-09-2020 06:53:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1 : Closed | Response satisfies query |
| Nov-05-2020 09:48:06 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1 : Answered | Date and time are correct. Site followed up on this AE the next day even though the subject did not dose. |

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|--|---|----------------------|--|---|
| Nov-04-2020 17:54:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY (b) (4) | Query 1 : Opened | DMW5284849; 'End Date' is after 'Date of Completion/Discontinuation '/Death' on the Disposition - Follow-up eCRF. Please clarify or correct. |
| Oct-21-2020 10:21:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date Time: Sep/ 21/2 020 14:5 3 | Initial Entry |

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-------------------------|---------------|
| Oct-21-2020 10:21:48 (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 |
|---|-----------------|------------------|--------------------------|---------------|
| Oct-21-2020 10:21:48 (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 |
|---|-----------------|------------------|--------------------------|---------------|
| Oct-21-2020 10:21:48 (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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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

| Date | Location | User | Value | Reason |
|---|---|---------------------------|---|---|
| Nov-06-2020 09:36:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Nov-05-2020 09:46:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | updated |
| Nov-05-2020 09:46:48 (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> unknown | updated |
| Nov-05-2020 06:34:14 (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 [vomiting]. Any symptoms, AEs or other key data should be collected on the appropriate page. Please review and update as necessary. (b) (4) |
| Oct-21-2020 10:23:49 (UTC-05:00) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT RELATED | New Information |

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| | | | |
|--|-----------------|------------------|--|
| Eastern Time (US & Canada) | | | If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> subject reported vomiting on 20 sept 2020 |
| Oct-21-2020 10:21:48 (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 |

10. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-21-2020 10:21:48 (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 |
|---|-----------------|------------------|--------------------------|---------------|
| Oct-21-2020 10:21:48 (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 |
|---|-----------------|------------------|---------------------------|---------------|
| Oct-21-2020 10:21:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

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

090177e196ae2f2b\Final\Final On: 01-Apr-2021 03:37 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Oct-21-2020 10:21:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RECOVERED/RESOLVED | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---------------------------|--|
| Oct-21-2020 10:25:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Oct-21-2020 10:25:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Transcription Error |
| Oct-21-2020 10:21:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Did the adverse event cause the subject to be discontinued from the study?' is Yes but neither DISPOSITION - TREATMENT form nor DISPOSITION - FOLLOW-UP has Status as "ADVERSE EVENT". Please review and update as appropriate. |
| Oct-21-2020 10:21:48 (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: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date of Completion/Discontinuation/Death :

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Nov-16-2020 11:45:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sep/21/2020 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------------|---------------|
| Nov-16-2020 11:45:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> VACCINATION | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|---|---|----------------------|-----------------------|---|
| Nov-17-2020 23:52:10 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Cl osed | Response satisfies query |
| Nov-17-2020 18:06:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Cl osed | Response satisfies query |
| Nov-17-2020 10:20:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: An swered | Subject did not dose due to AE. |
| Nov-17-2020 10:20:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: An swered | Subject did not dose due to AE. |
| Nov-17-2020 09:13:06 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY (b) (4) | Query 2: Op ened | DMW5388878;Status on the Disposition - Treatment form is not null but at least one Dose Date is missing. Please review and |

090177e196ae2f2b\Final\Final On: 01-Apr-2021 03:37 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|---|---|----------------------|--|--|
| | | | | update as appropriate. |
| Nov-16-2020 15:24:50 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY (b) (4) | Query 1: Opened | DMW5388813;Status is reported as Adverse Event, but there is no Adverse Event with 'Latest Action Taken with Study Treatment' reported as DRUG WITHDRAWN. Please review and update as appropriate. |
| Nov-16-2020 11:45:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry : ADVERSE EVENT | Initial Entry |

090177e196ae2f2b\Final\Final On: 01-Apr-2021 03:37 (GMT)

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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I. Date of Completion/Discontinuation/Death :

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|-----------------------------------|---|
| Nov-16-2020 09:38:56 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | Response satisfies query |
| Nov-16-2020 07:46:56 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Answered | As per query request. |
| Nov-16-2020 07:46:56 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/21/2020 | As per query request. |
| Nov-14-2020 05:26:42 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Balaji Prabu R (b) (4) | Query 2: Opened | Based on previous query, please either update this date as 21Sep2020 if contact was made with subject to collect resolution date or update the AE end date as ongoing to state that AEs were ongoing at the time of subject concluded the study on 20Sep2020. |
| Nov-10-2020 17:01:08 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Nov-10-2020 08:36:17 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Date is correct; AE was closed after report via phone with subject. AE ended after subject was technically excluded from the study. |
| Nov-10-2020 02:30:52 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Balaji Prabu R (b) (4) | Query 1: Opened | For the adverse event 'Vomiting' end date is reported as 21Sep2020 which is after the disposition follow up date. In |

090177e196ae2f2b\Final\Final On: 01-Apr-2021 03:37 (GMT)

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1248

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject No: 12481218

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|---|-----------------|------------------|-----------------------------------|---|
| | | | | case end date is correct, please consider updating this date. Else clarify. |
| Nov-04-2020 11:39:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/20/2020 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Nov-04-2020 11:39:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: FOLLOW-UP | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|-------------------------------------|---|
| Nov-04-2020 11:40:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Nov-04-2020 11:40:06 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Closed | Close Auto Query |
| Nov-04-2020 11:39:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Opened | Response to "Status" is ADVERSE EVENT but "Specify Status" is Provided. |
| Nov-04-2020 11:39:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened | Status is reported as Adverse Event, but there is no Adverse Event with 'Did the adverse event cause the subject to be discontinued from the study' reported as YES. Please check and correct the data. |
| Nov-04-2020 11:39:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: ADVERSE EVENT | Initial Entry |

4. Specify Status:

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae2f2b\Final\Final On: 01-Apr-2021 03:37 (GMT)

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|---|-----------------|---------------------|---|---------------------|
| Nov-04-2020 11:40:06 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Transcription Error |
| Nov-04-2020 11:39:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Discontinued by Medical Team due t o AEs during blood draw | Initial Entry |

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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I. Withdrawal of Consent Date :

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|--|
| Nov-07-2020 07:26:09 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Nov-06-2020 10:02:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Updated to Not Applicable |
| Nov-06-2020 10:02:06 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |
| Nov-06-2020 04:05:25 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | DM: Kindly consider to update this form if require else mark as Not applicable by selecting form level comment. Thank you. |
| Nov-04-2020 11:38:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | New Information |
| Oct-21-2020 10:25:56 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/20/2020 | Initial Entry |

090177e196ae2f2b\Final\Final On: 01-Apr-2021 03:37 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481218

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): 29-Mar-2021 18:51

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I. Subject Status

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|------------------------------------|---|
| Nov-16-2020 11:45:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DISCONTINUED | Initial Entry |
| Nov-04-2020 14:30:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DISCONTINUED | Initial Entry |
| Nov-04-2020 11:39:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DISCONTINUED | Initial Entry |
| Nov-04-2020 11:34:22 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SCREENED | New Information |
| Nov-03-2020 09:54:45 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Nov-02-2020 16:58:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Listed as "discontinued" on V1 page. Unable to update this page. |
| Nov-02-2020 11:47:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | Subject 12481218 was randomized in IMPALA and therefore cannot be considered a screen fail. Please consider changing subject status to discontinued. |
| Oct-27-2020 14:51:30 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SCREEN FAIL | New Information |
| Sep-21-2020 13:21:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SCREEN FAIL | Transcription Error |
| Sep-21-2020 12:19:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SCREENED | Initial Entry |

090177e196ae2f2b\Final\Final On: 01-Apr-2021 03:37 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1248

Subject No: 12481218

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): 29-Mar-2021 18:51

2. Subject Status Date

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------------|-----------------------|
| Nov-16-2020 11:45:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sep/21/2020 | Initial Entry |
| Nov-16-2020 07:46:56 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sep/21/2020 | As per query request. |
| Nov-04-2020 14:30:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sep/20/2020 | Initial Entry |
| Nov-04-2020 11:39:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sep/20/2020 | Initial Entry |
| Nov-04-2020 11:34:22 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sep/20/2020 | New Information |
| Oct-27-2020 14:51:30 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sep/20/2020 | New Information |
| Sep-21-2020 13:21:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sep/20/2020 | Transcription Error |
| Sep-21-2020 12:19:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sep/20/2020 | Initial Entry |

090177e196ae2f2b\Final\Final On: 01-Apr-2021 03:37 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1248

Subject No: 12481218

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Status: Data Complete, Signed, Verified

Site Name: (1248) SNBL Clinical Pharmacology Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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I. Casebook Signature

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Sep-21-2020 13:26:32 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Click Here to Enable | Initial Entry |