## Annotated Study Book for Study Design: C4591001

Study Design Version: 14.0

**Sponsor: Pfizer** 

Protocol: C4591001

#### Sponsor Drug Name: BLINDED THERAPY

C4591001 - COVID19

Generated by Central Designer TM

January 14, 2021 12:00PM

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| <b>MAIN INFORMED CONSENT</b>    |                               |
|---------------------------------|-------------------------------|
| DEMOGRAPHY                      |                               |
| <b>DATE OF VISIT</b>            |                               |
| INCLUSION/EXCLUSION CRIT        | ERIA (INCEXCS)                |
| INCLUSION/EXCLUSION CRIT        | ERIA (INCEXCS)                |
| INCLUSION/EXCLUSION CRIT        | ERIA (INCEXCS)                |
| INCLUSION/EXCLUSION CRIT        | ERIA (INCEXC)                 |
| DISPOSITION - SCREENING         |                               |
| <b>GENERAL MEDICAL HISTORY</b>  |                               |
| <b>CONCOMITANT MEDICATION</b>   | NS - BASELINE                 |
| <b>PHYSICAL EXAMINATION</b>     |                               |
| <b>VITAL SIGNS - BASELINE</b>   |                               |
| ELECTRONIC SAMPLE TRACK         | NG - PRIOR COVID-19 INFECTION |
| MICROBIOLOGY SPECIMEN (         | COV19 SITE)                   |
| <b>CENTRAL LAB SAMPLE COLLE</b> | CTION-BASELINE                |
| LAB URINALYSIS - PREGNANO       | CYTEST                        |
| V1 DAY1 VAX1 S                  |                               |
| DATE OF VISIT                   |                               |
| <b>PHYSICAL EXAMINATION</b>     |                               |
| <b>VITAL SIGNS</b>              |                               |
| LAB URINALYSIS - PREGNANO       | CYTEST                        |
| ELECTRONIC SAMPLE TRACK         | NG - NASAL SWAB               |
|                                 |                               |

MICROBIOLOGY SPECIMEN (SWAB SITE)

RANDOMIZATION

ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

VACCINATION

**VACCINATION DIARY** 

## V2\_DAY2\_POSTVAX1\_S

DATE OF VISIT PHYSICAL EXAMINATION VITAL SIGNS CENTRAL LAB SAMPLE COLLECTION

# V3\_WEEK1\_POSTVAX1\_S

DATE OF VISIT

**PHYSICAL EXAMINATION** 

- VITAL SIGNS
- **CENTRAL LAB SAMPLE COLLECTION**

ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

# V4\_WEEK3\_VAX2\_S

DATE OF VISIT VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES PHYSICAL EXAMINATION VITAL SIGNS LAB URINALYSIS - PREGNANCY TEST ELECTRONIC SAMPLE TRACKING - NASAL SWAB

| MIC              | ROBIOLOGY SPECIMEN (SWAB SITE)                   |
|------------------|--|
|                  | TRAL LAB SAMPLE COLLECTION                       |
| ELEC             | CTRONIC SAMPLE TRACKING - IMMUNOGENICITY         |
| VAC              | CINATION   |
| VAC              | CINATION DIARY                                   |
| V5_WEEK1_POS     | TVAX2_S  |
|                  | EOFVISIT   |
| PHY              | SICALEXAMINATION                                 |
| VITA             | AL SIGNS   |
| CEN              | TRAL LAB SAMPLE COLLECTION                       |
| ELEC             | CTRONIC SAMPLE TRACKING - IMMUNOGENICITY         |
| V6_WEEK2_POS     | TVAX2_S  |
| DAT              | E OF VISIT                                       |
| VAC              | CINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES |
| PHY              | SICALEXAMINATION                                 |
| VITA             | AL SIGNS   |
| ELEC             | TRONIC SAMPLE TRACKING - IMMUNOGENICITY          |
| VAC              | CINATION DIARY                                   |
| V7_MONTH1_S      |  |
|                  | E OF VISIT                                       |
| ELEC             | CTRONIC SAMPLE TRACKING - IMMUNOGENICITY         |
| V4_WEEK3_VAX     |  |
| DAT              | E OF VISIT                                       |
| VAC              | CINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES |
|                  | SICALEXAMINATION                                 |
|                  | AL SIGNS   |
|                  | URINALYSIS - PREGNANCY TEST                      |
|                  | CTRONIC SAMPLE TRACKING - NASAL SWAB             |
|                  | ROBIOLOGY SPECIMEN (SWAB SITE)                   |
|                  | TRAL LAB SAMPLE COLLECTION                       |
|                  | CTRONIC SAMPLE TRACKING - IMMUNOGENICITY         |
|                  | CINATION   |
|                  | CINATION DIARY                                   |
| V5_WEEK1_POS     |  |
|                  | E OF VISIT                                       |
|                  |  |
|                  | AL SIGNS   |
|                  | TRALLAB SAMPLE COLLECTION                        |
|                  | CTRONIC SAMPLE TRACKING - IMMUNOGENICITY         |
| V6_WEEK2_POS     | E OF VISIT                                       |
|                  | CINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES |
| -                | SICAL EXAMINATION                                |
|                  | ALSIGNS  |
|                  | TRONIC SAMPLE TRACKING - IMMUNOGENICITY          |
|                  | CINATION DIARY                                   |
| VAC<br>V7 MONTH1 |  |
|                  | -  |
| DAT              | EOFVISIT   |

**ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY** V8\_MONTH6\_S **DATE OF VISIT ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY** V9 MONTH12 S **DATE OF VISIT ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY** V10 MONTH24 S **DATE OF VISIT ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY** V1 DAY1 VAX1 NS **DATE OF VISIT** INCLUSION/EXCLUSION CRITERIA (INCEXCNS) INCLUSION/EXCLUSION CRITERIA (INC EXC NS) INCLUSION/EXCLUSION CRITERIA (INC EXC NS) **DISPOSITION - SCREENING GENERAL MEDICAL HISTORY PHYSICAL EXAMINATION VITAL SIGNS - BASELINE** LAB URINALYSIS - PREGNANCY TEST RANDOMIZATION **ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY ELECTRONIC SAMPLE TRACKING - NASAL SWAB** VACCINATION V2\_VAX2\_NS **DATE OF VISIT VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES VITAL SIGNS - TEMP** LAB URINALYSIS - PREGNANCY TEST **ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY ELECTRONIC SAMPLE TRACKING - NASAL SWAB** VACCINATION **V3 WEEK2 POSTVAX2 NS DATE OF VISIT VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY** V4 MONTH1 NS **DATE OF VISIT ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY** V5\_MONTH6\_NS **DATE OF VISIT ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY** V6\_MONTH12\_NS **DATE OF VISIT ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY** V7 MONTH24 NS **DATE OF VISIT ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY** 

V1\_DAY1\_VAX1\_L

**DATE OF VISIT** 

**INCLUSION/EXCLUSION CRITERIA (IN EX STG3) INCLUSION/EXCLUSION CRITERIA (IN EX STG3) INCLUSION/EXCLUSION CRITERIA (IN EX STG3)** INCLUSION/EXCLUSION CRITERIA (INCEXC) **DISPOSITION - SCREENING GENERAL MEDICAL HISTORY PHYSICAL EXAMINATION** LAB CHEMISTRY LABORATORY DATA - HEMATOLOGY **VITAL SIGNS - BASELINE VITAL SIGNS - BASELINE** LAB URINALYSIS - PREGNANCY TEST RANDOMIZATION **ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY ELECTRONIC SAMPLE TRACKING - NASAL SWAB** VACCINATION **VACCINATION DIARY** 

## V2\_VAX2\_L

DATE OF VISIT VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES VITAL SIGNS - TEMP LAB URINALYSIS - PREGNANCY TEST ELECTRONIC SAMPLE TRACKING - NASAL SWAB VACCINATION VACCINATION DIARY

#### V3\_MONTH1\_POSTVAX2\_L

DATE OF VISIT VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES LAB CHEMISTRY LABORATORY DATA - HEMATOLOGY ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY VACCINATION DIARY

## V4\_MONTH6\_L

DATE OF VISIT CONTACT OUTCOME LAB CHEMISTRY LABORATORY DATA - HEMATOLOGY ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY V5\_MONTH12\_L DATE OF VISIT ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY LAB CHEMISTRY LABORATORY DATA - HEMATOLOGY

### V6\_MONTH24\_L

DATE OF VISIT ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

|        | LAB CHEMISTRY   |
|--------|---|
|        | LABORATORY DATA - HEMATOLOGY                            |
| POT_CO | VID_ILL   |
|        | DATE OF VISIT - ILLNESS                                 |
|        | CONTACT OUTCOME - MONTH 1                               |
|        | SIGNS AND SYMPTOMS OF POTENTIAL COVID-19                |
|        | SIGNS AND SYMPTOMS OF POTENTIAL COVID-19                |
|        | MICROBIOLOGY SPECIMEN (COVID TEST)                      |
|        | ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF            |
|        | ELECTRONIC SAMPLE TRACKING - NASAL SWAB                 |
|        | HEALTH CARE UTILIZATION                                 |
|        | HOSPITALIZATION DETAILS                                 |
|        | RESPIRATORY TREATMENT                                   |
|        | RESPIRATORY TREATMENT                                   |
|        | ILLNESS DETAILS   |
|        | ILLNESS DETAILS - SEVERE                                |
|        | ILLNESS DETAILS - SEVERE                                |
|        | LOCAL LABORATORY DATA - REPEATING CHEMISTRY             |
|        | LOCAL LABORATORY DATA - REPEATING CHEMISTRY             |
|        | LOCAL LABORATORY DATA - REPEATING HEMATOLOGY            |
|        | VITAL SIGNS - COVID                                     |
|        | VITAL SIGNS - PULSE OX ROOM AIR                         |
|        | OXYGENATION PARAMETERS                                  |
|        | CONCOMITANT MEDICATIONS - VASOPRESSORS                  |
|        | IMAGING   |
|        | VACCINATION DIARY                                       |
| POT_CO | VID_CONVA   |
|        | DATE OF VISIT - ILLNESS CONVALESCENT                    |
|        | ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY             |
|        | VACCINATION DIARY                                       |
| POT_CO | VID_REPEAT_SWAB   |
|        | DATE OF VISIT - REPEAT SWAB                             |
|        | ELECTRONIC SAMPLE TRACKING - REPEAT SWAB                |
|        | VACCINATION DIARY                                       |
| LOGS   |   |
|        | ADVERSE EVENT REPORT                                    |
|        | MEDICATION ERROR  |
|        | CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS        |
|        | CONCOMITANT MEDICATIONS - PROHIBITED                    |
|        | RADIATION TREATMENT                                     |
|        | TRANSFUSIONS  |
| UNPL   |   |
|        | DATE OF VISIT   |
|        | CONTACT OUTCOME - UNPLANNED                             |
|        | VITAL SIGNS - TEMP                                      |
|        | UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT |
| UNPLAN | INED_VACCINATION  |
|        | DATEOFVISIT   |

```
VITAL SIGNS - TEMP
        LAB URINALYSIS - PREGNANCY TEST
        VACCINATION
        CONTACT OUTCOME - MONTH 1
        CONTACT OUTCOME - MONTH 6
V201 SURVEIL CONSENT
        DATE OF VISIT
        INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE
        ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
        ELECTRONIC SAMPLE TRACKING - NASAL SWAB
V202 SURVEIL SWAB
        DATE OF VISIT - ASYMPTOMATIC SURVEILLANCE
        ELECTRONIC SAMPLE TRACKING - REPEAT SWAB
DISP
        TREATMENT UNBLINDED
        WITHDRAWAL OF CONSENT
        DEATH DETAILS CODED
END_OF_TRT
        DISPOSITION – TREATMENT
REVAX_CONTACT
        DATE OF VISIT
V101_VAX3
        DATE OF VISIT
        INFORMED CONSENT - FURTHER VACCINATION
        INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION(REVAXIE)
        DISPOSITION - SCREENING FOR FURTHER VACCINATION
        LAB CHEMISTRY
        LABORATORY DATA - HEMATOLOGY
        LAB URINALYSIS - PREGNANCY TEST
        ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
        ELECTRONIC SAMPLE TRACKING - NASAL SWAB
        VACCINATION
V102_VAX4
        DATE OF VISIT
        LAB URINALYSIS - PREGNANCY TEST
        ELECTRONIC SAMPLE TRACKING - NASAL SWAB
        VACCINATION
V103_MONTH1
        DATE OF VISIT
        CONTACT OUTCOME
        LAB CHEMISTRY
        LABORATORY DATA - HEMATOLOGY
V104_MONTH6
        DATE OF VISIT
        CONTACT OUTCOME
        LAB CHEMISTRY
        LABORATORY DATA - HEMATOLOGY
V105_MONTH18
```

**CONTACT OUTCOME** LAB CHEMISTRY LABORATORY DATA - HEMATOLOGY FURTHER\_VACCINATION\_EOT **DISPOSITION - TREATMENT** FOLLOW\_UP **DISPOSITION - FOLLOW-UP Domains AE=ADVERSE EVENTS VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES ADVERSE EVENT REPORT MEDICATION ERROR CE=CLINICAL EVENTS VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 **ILLNESS DETAILS ILLNESS DETAILS - SEVERE ILLNESS DETAILS - SEVERE CM=CONCOMITANT MEDICATIONS CONCOMITANT MEDICATIONS - BASELINE CONCOMITANT MEDICATIONS - VASOPRESSORS CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS CONCOMITANT MEDICATIONS - PROHIBITED CO=COMMENTS ELECTRONIC SAMPLE TRACKING - PRIOR COVID-19 INFECTION MICROBIOLOGY SPECIMEN (COV19 SITE) ELECTRONIC SAMPLE TRACKING - NASAL SWAB MICROBIOLOGY SPECIMEN (SWAB SITE) ELECTRONICSAMPLE TRACKING - IMMUNOGENICITY MICROBIOLOGY SPECIMEN (COVID TEST) ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF ELECTRONIC SAMPLE TRACKING - REPEAT SWAB DD=DEATH DETAILS DEATH DETAILS CODED DI=DEVICE IDENTIFIERS** 

**DATE OF VISIT** 

# MICROBIOLOGY SPECIMEN (COV19 SITE) MICROBIOLOGY SPECIMEN (SWAB SITE)

# MICROBIOLOGY SPECIMEN (COVID TEST)

# DM=DEMOGRAPHICS

# DEMOGRAPHY

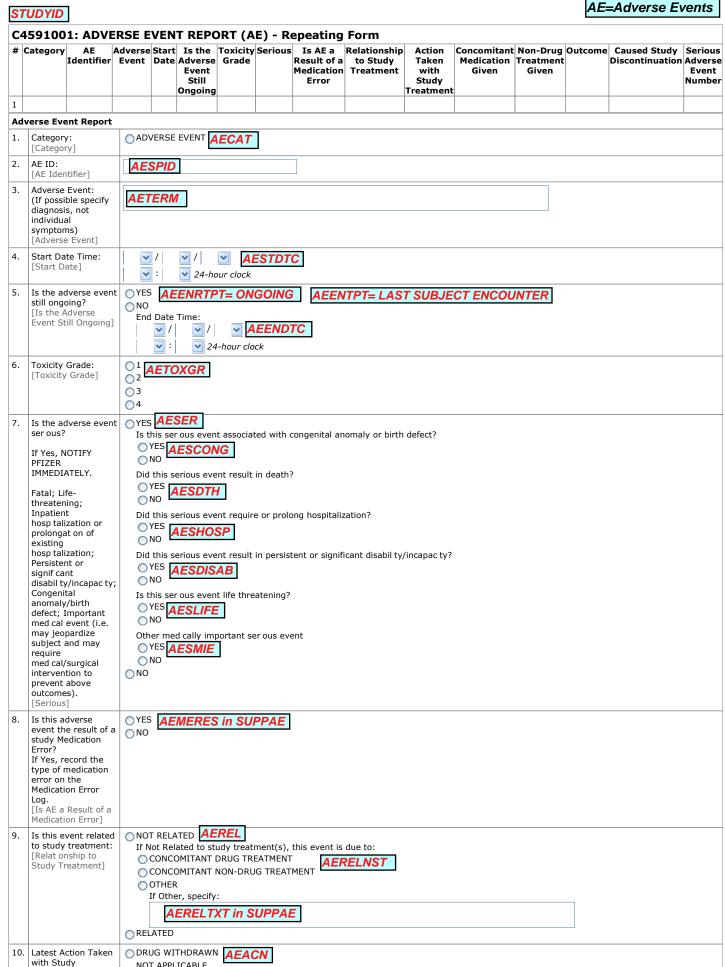
# REACTOGENICITY DIARY

# DS=DISPOSITION

MAIN INFORMED CONSENT DISPOSITION - SCREENING RANDOMIZATION

| TREATMENT UNBLINDED  |          |
|--|----------|
| WITHDRAWAL OF CONSENT  |          |
| DISPOSITION - TREATMENT                                      |          |
| DISPOSITION - FOLLOW-UP                                      |          |
| <b>INFORMED CONSENT - FURTHER VACCINATION</b>                |          |
| <b>DISPOSITION - SCREENING FOR FURTHER VACCINATION</b>       |          |
| INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE                 |          |
| EC=EXPOSURE AS COLLECTED                                     |          |
| VACCINATION  |          |
| VACCINATION  |          |
| EX=EXPOSURE  |          |
| VACCINATION  |          |
| VACCINATION  |          |
| FA=FINDINGS ABOUT EVENTS OR INTERVENTIONS                    |          |
| VACCINATION DIARY  |          |
| <b>VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DAT</b>     | ES       |
| SIGNS AND SYMPTOMS OF POTENTIAL COVID-19                     |          |
| SIGNS AND SYMPTOMS OF POTENTIAL COVID-19                     |          |
| HEALTH CARE UTILIZATION                                      |          |
| UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMICE           | /ENT     |
| HO=HEALTHCARE ENCOUNTERS                                     |          |
| HEALTH CARE UTILIZATION                                      |          |
| HOSPITALIZATION DETAILS                                      |          |
| IE=INCLUSION/EXCLUSION CRITERIA NOT MET                      |          |
| INCLUSION/EXCLUSION CRITERIA (INCEXCS)                       |          |
| INCLUSION/EXCLUSION CRITERIA (INC EXC S)                     |          |
| INCLUSION/EXCLUSION CRITERIA (INC EXC S)                     |          |
| INCLUSION/EXCLUSION CRITERIA (INC EXC NS)                    |          |
| INCLUSION/EXCLUSION CRITERIA (INC EXC NS)                    |          |
| INCLUSION/EXCLUSION CRITERIA (INC EXC NS)                    |          |
| INCLUSION/EXCLUSION CRITERIA (IN EX STG3)                    |          |
| INCLUSION/EXCLUSION CRITERIA (IN EX STG3)                    |          |
| INCLUSION/EXCLUSION CRITERIA (IN EX STG3)                    |          |
| INCLUSION/EXCLUSION CRITERIA (INC EXC)                       |          |
| INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION (R        | EVAX IE) |
| IS=IMMUNOGENICITY SPECIMEN ASSESSMENTS                       |          |
| <b>ELECTRONIC SAMPLE TRACKING - PRIOR COVID-19 INFECTION</b> |          |
| <b>ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY</b>           |          |
| LB=LABORATORY TEST RESULTS                                   |          |
| <b>CENTRAL LAB SAMPLE COLLECTION - BASELINE</b>              |          |
| LAB URINALYSIS - PREGNANCY TEST                              |          |
| CENTRAL LAB SAMPLE COLLECTION                                |          |
| LAB CHEMISTRY  |          |
| LABORATORY DATA - HEMATOLOGY                                 |          |
| LOCAL LABORATORY DATA - REPEATING CHEMISTRY                  |          |
| LOCAL LABORATORY DATA - REPEATING CHEMISTRY                  |          |
| LOCAL LABORATORY DATA - REPEATING HEMATOLOGY                 |          |
| OXYGENATION PARAMETERS                                       |          |

# **MB=MICROBIOLOGY SPECIMEN MICROBIOLOGY SPECIMEN (COV19 SITE) CENTRAL LAB SAMPLE COLLECTION - BASELINE ELECTRONIC SAMPLE TRACKING - NASAL SWAB MICROBIOLOGY SPECIMEN (SWAB SITE) CENTRAL LAB SAMPLE COLLECTION MICROBIOLOGY SPECIMEN (COVID TEST) ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF ELECTRONIC SAMPLE TRACKING - REPEAT SWAB MH=MEDICAL HISTORY GENERAL MEDICAL HISTORY MO=MORPHOLOGY** IMAGING **PE=PHYSICAL EXAMINATION PHYSICAL EXAMINATION PR=PROCEDURES RESPIRATORY TREATMENT RESPIRATORY TREATMENT RADIATION TREATMENT** TRANSFUSIONS SV=SUBJECT VISITS **DATE OF VISIT CONTACT OUTCOME DATE OF VISIT - ILLNESS ONSET CONTACT OUTCOME - MONTH 1 DATE OF VISIT - ILLNESS CONVALESCENT DATE OF VISIT - REPEAT SWAB CONTACT OUTCOME - UNPLANNED CONTACT OUTCOME - MONTH 6 DATE OF VISIT - ASYMPTOMATIC SURVEILLANCE VS=VITAL SIGNS VITAL SIGNS - BASELINE VITAL SIGNS VACCINATION DIARY VITAL SIGNS - BASELINE VITAL SIGNS - TEMP VITAL SIGNS - COVID VITAL SIGNS - PULSE OX ROOM AIR**



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NOT APPLICABLE

|     | <b>Treatment:</b><br>[Act on Taken with<br>Study Treatment]   | 0  |
|-----|---|--|
| 11. | Was a Concomitant<br>Medication given?<br>[Concom tant<br>Med cat on Given]   | O YES     AECONTRT       O NO     AECMGIV in SUPPAE  |
| 12. | Was a Non-Drug<br>Treatment given?<br>[Non-Drug<br>Treatment Given]   | O YES     AECONTRT     AENDGIV in SUPPAE   |
| 13. | What was the<br>outcome of this<br>adverse event?:<br>[Outcome]   | <ul> <li>FATAL</li> <li>NOT RECOVERED/NOT RESOLVED</li> <li>RECOVERED/RESOLVED</li> <li>RECOVERED/RESOLVED WITH SEQUELAE</li> <li>RECOVERING/RESOLVING</li> <li>UNKNOWN</li> </ul> |
| 14. | D d the adverse<br>event cause the<br>subject to be<br>discontinued from<br>the study?<br>[Caused Study<br>Discontinuat on] | O YES       AESUBJDC in SUPPAE       Linked to related DS record via RELREC         NO       NO  |
| 15. | Ser ous Adverse<br>Event Number: For<br>Pfizer Use Only<br>[Serious Adverse<br>Event Number]                                | AEREFID  |
| 16. | Comparison Term<br>[hidden]<br>[Comparison Term]  | NOT SUBMITTED  |
| 17. | Lowest Level Term<br>[hidden]<br>[Lowest Level Term]  | AELLT  |
| 18. | Lowest Level Term<br>Code [hidden]<br>[Lowest Level Term<br>Code]   | AELLTCD  |
| 19. | D ctionary-Derived<br>Term [hidden]<br>[D ctionary-Derived<br>Term]   | AEDECOD  |
| 20. | Preferred Term<br>Code [hidden]<br>[Preferred Term<br>Code]   | AEPTCD   |
| 21. | High Level Term<br><i>[hidden]</i><br>[High Level Term]   | AEHLT  |
| 22. | High Level Term<br>Code [hidden]<br>[High Level Term<br>Code]   | AEHLTCD  |
| 23. | High Level Group<br>Term [hidden]<br>[High Level Group<br>Term]   | AEHLGT   |
| 24. | High Level Group<br>Term Code [hidden]<br>[High Level Group<br>Term Code]   | AEHLGTCD   |
| 25. | Primary System<br>Organ Class<br>[hidden]<br>[Primary System<br>Organ Class]  | AEBODSYS AESOC   |
| 26. | Primary System<br>Organ Class Code<br>[hidden]<br>[Primary System<br>Organ Class Code]                                      | AEBDSYCD AESOCCD   |

AE=Adverse Events

LB=Laboratory Test Results

|--|

| La  | boratory Data Hematology                               |              |                                     |         |           |                  |  |  |  |
|-----|--|--------------|-------------------------------------|---------|-----------|------------------|--|--|--|
| 1.  | Lab Panel:<br>[Category for Lab Test]                  | OHEMATO      | OLOGY LBCAT                         |         |           |                  |  |  |  |
| 2.  | Laboratory Name and Address<br>[Vendor Name (DERIVED)] | LBNAI        | LBNAM                               |         |           |                  |  |  |  |
| 3.  | Collection Date:<br>[Collect on Date:]                 | /            |                                     |         |           |                  |  |  |  |
| 4.  | Specimen Type:<br>[Specimen Type]                      | OBLOOD       | LBSPEC                              |         |           |                  |  |  |  |
| Lal | o Result   |              |                                     |         |           |                  |  |  |  |
| #   | Sponsor-Defined Identifier                             |              | Test:                               | Result: | Not Done: | Lab Normal Range |  |  |  |
| 5.a |  |              | CD4_PX4722                          |         |           |                  |  |  |  |
| La  | b Result Entry   |              |                                     |         |           |                  |  |  |  |
| 5.1 | Sponsor ID:<br>[Sponsor-Defined Identifier]            |              | LBSPID                              |         |           |                  |  |  |  |
| 5.2 | Test:<br>[Test:]                                       | OCD4_I       | PX4722 LBTEST                       |         |           |                  |  |  |  |
| 5.3 | Result:<br>[Result:]                                   | LBO          | RRES                                |         |           |                  |  |  |  |
| 5.4 | Not Done: [hidden]<br>[Not Done:]                      |              | DONE LBSTAT                         |         |           |                  |  |  |  |
| 5.5 | LNMT<br>[Lab Normal Range]                             | High<br>Un t | BORNRLO<br>BORNRHI<br>/mm3 LBORRESU |         |           |                  |  |  |  |

| C  | 4591001: COHORT SEL  | ECTION (COHORT SEL) NOT SUBMITTED   |
|----|--|---|
| Co | ohort Selection  |   |
| DC | ONOT 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 -<br>Protocol version<br>[Trigger Response 1]                            |   |
| 2. | Select appropriate response -<br>What cohort does the subject<br>belong to?<br>[Trigger Response 10] | <ul> <li>STAGE 1 SENTINEL COHORTS</li> <li>STAGE 1 NONSENTINEL COHORTS</li> <li>STAGE 2 COHORTS</li> <li>STAGE 3 COHORTS</li> </ul> |

| ST  | UDYID   |   |   |                         | C                   | M=Con        | comitant N        | /ledica | ntions        |
|-----|---|---|---|-------------------------|---------------------|--------------|-------------------|---------|---------------|
| C4  | C4591001: CONCOMITANT MEDICATIONS - BASELINE (CONMED BSL) - Repeating Form  |   |   |                         |                     |              |                   |         |               |
| #   | Sponsor-Defined<br>Identifier   | Category for<br>Medication  | Concomitant Medications Pre-<br>specified | - Name of<br>Medication | Dose<br>Description | Dose<br>Unit | Dose<br>Frequency | Route   | Start<br>Date |
| 1   |   |   |   |                         |                     |              |                   |         |               |
| Cor | ncomitant Medications   |   |   |                         |                     |              |                   |         |               |
| 1.  | What is the medication<br>[Sponsor-Defined Identi   |   | CMSPID                                    |                         |                     |              |                   |         |               |
| 2.  | Category:<br>[Category for Medication   | n]  | GENERAL CONCOMITANT ME                    | DICATIONS CMC           | 4 <i>T</i>          |              |                   |         |               |
| 3.  | Concomitant Medication<br>[Concom tant Medication   |   | ONO NOT SUBMITTED                         |                         |                     |              |                   |         |               |
| 4.  | Med cation:   |   | CMTRT                                     |                         |                     |              |                   |         |               |
|     | Prov de the complete ge<br>(including salt form, who<br>generic name is unknow<br>proprietary name. Inclur<br>in the Med cat on text (e<br>route, use, formulation)<br>[Name of Medication] | ere applicable). Where<br>vn, enter the full trade o<br>de clarifying informatior<br>e.g., Ingredient(s), |   |                         |                     |              |                   |         |               |
| 5.  | Dose:<br>[Dose Description]   |   | CMDOSE CMDOSTX                            | Τ                       |                     |              |                   |         |               |
| 6.  | Dose Unit:<br>[Dose Unit]   |   |   |                         |                     |              |                   |         |               |
| 7.  | Dose Frequency:<br>[Dose Frequency]   |   |   |                         |                     |              |                   |         |               |
| 8.  | Route:<br>[Route]   |   |   |                         |                     |              |                   |         |               |
| 9.  | Start Date:<br>[Start Date]   |   |   | STDTC                   |                     |              |                   |         |               |
| 10. | Comparison Term [hidde<br>[Comparison Term]   | en]   | NOT SUBMITTED                             |                         |                     |              |                   |         |               |
| 11. | Standardized Med cat or<br>derived. [hidden]<br>[Standardized Med cat o   | ,   | CMDECOD                                   |                         |                     |              |                   |         |               |
| 12. | Standardized Med cat or derived [hidden]  |   | СМСС                                      | DDE in SUPPC            | M                   |              |                   |         |               |

CM=Concomitant Medications

| S  | TUDYID  |  |               |                                       | CM=Concomitant Me     | dications  |
|----|---|--|---------------|---------------------------------------|-----------------------|------------|
| C  | 4591001: CONCOMITANT  | MEDICATI                                     | ONS - NON S   | TUDY VACCINATIONS (CONMED             | VAX) - Repeating Form | n          |
| #  | Sponsor-Defined Identifier  | Category fo                                  | or Medication | Concomitant Medications Pre-specified | d Name of Medication  | Start Date |
| 1  |   |  |               |                                       |                       |            |
| Co | ncomitant Medications   |  |               |                                       |                       |            |
| 1. | What is the medication identifier?<br>[Sponsor-Defined Identifier]  |  | CMSPID        |                                       |                       |            |
| 2. | Category:<br>[Category for Med cat on]  | 0  |               | CMCAT                                 |                       |            |
| 3. | Concomitant Medications Pre-specific<br>[Concomitant Medications Pre-specific   |  | NO NOT SUB    | MITTED                                |                       |            |
| 4. | Medication:<br>Provide the complete gener c drug na<br>(including salt form, where applicabl<br>generic name is unknown, enter the<br>or proprietary name. Include clarifyin<br>information in the Med cat on text (e<br>Ingredient(s), route, use, formulation<br>[Name of Medication] | ame<br>e). Where<br>full trade<br>ng<br>.g., | CMTRT         |                                       |                       | ]          |
| 5. | Date:<br>[Start Date]   |  | ✓ /           | CMSTDTC                               |                       |            |
| 6. | Comparison Term [hidden]<br>[Comparison Term]   |  | NOT SUBMIT    | TED                                   |                       |            |
| 7. | Standardized Medicat on Name - Dict<br>derived. [hidden]<br>[Standardized Med cat on Name]  | t onary                                      | MDECOD        |                                       |                       |            |
| 8. | Standardized Med cat on Code - Dicti<br>derived [hidden]<br>[Standardized Med cat on Code]  | ionary                                       |               | CMCODE in SUPPCM                      |                       |            |



# C4591001: MAIN INFORMED CONSENT (CONSENT) DSCAT=PROTOCOL MILESTONE

| 1 | Informed Consent |                               |                                 |  |  |  |  |
|---|------------------|-------------------------------|---------------------------------|--|--|--|--|
|   | Consent Was:     | OBTAINED                      | DSSTDTC when                    |  |  |  |  |
|   | [Consent Was:]   | Date Written Consent Obtained | DSTERM/DSDECOD=INFORMED CONSENT |  |  |  |  |
|   |                  |                               | OBTAINED                        |  |  |  |  |

DS=Disposition

| C  | C4591001: CONTACT OUTCOME - MONTH 1 (CONTACT 1M)                       |  |  |  |  |  |
|----|--|--|--|--|--|--|
| Co | ontact Outcome   |  |  |  |  |  |
| 1. | Follow-Up Contact Category<br>[hidden]<br>[Follow Up Contact Category] | CONTACT OUTCOME NOT SUBMITTED  |  |  |  |  |
| 2. | Contact Type:<br>[Type of Contact/Visit]                               | OCLINIC VISIT  |  |  |  |  |
| 3. | Was contact made?<br>[Was Contact Made]                                | YES       NOT SUBMITTED         Date of Contact:       Image: SVSTDTC SVENDTC when UNPLANNED VISITS         NO       If No, why?         NOT SUBMITTED |  |  |  |  |
| 4. | Comments:<br>[Comments/Findings/Details]                               | NOT SUBMITTED  |  |  |  |  |

| C  | C4591001: CONTACT OUTCOME - MONTH 6 (CONTACT 6M)                       |   |  |  |  |
|----|--|---|--|--|--|
| Co | ontact Outcome   |   |  |  |  |
| 1. | Follow-Up Contact Category<br>[hidden]<br>[Follow Up Contact Category] | CONTACT OUTCOME NOT SUBMITTED   |  |  |  |
| 2. | Contact Type:<br>[Type of Contact/Visit]                               | CLINIC VISIT  |  |  |  |
| 3. | Was contact made?<br>[Was Contact Made]                                | YES       NOT SUBMITTED         Date of Contact:       SVSTDTC         SVSTDTC       SVENDTC when UNPLANNED VISITS         NO       If No, why?         NOT SUBMITTED |  |  |  |
| 4. | Comments:<br>[Comments/Findings/Details]                               | NOT SUBMITTED   |  |  |  |

| S  | TUDYID   | SV=Subject Visits   |  |  |  |  |
|----|--|---|--|--|--|--|
| С  | 4591001: CONTACT OU  | ITCOME (CONTACT SV)   |  |  |  |  |
| C  | ontact Outcome   |   |  |  |  |  |
| 1. | Follow-Up Contact Category<br>[hidden]<br>[Follow Up Contact Category] | CONTACT OUTCOME NOT SUBMITTED   |  |  |  |  |
| 2. | Contact Type:<br>[Type of Contact/Visit]                               | TELEPHONE VISIT SVREFID   |  |  |  |  |
| 3. | Was contact made?<br>[Was Contact Made]                                | YES       NOT SUBMITTED         Date of Contact:       SVSTDTC         NO       If No, why?         NOT SUBMITTED |  |  |  |  |
| 4. | Comments:<br>[Comments/Findings/Details]                               | NOT SUBMITTED   |  |  |  |  |

| C  | 4591001: CONTACT OU  | TCOME - UNPLANNED (CONTACT UV)   |  |  |  |  |
|----|--|--|--|--|--|--|
| Co | ontact Outcome   |  |  |  |  |  |
| 1. | Follow-Up Contact Category<br>[hidden]<br>[Follow Up Contact Category] | CONTACT OUTCOME NOT SUBMITTED  |  |  |  |  |
| 2. | Contact Type:<br>[Type of Contact/Visit]                               | O TELEPHONE VISIT SVREFID  |  |  |  |  |
| 3. | Was contact made?<br>[Was Contact Made]                                | YES       NOT SUBMITTED         Date of Contact:       SVSTDTC         SVSTDTC       SVENDTC when UNPLANNED VISITS         Contact Outcome:       VISIT ARRANGED         VISIT ARRANGED, BUT NOT ATTENDED       NOT SUBMITTED         VISIT NOT ARRANGED, REACTION NO LONGER PRESENT       VISIT NOT ARRANGED, UNABLE TO ATTEND         VISIT NOT ARRANGED, UNABLE TO ATTEND       VISIT NOT ARRANGED, UNABLE TO ATTEND         VISIT NOT REQUIRED, DATA ENTRY ERROR IN E-DIARY       VISIT NOT REQUIRED, INVESTIGATOR DECISION         NO       If No, why?         NOT SUBMITTED       NOT SUBMITTED |  |  |  |  |
| 4. | Comments:<br>[Comments/Findings/Details]                               | NOT SUBMITTED  |  |  |  |  |

| <b>S</b> 7 | TUDYID MB=Microbiology Specimen DI=Device Identifiers CO=Comments |   |  |                |           |           |  |
|------------|---|---|--|----------------|-----------|-----------|--|
| C          | 4591001: MICROBIOLC   | <b>OGY SPECIMEN (CO</b>   | V19 SITE) - Repeating Form MBC                           | CAT=CONFIRMATI | ON OF INF | ECTION    |  |
| #          | Date of Collection  | Specimen Type   | Assay Code and Description                               | Device Type    | Result    | Comments: |  |
| 1          |   |   |  |                |           |           |  |
| Mi         | crobiology Specimen   |   |  |                |           |           |  |
| 1.         | Actual Date of Collection:<br>[Date of Collection]                |   | MBDTC  |                |           |           |  |
| 2.         | Specimen Type:<br>[Specimen Type]                                 | SERUM<br>BLOOD<br>PLASMA  |  |                |           |           |  |
| 3.         | Assay Code and Description:<br>[Assay Code and Description]       | SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2 <b>MBTEST</b>                        |  |                |           |           |  |
| 4.         | Device Type:<br>[Device Type]                                     | SARS-COV-2 DIAGNOS  | SARS-COV-2 DIAGNOSTIC TEST DIVAL when DIPARMCD = DEVTYPE |                |           |           |  |
| 5.         | Test Result:<br>[Result]  | <pre> POSITIVE MBORRES when MBTESTCD = SARSCOV2 NEGATIVE INDETERMINATE </pre> |  |                |           |           |  |
| 6.         | Comments/Findings/Details:<br>[Comments:]                         | COVAL when RDO  | MAIN = MB  |                |           |           |  |

| S  | TUDYID  |                  | Л   | /IB=Microbiology Sp                                    | pecimen        | DI=Dev        | ice la | entifiers | CO=Comments                  |
|----|---|------------------|---|--|----------------|---------------|--------|-----------|------------------------------|
| С  | 4591001: MI   | CROBIOLO         | GY SPECIMEN (COVI   | D TEST) - Repeating                                    | Form M         | BCAT=CC       | ONFIR  | MATION O  | F INFECTION                  |
| #  | Date of<br>Collection   | Specimen<br>Type | Specimen Collection<br>Location                                       | Assay Code and<br>Description                          | Device<br>Type | Trade<br>Name |        | Comments: | Trade Name Other,<br>Specify |
| 1  |   |                  |   |  |                |               |        |           |                              |
| м  | icrobiology Speci   | men              |   |  |                |               |        |           |                              |
| 1. | Actual Date of Col<br>[Date of Collection   |                  |   | BDTC   |                |               |        |           |                              |
| 2. | Specimen Type:<br>[Specimen Type]   |                  | SWABBED MATERIAL  | S MBSPEC   |                |               |        |           |                              |
| 3. | 3. Specimen Collection Location:<br>[Specimen Collection Location] NASOPHARYNX<br>COUVER RESPIRATORY SYSTEM MBLOC<br>THROAT |                  |   |  |                |               |        |           |                              |
| 4. | Assay Code and D<br>[Assay Code and I   |                  | SEVERE ACUTE RESP SYN   | SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2 <b>MBTEST</b> |                |               |        |           |                              |
| 5. | Device Type:<br>[Device Type]   |                  | SARS-COV-2 DIAGNOSTIC   | TEST <b>DIVAL when DIP</b>                             | ARMCD =        | DEVTYP        | E      |           |                              |
| 6. | Trade Name:<br>[Trade Name]   |                  | DIVAL when D  | IPARMCD = TRADEN                                       | AM             |               |        |           |                              |
| 7. | Test Result:<br>[Result]  |                  | <ul> <li>POSITIVE</li> <li>NEGATIVE</li> <li>INDETERMINATE</li> </ul> |  |                |               |        |           |                              |
| 8. | Comments/Finding<br>[Comments:]   | gs/Details:      | COVAL when RDO  | OMAIN = MB   |                |               |        |           |                              |
| 9. | Trade Name Othe   |                  | SUPPMB in TRADE   | ОТН  |                |               |        |           |                              |

| Annc    | otated Study Book - C4591001  |  |             |                  |
|---------|---|--|-------------|------------------|
| รтเ     | IDYID   |  |             | DD=Death Details |
|         |   | LS CODED (DEATH DTL)                                 | TAILS CODED |                  |
|         | th Details  |  |             |                  |
| 0<br>[] | ate of Collect on / Notification<br>f Death:<br>Date of Collect on / Notif cat on<br>f Death] |  |             |                  |
|         | ,   | Cause of Death Status                                | Cause of D  | eath             |
| 2.      |   |  |             |                  |
|         | se of Death Entry   |  |             |                  |
| 2.1     | Cause of Death Status:<br>[Cause of Death Status]   | OPRIMARY CAUSE OF DEATH<br>OSECONDARY CAUSE OF DEATH |             |                  |
| 2.2     | Cause of Death:<br>[Cause of Death]   | DDORRES  |             |                  |
| 2.3     | Comparison Term [hidden]<br>[Comparison Term]   | NOT SUBMITTED  |             |                  |
| 2.4     | Lowest Level Term [hidden]<br>[Lowest Level Term]   | NOT SUBMITTED  |             |                  |
| 2.5     | Lowest Level Term Code<br>[hidden]<br>[Lowest Level Term Code]                                | NOT SUBMITTED  |             |                  |
| 2.6     | Dict onary-Derived Term<br>[hidden]<br>[Dictionary-Derived Term]                              | DDSTRESC   |             |                  |
| 2.7     | Preferred Term Code [hidden]<br>[Preferred Term Code]   | NOT SUBMITTED  |             |                  |
| .8      | High Level Term [hidden]<br>[High Level Term]   | NOT SUBMITTED  |             |                  |
| 2.9     | High Level Term Code<br>[hidden]<br>[High Level Term Code]                                    | NOT SUBMITTED  |             |                  |
| 2.10    | High Level Group Term<br>[hidden]<br>[High Level Group Term]                                  | NOT SUBMITTED  |             |                  |
| 2.11    | High Level Group Term Code<br>[hidden]<br>[High Level Group Term Code]                        | NOT SUBMITTED  |             |                  |
| 2.12    | Primary System Organ Class<br>[hidden]<br>[Primary System Organ Class]                        | NOT SUBMITTED  |             |                  |

2.13 Primary System Organ Class Code [hidden] [Primary System Organ Class Code]

**VOT SUBMITTED** 

## C4591001: DEMOGRAPHY (DEMOG)

| D  | lemography   |   |  |  |  |  |
|----|--|---|--|--|--|--|
| 1. | Subject ID<br>[Subject ID]                           | SUBJID  |  |  |  |  |
| 2. | Birth Date:<br>[Birth Date]                          |   |  |  |  |  |
| 3. | Sex:<br>[Sex]  | O FEMALE SEX  |  |  |  |  |
| 4. | Ethnicity:<br>[Ethnicity]                            | <ul> <li>HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN</li> <li>NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN</li> <li>NOT REPORTED</li> </ul>                          |  |  |  |  |
| 5. | Race: (Check X all that apply):<br>[Race Of Subject] | BLACK OR AFRICAN AMERICAN         AMERICAN INDIAN OR ALASKA NATIVE         ASIAN         NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER         WHITE         NOT REPORTED |  |  |  |  |
| 6. | Racial Designation:<br>[Racial Designat on]          | O JAPANESE<br>O OTHER RACIALD in SUPPDM   |  |  |  |  |

| S  | TUDYID   | nked to related AE record via RELREC DS=Disposition |
|----|--|---|
| C  | 4591001: DISPOSITION - FOLLOW-UP (DIS  | P FUP) DSCAT = DISPOSITION EVENT                    |
| Di | sposition - Follow-Up  |   |
| 1. | Date of Complet on/Discontinuation/Death :<br>[Date of Completion/Discontinuation/Death :] |   |
| 2. | Phase of Disposition:<br>[Disposition Phase]   | O FOLLOW-UP DSPHASE in SUPPDS                       |
| 3. | Status:<br>[Status]  |   |
| 4. | Specify Status:<br>[Specify Status]  | DSTERM  |

Linked to related AE record via RELREC

DS=Disposition

| C  | C4591001: DISPOSITION - SCREENING FOR FURTHER VACCINATION (DISP RESCR) DSCAT = DISPOSITION EVENT |  |  |  |  |  |
|----|--|--|--|--|--|--|
| Di | Disposition - Screening for Further Vaccination  |  |  |  |  |  |
| 1. | Date of Complet on/Discontinuation/Death :<br>[Date of Completion/Discontinuation/Death :]       |  |  |  |  |  |
| 2. | Phase of Disposition:<br>[Disposition Phase]   | © REPEAT SCREENING 1 DSPHASE in SUPPDS |  |  |  |  |
| 3. | Status:<br>[Status]  |  |  |  |  |  |
| 4. | Specify Status:<br>[Specify Status]  | DSTERM                                 |  |  |  |  |

| S  | TUDYID   | inked to related AE record via RELREC DS=Disposition |  |  |  |  |  |
|----|--|--|--|--|--|--|--|
| С  | 4591001: DISPOSITION - SCREENING (DISP SCR) DSCAT = DISPOSITION EVENT                  |  |  |  |  |  |  |
| D  | sposition - Screening  |  |  |  |  |  |  |
| 1. | Date of Complet on/Discontinuation/Death<br>[Date of Completion/Discontinuation/Death] |  |  |  |  |  |  |
| 2. | Phase of Disposition:<br>[Disposition Phase]   | OSCREENING DSPHASE in SUPPDS                         |  |  |  |  |  |
| 3. | Status:<br>[Status]  |  |  |  |  |  |  |
| 4. | Specify Status:<br>[Specify Status]  | DSTERM   |  |  |  |  |  |

| S  | TUDYID   | Linked to related AE record via RELREC                 | DS=Disposition |
|----|--|--|----------------|
| С  | 4591001: DISPOSITION - TREATMENT   | (DISP TRT) DSCAT = DISPOSITION EVENT                   |                |
| Di | sposition - Treatment  |  |                |
| 1. | Date of Complet on/Discontinuation/Death :<br>[Date of Completion/Discontinuation/Death :] |  |                |
| 2. | Phase of Disposition:<br>[Disposition Phase]   | OVACCINATION DSPHASE in SUPPDS<br>OPEN LABEL TREATMENT |                |
| 3. | Status:<br>[Status]  |  |                |
| 4. | Specify Status:<br>[Specify Status]  | DSTERM   |                |

| S  | TUDYID                           |   | SV=Subject Visits |
|----|----------------------------------|---|-------------------|
| С  | C4591001: DATE OF VISIT (DOV)    |   |                   |
| D  | Date of Visit                    |   |                   |
| 1. | Date of Visit<br>[Date of Visit] | ✓ / SVSTDTC SVENDTC when UNPLANNED VISITS |                   |
| 2. | Erroneous Visit<br>[Visit Error] | ○ ERRONEOUS VISIT NOT SUBMITTED           |                   |

# C4591001: DATE OF VISIT - ILLNESS CONVALESCENT (DOV CONV) Date of Visit 1. Date of Visit [Date of Visit] Image: Conversion of Visit 2. Erroneous Visit [Visit Error] COVID-19 Illness Visit: [COVID-19 Illness Visit: [COVID-19 Illness Visit]

| STUDYID SV=Subject Visits                         |             |  |  |  |
|---|-------------|--|--|--|
| C4591001: DATE OF VISIT - ILLNESS ONSET (DOV ILL) |             |  |  |  |
| Date of Visit                                     |             |  |  |  |
| 1. Date of Visit                                  | V/V/SVSTDTC |  |  |  |

| 2. | [Visit Error]                                       | OFKOMEOUS VISIT NOT SUBMITTED |
|----|---|-------------------------------|
| С  | VID-19 Illness Visit                                |                               |
|    | COVID-19 Illness Visit:<br>[COVID-19 Illness Vis t] | VISIT                         |

| <b>S</b> 1 | SV=Subject Visits  |   |  |
|------------|--|---|--|
| C          | C4591001: DATE OF VISIT - ASYMPTOMATIC SURVEILLANCE (DOV SURV) |   |  |
| Da         | Date of Visit  |   |  |
| 1.         | Date of Visit<br>[Date of Visit]                               | ✓ / ✓ / SVSTDTC SVENDTC when UNPLANNED VISITS |  |
| 2.         | Erroneous Visit<br>[Visit Error]                               | © ERRONEOUS VISIT NOT SUBMITTED               |  |
| С          | COVID-19 Surveillance Visit                                    |   |  |
| 3.         | COVID-19 Surveillance Vist:<br>[COVID-19 Surveillance Visit]   | NOT SUBMITTED                                 |  |

| S  | TUDYID   |                                 | SV=Subject Visits |
|----|--|---------------------------------|-------------------|
| С  | C4591001: DATE OF VISIT - REPEAT SWAB (DOV SWAB) |                                 |                   |
| Da | Date of Visit                                    |                                 |                   |
| 1. | Date of Visit<br>[Date of Visit]                 |                                 |                   |
| 2. | Erroneous Visit<br>[Visit Error]                 | © ERRONEOUS VISIT NOT SUBMITTED |                   |
| С  | COVID-19 Repeat Swab                             |                                 |                   |
| 3. | COVID-19 Repeat Swab:<br>[COVID-19 Repeat Swab]  |                                 |                   |

| С  | C4591001: INFORM ENROLLMENT (ENROLL) NOT SUBMITTED |  |  |
|----|--|--|--|
| Ir | InForm Enrollment                                  |  |  |
| 1. | Subject ID<br>[Subject ID]                         |  |  |

| C  | C4591001: HIV STATUS (HIV) NOT SUBMITTED   |   |  |
|----|--|---|--|
| HI | HIV Status   |   |  |
|    | Select appropriate response -<br>What is the subject HIV status?<br>[Trigger Response 2] | The subject is known to be HIV POSITIVE The subject is NOT known to be HIV POSITIVE |  |

| LB=Laborator | y Test Results |
|--------------|----------------|
|--------------|----------------|

| C2  | C4591001: LAB CHEMISTRY (HIV RNA)            |  |         |           |           |       |  |
|-----|--|--|---------|-----------|-----------|-------|--|
| La  | Lab Chemistry Details                        |  |         |           |           |       |  |
| 1.  | Lab Panel:<br>[Category for Lab Test]        | CLINICAL CHEMISTRY   |         |           |           |       |  |
| 2.  | Laboratory Name and Address<br>[Vendor Name] | LBNAM  |         |           |           |       |  |
| 3.  | Collection Date:<br>[Collect on Date:]       |  |         |           |           |       |  |
| 4.  | Specimen Type:<br>[Specimen Type]            | BLOOD <b>LBSPEC</b>  |         |           |           |       |  |
| La  | b Result                                     |  |         |           |           |       |  |
| #   | Sponsor-Defined Identifier                   | Test:  | Result: | Not Done: | Lab Norma | Range |  |
| 5.a | a  | HIV RNA (Ultrasensitive)                                     |         |           |           |       |  |
| La  | b Result Entry                               |  |         |           |           |       |  |
| 5.1 | Sponsor ID:<br>[Sponsor-Defined Identifier]  | LBSPID   |         |           |           |       |  |
| 5.2 | 2 Test:<br>[Test:]                           | ○ HIV RNA (Ultrasens tive) LBTEST                            |         |           |           |       |  |
| 5.3 | B Result:<br>[Result:]                       | LBORRES  |         |           |           |       |  |
| 5.4 | Not Done: [hidden]<br>[Not Done:]            | ONOT DONE  |         |           |           |       |  |
| 5.5 | 5 [LAMT<br>[Lab Normal Range]                | Low<br>LBORNRLO<br>High<br>LBORNRHI<br>Un t<br>_/mL LBORRESU |         |           |           |       |  |

Annotated Study Book - C4591001

|        |  | HO-Healthcare Encour   | itors    | EA-Eindii        | ngs About Events or Interventions |
|--------|--|--|----------|------------------|-----------------------------------|
|        | UDYID  |  |          |                  |                                   |
|        |  | ARE UTILIZATION (HLTHCARE)HOCAT=HE   | ALTHO    | CARE<br>SESSMENT | FACAT=HEALTHCARE<br>UTILIZATION   |
| Hea    | alth Care Utilization  |  |          |                  |                                   |
|        | Evaluation Interval: [hidden]<br>[Evaluation Interval]   | Ŭ  |          | IOEVINTX         | FAEVINTX                          |
|        | Disease Name: <i>[hidden]</i><br>[Disease Name]  | © RESPIRATORY ILLNESS HCUIDIS in SUPPHO  |          |                  |                                   |
| Hea    | alth Care Utilization  |  |          |                  |                                   |
| #<br>✔ | Pre-Specified  | Type of Practitioner   |          | 0                | ccurrence of Visits or Contacts   |
| 3.a    | YES  | SPECIALIST   |          |                  |                                   |
| 3.b    | YES  | EMERGENCY ROOM   |          |                  |                                   |
| 3.c    | YES  | PRIMARY CARE PHYSICIAN   |          |                  |                                   |
| 3.d    | YES  | URGENT CARE  |          |                  |                                   |
| 3.e    | YES  | TELEPHONE CONSULTATION   |          |                  |                                   |
| 3.f    | YES  | OTHER  |          |                  |                                   |
| Hea    | alth Care Utilization Entry  |  |          |                  |                                   |
| 3.1    | Pre-Specified: [hidden]<br>[Pre-Specified]   | O YES HOPRESP  |          |                  |                                   |
| 3.2    | Physician or Healthcare<br>Professional:<br>[Type of Practitioner]   | <ul> <li>SPECIALIST</li> <li>EMERGENCY ROOM</li> <li>PRIMARY CARE PHYSICIAN</li> <li>URGENT CARE</li> <li>TELEPHONE CONSULTATION</li> <li>OTHER</li> </ul> |          |                  |                                   |
| 3.3    | 3.3 Occurrence of Visits or<br>Contacts:<br>[Occurrence of Vis ts or<br>Contacts] VESHOOCCUR<br>Number of Vis ts or Contacts:<br>[FAORRES when FATESTCD=NUMBER<br>NO |  |          |                  |                                   |
| Hea    | alth Care Utilization Other  |  |          |                  |                                   |
| ;      | <b>Other Type of Pract tioner</b><br><b>Specify:</b><br>[Other Type of Pract t oner<br>Specify]  | HOTERM   |          |                  |                                   |
| Hea    | alth Care Utilization  | · · · · · · · · · · · · · · · · · · ·  |          |                  |                                   |
|        | Has the subject been<br>hospitalized due to potential<br>COVID-19 illness?<br>[Been Hospitalized]  | VES HCUHSP in SUPPHO<br>Has the subject been in intensive care due to potent<br>VES HCUICU in SUPPHO<br>NO   | al COVID | )-19 illness?    |                                   |

### HO=Healthcare Encounters

| C  | C4591001: HOSPITALIZATION DETAILS (HOSP) - Repeating Form |  |                  |              |                      |         |  |
|----|---|--|------------------|--------------|----------------------|---------|--|
| #  | Hospitalization Category                                  |  | Hospitali        | zation Term  | Admission Date       | Ongoing |  |
| 1  |   |  |                  |              |                      |         |  |
| H  | ospitalization Details                                    |  |                  |              |                      |         |  |
| 1. | Hosp talization Category:<br>[Hospitalization Category]   |  | STATUS HOCAT     |              |                      |         |  |
| 2. | Hosp talization Term:<br>[Hospitalization Term]           | OICU HOTEI<br>HOSPITAL   | RM               |              |                      |         |  |
| 3. | Admission Date:<br>[Admission Date]                       | ▼ / ▼ /  |                  |              |                      |         |  |
| 4. | Ongoing?<br>[Ongoing]                                     | YES     HOENRTF     NO     Discharge Date:     V     √     V     V | PT= ONGOING   HO | DENTPT= ONGO | ING AT CURRENT VISIT |         |  |

| ST  | UDYID   | CE=Clinical Event  |
|-----|---|--|
| C4  | 591001: ILLNESS DET   | AILS (ILL POTEN) CECAT = EFFICACY  |
|     | ess Details   |  |
| 1.  | Category of Clinical Event:<br>[Category of Clin cal Event:]                        | OPOTENTIAL COVID-19 ILLNESS NOT SUBMITTED  |
| 2.  | Was a diagnosis obtained for<br>Potential COVID-19 Illness?<br>[Diagnosis Obtained] | YES<br>Respiratory Illness Diagnosis:     CETERM     Date of Diagnosis:                        |
| 3.  | Toxicity Grade:<br>[Toxicity Grade]   | O         CETOXGR           01         CETOXGR           02         03           04         05 |
| 4.  | Comparison Term: [hidden]<br>[Comparison Term]                                      | NOT SUBMITTED  |
| 5.  | Lowest Level Term [hidden]<br>[Lowest Level Term]                                   | CELLT  |
| 6.  | Lowest Level Term Code<br>[hidden]<br>[Lowest Level Term Code]                      | CELLTCD  |
| 7.  | D ctionary Derived Term<br>[hidden]<br>[D ctionary Derived Term]                    | CEDECOD  |
| 8.  | Preferred Term Code [hidden]<br>[Preferred Term Code]                               | CEPTCD   |
| 9.  | High Level Term [hidden]<br>[High Level Term]                                       | CEHLT  |
| 10. | High Level Term Code [hidden]<br>[High Level Term Code]                             | CEHLTCD  |
| 11. | High Level Group Term<br>[hidden]<br>[High Level Group Term]                        | CEHLGT   |
| 12. | High Level Group Term Code<br>[hidden]<br>[High Level Group Term Code]              | CEHLGTCD   |
| 13. | Primary System Organ Class<br>[hidden]<br>[Primary System Organ Class]              | CEBODSYS CESOC   |
| 14. | Primary System Organ Class<br>Code [hidden]<br>[Primary System Organ Class<br>Code] | CEBDSYCD CESOCCD   |

| C4   | C4591001: ILLNESS DETAILS - SEVERE (ILL SEVERE)                            |  |  |  |  |  |
|------|--|--|--|--|--|--|
| Illn | Iness Details  |  |  |  |  |  |
| 1.   | Category of Clinical Event:<br>[Category of Clin cal Event:]               | SEVERE COVID-19 ILLNESS CECAT  |  |  |  |  |
| 2.   | Subcategory of Clin cal Event:<br>[Subcategory of Clin cal Event]          | <ul> <li>SIGNIFICANT ACUTE RENAL DYSFUNCTION</li> <li>SIGNIFICANT ACUTE HEPATIC DYSFUNCTION</li> <li>SIGNIFICANT ACUTE NEUROLOGIC DYSFUNCTION</li> </ul>   |  |  |  |  |
| 3.   | Was a diagnosis obtained?<br>[Diagnosis Obtained]                          | YES         Diagnosis:         CETERM         Start Date:         Y I         YES         CEENRTPT= ONGOING/BEFORE         End Date:         Y I         Y I         Image:         YES         CEENRTPT= ONGOING/BEFORE         End Date:         Y I         Y I         Image:         Y I         Y I         Y I         Image:         Y I |  |  |  |  |
| 4.   | Toxicity Grade:<br>[Toxicity Grade]  | 01<br>2<br>3<br>CETOXGR<br>4<br>5  |  |  |  |  |
| 5.   | Comparison Term: [hidden]<br>[Comparison Term]                             | NOT SUBMITTED  |  |  |  |  |
| 6.   | Lowest Level Term [hidden]<br>[Lowest Level Term]                          | CELLT  |  |  |  |  |
| 7.   | Lowest Level Term Code<br>[hidden]<br>[Lowest Level Term Code]             | CELLTCD  |  |  |  |  |
| 8.   | D ctionary Derived Term<br>[hidden]<br>[D ctionary Derived Term]           | CEDECOD  |  |  |  |  |
| 9.   | Preferred Term Code [hidden]<br>[Preferred Term Code]                      | CEPTCD   |  |  |  |  |
| 10.  | High Level Term [hidden]<br>[High Level Term]                              | CEHLT  |  |  |  |  |
| 11.  | High Level Term Code [hidden]<br>[High Level Term Code]                    | CEHLTCD  |  |  |  |  |
| 12.  | High Level Group Term<br>[hidden]<br>[High Level Group Term]               | CEHLGT   |  |  |  |  |
| 13.  | High Level Group Term Code<br>[hidden]<br>[High Level Group Term Code]     | CEHLGTCD   |  |  |  |  |
| 14.  | Primary System Organ Class<br>[hidden]<br>[Primary System Organ Class]     | CEBODSYS CESOC   |  |  |  |  |
| 15.  | Primary System Organ Class<br>Code [hidden]<br>[Primary System Organ Class | CEBDSYCD CESOCCD   |  |  |  |  |

CE=Clinical Events

| ST   | UDYID   |  |   |               |             | CE=Clinical Ev |
|------|---|--|---|---------------|-------------|----------------|
| C4   | 591001: ILLNESS DET   | AILS - SEVI  | ERE (ILL SEVERE) - Repeating  | J Form        |             |                |
| #    | Category of Clinical E  | vent:  | Subcategory of Clinical Event   | Diagnos       | is Obtained | Toxicity Gra   |
| 1    |   |  |   |               |             |                |
| Illn | less Details  |  |   |               |             |                |
| 1.   | Category of Clinical Event:<br>[Category of Clin cal Event:]      | OSEVERE COV  | /ID-19 ILLNESS CECAT  |               |             |                |
| 2.   | Subcategory of Clin cal Event:<br>[Subcategory of Clin cal Event] | SIGNIFICAN   | T ACUTE RENAL DYSFUNCTION<br>T ACUTE HEPATIC DYSFUNCTION CESC<br>T ACUTE NEUROLOGIC DYSFUNCTION | 47            |             |                |
| 3.   | Was a diagnosis obtained?<br>[Diagnosis Obtained]                 | ○ YES<br>Diagnosis:<br>CETER<br>Start Date:<br>○ YES<br>○ NO<br>End Date |   | CEENTPT= LAST | SUBJECT E   | NCOUNTER       |

✓ /

ONO

✓ /

T SUBMITTED

| 4.  | Toxicity Grade:<br>[Toxicity Grade]   | 01<br>02<br>03<br>04<br>05 |
|-----|---|----------------------------|
| 5.  | Comparison Term: [hidden]<br>[Comparison Term]                                      | NOT SUBMITTED              |
| 6.  | Lowest Level Term [hidden]<br>[Lowest Level Term]                                   | CELLT                      |
| 7.  | Lowest Level Term Code<br>[hidden]<br>[Lowest Level Term Code]                      | CELLTCD                    |
| 8.  | D ctionary Derived Term<br>[hidden]<br>[D ctionary Derived Term]                    | CEDECOD                    |
| 9.  | Preferred Term Code [hidden]<br>[Preferred Term Code]                               | CEPTCD                     |
| 10. | High Level Term [hidden]<br>[High Level Term]                                       | CEHLT                      |
| 11. | High Level Term Code [hidden]<br>[High Level Term Code]                             | CEHLTCD                    |
| 12. | High Level Group Term<br>[hidden]<br>[High Level Group Term]                        | CEHLGT                     |
| 13. | High Level Group Term Code<br>[hidden]<br>[High Level Group Term Code]              | CEHLGTCD                   |
| 14. | Primary System Organ Class<br>[hidden]<br>[Primary System Organ Class]              | CEBODSYS CESOC             |
| 15. | Primary System Organ Class<br>Code [hidden]<br>[Primary System Organ Class<br>Code] | CEBDSYCD CESOCCD           |
|     |   |                            |

## MO=Morphology

| C  | C4591001: IMAGING (IMAGING) - Repeating Form MOCAT=CLINICAL ASSESSMENT OF RADIOGRAPHS - IMAGING |   |                |                    |  |  |  |
|----|---|---|----------------|--------------------|--|--|--|
| #  | Date of Assessment  | Location of Assessment  | Imaging Method | Overall Assessment |  |  |  |
| 1  |   |   |                |                    |  |  |  |
| In | naging  |   |                |                    |  |  |  |
| 1. | Date of Assessment:<br>[Date of Assessment]   |   |                |                    |  |  |  |
| 2. | [Location of Assessment]  | CHEST<br>HEAD<br>OTHER<br>If other, specify: LOCOTH in SUPPMO   |                |                    |  |  |  |
|    | [Îmaging Method]  | CT SCAN<br>X-RAY<br>ULTRASOUND<br>MRI<br>OTHER<br>If other, specify: <b>METHOTH in SUPPMO</b>   |                |                    |  |  |  |
| 4. | [Overall Assessment]  | ABNORMAL MOORRES<br>If abnormal, specify findings:<br>ASPECIFY IN SUPPMO<br>INDETERMINATE<br>NORMAL MOORRES<br>UNKNOWN<br>NOT EVALUABLE |                |                    |  |  |  |

### IE=Inclusion/Exclusion Criteria Not Met

| C4591001: INCLUSION/EXCLUSION | CRITERIA (IN EX STG3) |
|-------------------------------|-----------------------|
|-------------------------------|-----------------------|

| Inc  | inclusion Criteria                      |  |  |  |  |  |  |
|--|---|--|--|--|--|--|--|
| #  | Inclusion Number                        | Criterion Description  | Criterion met? Criterion ID: (For Pfizer use only) |  |  |  |  |
| 1.a  | 1                                       | Male or female part cipants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage) | IN01A00  |  |  |  |  |
| 1.b  | 2                                       | Participants who are willing and able to comply with all scheduled visits, vaccination plan, aboratory tests, lifestyle considerations, and other study procedures                   |  |  |  |  |  |
| 1.c  | 3                                       | Healthy participants who are determined by medical history, physical examination, and<br>clinical judgment of the investigator to be eligible for inclusion in the study             |  |  |  |  |  |
| 1.d  | 4                                       | Capable of giving personal signed informed consent, which includes compliance with the<br>requirements and restr ctions listed in the ICD and in this protocol                       | IN04A00  |  |  |  |  |
| Inclusion Criteria Entry IECAT = INCLUSION |   |  |  |  |  |  |  |
| 1.1  | Inclusion Number:<br>[Inclusion Number] |  |  |  |  |  |  |

|     |  | 04   |
|-----|--|--|
| 1.2 | Cr terion Description:<br>[Criter on Descript on]                                  | ✓ IETEST   |
| 1.3 | Cr terion met?<br>[Criter on met?]   | VES IEORRES<br>NO<br>Describe details if relevant<br>IEDESC in SUPPIE          |
| 1.4 | Cr terion ID: (For Pfizer use<br>only)<br>[Criter on ID: (For Pfizer use<br>only)] | <ul> <li>IN01A00</li> <li>IN02A00</li> <li>IN03A00</li> <li>IN04A00</li> </ul> |

| #   | Exclusion Number                                | Criterion Description  | Criterion met? Criterion ID: (For Pfizer use only |
|-----|---|--|---|
| 2.a | 1   | Other medical or psychiatric condition incl. recent (within past year) or active suicidal deation/behavior/lab abnormal ty that may increase the risk of study participation                             | EX01A00   |
| 2.b | 2   | Known infection w th human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)   | EX02A00   |
| 2.c | 3   | History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)   | EX03A00   |
| 2.d | 4   | Receipt of medicat ons intended to prevent COVID-19  | EX04A00   |
| 2.e | 8   | Immunocompromised indiv duals with known or suspected immunodeficiency, as determined by history and/or laboratory/phys cal examination  | EX08A00   |
| 2.f | 9   | Individuals with a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention  | EX09A00   |
| 2.g | 10  | Bleeding diathesis or condition associated wth prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular inject on   | EX10A00   |
| 2.h | 11  | Women who are pregnant or breastfeeding  | EX11A00   |
| 2.i | 12  | Previous vaccinat on with any coronavirus vaccine  | EX12A00   |
| 2.j | 13  | Individuals who receive immunosuppressive therapy, such as cytotoxic agents or<br>systemic corticosteroids. Inhaled/nebulized, Intra-art cular, intrabursal, or topical<br>cort costeroids are permitted | EX13A00   |
| 2.k | 14  | Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administrat on or planned receipt throughout the study  | EX14A00   |
| 2.1 | 15  | Participation in other studies involving study intervention w thin 28 days pr or to study entry and/or during study participation  | EX15A00   |
| 2.m | 16  | Previous part cipation in other studies involving study intervent on containing lip d nanopart cles  | EX16A00   |
| 2.n | 21  | Investigator s te staff or Pfizer employees directly involved in the conduct of the study,<br>site staff otherwise supervised by the investigator, and their respective family members                   | EX21A00   |
| Exc | lusion Criteria Entry                           | IECAT = EXCLUSION  |   |
|     | Exclusion Number:<br>[Exclusion Number]         |  |   |
| 2.2 | Cr terion Description<br>[Criter on Descript or |  |   |
| 2.3 | Cr terion met?<br>[Criter on met?]              | VES  |   |

|  | IE=Inclusion/Exclusion Criteria Not Met |
|--|---|
|  | © NO                                    |
| 2.4 Cr terion ID: (For Pfizer use<br>only)<br>[Criter on ID: (For Pfizer use<br>only)] | ✓ IETESTCD                              |

Π.

### IE=Inclusion/Exclusion Criteria Not Met

| C4591001: INCLUSION | <b>/EXCLUSION CRITERIA</b> | (IN EX STG3) |  |
|---------------------|----------------------------|--------------|--|
|                     |                            | (=           |  |

| Inc  | Inclusion Criteria   |  |  |  |  |
|--|----------------------|--|--|--|--|
| #  | Inclusion Number     | Criterion Description  | Criterion met? Criterion ID: (For Pfizer use only) |  |  |
| 1.a  | 1                    | Male or female part cipants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage) | IN01A00  |  |  |
| 1.b  | 2                    | Participants who are willing and able to comply w th all scheduled vis ts, vaccination plan, laboratory tests, lifestyle cons derat ons, and other study procedures                  | IN02A00  |  |  |
| 1.c     3     Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study     INO. |                      | IN03A00  |  |  |  |
| 1.d     4     Capable of giving personal signed informed consent, which includes compliance with the requirements and restr ctions listed in the ICD and in this protocol     IN04A00        |                      | IN04A00  |  |  |  |
| Inc  | lusion Criteria Entr | y IECAT = INCLUSION  | · · · · · · · · · · · · · · · · · · ·              |  |  |

| 1.1 | Inclusion Number:<br>[Inclusion Number]  | 01<br>22<br>3<br>4  |
|-----|--|---|
| 1.2 | Cr terion Description:<br>[Criter on Descript on]                                  | I I I I I I I I I I I I I I I I I I I                                 |
| 1.3 | Cr terion met?<br>[Criter on met?]   | VES IEORRES<br>NO<br>Describe details if relevant<br>IEDESC in SUPPIE |
| 1.4 | Cr terion ID: (For Pfizer use<br>only)<br>[Criter on ID: (For Pfizer use<br>only)] | IN01A00           IN02A00           IN03A00           IN04A00         |

| Excl | usion Criteria                                  |  |                       |                                      |
|------|---|--|-----------------------|--------------------------------------|
| #    | Exclusion Number                                | Criterion Description  | <b>Criterion met?</b> | ? Criterion ID: (For Pfizer use only |
| 2.a  | 1   | Other medical or psychiatric condition incl. recent (within past year) or active suicidal deation/behavior/lab abnormal ty that may increase the risk of study participation           |                       | EX01A00                              |
| 2.b  | 2   | Known infection w th human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)   |                       | EX02A00                              |
| 2.c  | 3   | History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)                           |                       | EX03A00                              |
| 2.d  | 4   | Receipt of medicat ons intended to prevent COVID-19  |                       | EX04A00                              |
| 2.e  | 8   | Immunocompromised indiv duals w th known or suspected immunodeficiency, as determined by history and/or laboratory/phys cal examination  |                       | EX08A00                              |
| 2.f  | 10  | Bleeding diathesis or condition associated w th prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular inject on                              |                       | EX10A00                              |
| 2.g  | 11  | Women who are pregnant or breastfeeding  |                       | EX11A00                              |
| 2.h  | 12  | Previous vaccinat on with any coronavirus vaccine  |                       | EX12A00                              |
| 2.i  | 13  | Subjects who receive immunosuppressive therapy, such as cytotox c agents or systemic cort costeroids   |                       | EX13A01                              |
| 2.j  | 15  | Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administrat on or planned receipt throughout the study                                      |                       | EX14A01                              |
| 2.k  | 16  | Participation in other studies involving study intervention w thin 28 days pr or to study entry and/or during study participation  |                       | EX15A01                              |
| 2.1  | 17  | Previous part cipation in other studies involving study intervent on containing lip d nanopart cles  |                       | EX16A01                              |
| 2.m  | 22  | Investigator s te staff or Pfizer employees directly involved in the conduct of the study,<br>site staff otherwise supervised by the investigator, and their respective family members |                       | EX21A01                              |
| Exc  | usion Criteria Entr                             | , IECAT = EXCLUSION  |                       | -<br>-                               |
| 2.1  | Exclusion Number:<br>[Exclusion Number]         |  |                       |                                      |
| 2.2  | Cr terion Description<br>[Criter on Descript or |  |                       |                                      |
| 2.3  | Cr terion met?<br>[Criter on met?]              | VES IEORRES<br>Describe details if relevant<br>IEDESC in SUPPIE  |                       |                                      |
| 2.4  | Cr terion ID: (For Pfi                          | zer use IETESTCD   |                       |                                      |

only) [Criter on ID: (For Pfizer use only)] IE=Inclusion/Exclusion Criteria Not Met

#### IE=Inclusion/Exclusion Criteria Not Met

| C4591001 · TNCI USTON | /EXCLUSION CRITERIA  | (IN FX STG3) |
|-----------------------|----------------------|--------------|
| CHURCHONT: THEFORE    | / LACEOSION CRITERIA |              |

| Inc | Inclusion Criteria                         |  |  |  |  |
|-----|--|--|--|--|--|
| #   | Inclusion Number                           | Criterion Description  | Criterion met? Criterion ID: (For Pfizer use only) |  |  |
| 1.a | 1  | Male or female part cipants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage) | IN01A00  |  |  |
| 1.b | 2  | Participants who are willing and able to comply w th all scheduled vis ts, vaccination plan, laboratory tests, lifestyle cons derat ons, and other study procedures                  | IN02A00  |  |  |
| 1.c | 3  | Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study                | IN03A00  |  |  |
| 1.d | 4  | Capable of giving personal signed informed consent, which includes compliance with the requirements and restr ctions listed in the ICD and in this protocol                          | IN04A00  |  |  |
| Inc | Inclusion Criteria Entry IECAT = INCLUSION |  |  |  |  |

| 1.1 | Inclusion Number:<br>[Inclusion Number]  | 0 1<br>2 <b>IESPID</b><br>0 3<br>0 4                               |
|-----|--|--|
| 1.2 | Cr terion Description:<br>[Criter on Descript on]                                  |  |
| 1.3 | Cr terion met?<br>[Criter on met?]   | VES IEORRES<br>NO Describe details if relevant<br>IEDESC in SUPPIE |
| 1.4 | Cr terion ID: (For Pfizer use<br>only)<br>[Criter on ID: (For Pfizer use<br>only)] | IN01A00     IN02A00     IETESTCD     IN03A00     IN04A00           |

| #        | Exclusion Number                                     |                            | Criterion Description  | Criterion met? Criterion ID: (For Pfizer |          |
|----------|--|----------------------------|--|--|----------|
| #<br>2.a | 1  | Other med                  | cal or psychiatric condition incl. recent (within past year) or active suicidal<br>havior/lab abnormal ty that may increase the risk of study participation  | EX01A00                                  | use only |
| 2.b      | 2  |                            | ction w th human immunodeficiency virus (HIV), hepatitis C virus (HCV), or virus (HBV)   | EX02A00                                  |          |
| 2.c      | 3  |                            | evere adverse reaction associated with a vaccine and/or severe allergic<br>g, anaphylaxis) to any component of the study intervention(s)                     | EX03A00                                  |          |
| 2.d      | 4  | Receipt of                 | medicat ons intended to prevent COVID-19   | EX04A00                                  |          |
| 2.e      | 8  |                            | npromised indiv duals w th known or suspected immunodeficiency, as<br>I by history and/or laboratory/phys cal examination                                    | EX08A00                                  |          |
| 2.f      | 9  |                            | with a history of autoimmune disease or an active autoimmune disease nerapeutic intervention   | EX09A00                                  |          |
| 2.g      | 10   |                            | athesis or condition associated w th prolonged bleeding that would, in the<br>the investigator, contraindicate intramuscular inject on                       | EX10A00                                  |          |
| 2.h      | 11   | Women wh                   | o are pregnant or breastfeeding  | EX11A00                                  |          |
| 2.i      | 12   | Previous va                | accinat on with any coronavirus vaccine  | EX12A00                                  |          |
| 2.j      | 13   | Subjects w cort costere    | ho receive immunosuppressive therapy, such as cytotox c agents or systemic bids  | EX13A01                                  |          |
| 2.k      | 15   |                            | olood/plasma products or immunoglobulin, from 60 days before study<br>n administrat on or planned receipt throughout the study                               | EX14A01                                  |          |
| 2.1      | 16   |                            | n in other studies involving study intervention w thin 28 days pr or to study<br>or during study participation   | EX15A01                                  |          |
| 2.m      | 17   | Previous pa<br>nanopart cl | art cipation in other studies involving study intervent on containing lip d<br>es  | EX16A01                                  |          |
| 2.n      | 22   |                            | r s te staff or Pfizer employees directly involved in the conduct of the study, therwise supervised by the investigator, and their respective family members | EX21A01                                  |          |
| Exc      | lusion Criteria Entr                                 | IECAT :                    | = EXCLUSION  |  |          |
| 2.1      | Exclusion Number:<br>[Exclusion Number]              |                            |  |  |          |
| 2.2      | .2 Cr terion Description:<br>[Criter on Descript on] |                            | IETEST   |  |          |
| 2.3      | .3 Cr terion met?<br>[Criter on met?]                |                            | O YES IEORRES<br>Describe details if relevant  |  |          |

|     |  | IE=Inclusion/Exclusion Criteria Not Met |
|-----|--|---|
|     |  | ○ NO                                    |
| 2.4 | Cr terion ID: (For Pfizer use<br>only)<br>[Criter on ID: (For Pfizer use<br>only)] | ✓ IETESTCD                              |

2.1 Description of Exclusion Cr terion Met [Criter on Descript on]

### ST

| ST  | UDYID  |                              | IE=Inclusion/Exclusion Criteria Not Met |  |  |  |
|-----|--|------------------------------|---|--|--|--|
| C4  | 591001: INCLUSION/E  | EXCLUSION CRITERIA (INC EXC) |   |  |  |  |
|     |  | Criterion Description        |   |  |  |  |
| 1.  |  |                              |   |  |  |  |
| Inc | lusion Criteria Not Met Entry  |                              |   |  |  |  |
| 1.1 | Description of Inclusion<br>Cr terion Not Met<br>[Criter on Descript on] | IETEST when IEORRES=N        |   |  |  |  |
|     |  | Criterion Description        |   |  |  |  |
| 2.  |  |                              |   |  |  |  |
| Exc | Exclusion Criteria Met Entry   |                              |   |  |  |  |

✓ IETEST when IEORRES=Y

### IE=Inclusion/Exclusion Criteria Not Met

| C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC NS) |
|---|
|---|

| Incl   | Inclusion Criteria |  |  |                |                                     |  |  |
|--|--------------------|--|--|----------------|-------------------------------------|--|--|
| #  | Inclusion Number   |  | Criterion Description  | Criterion met? | Criterion ID: (For Pfizer use only) |  |  |
| 1.a  | 1                  |  | ale part cipants between the ages of 18 and 55 years, inclusive, 65 and 85 sive, or 18 and 85 years, inclusive, at randomization (dependent upon study |                | IN01A00                             |  |  |
| 1.b  | 2                  |  | who are willing and able to comply with all scheduled visits, vaccination plan, ests, lifestyle considerations, and other study procedures             |                | IN02A00                             |  |  |
|  |                    |  | ticipants who are determined by medical history, physical examination, and ment of the investigator to be eligible for inclusion in the study          |                | IN03A00                             |  |  |
| 1.d 4 Capable of giving personal signed informed consent, which includes compliance w requirements and restr ctions listed in the ICD and in this protocol |                    | ts and restr ctions listed in the ICD and in this protocol |  | IN04A00        |                                     |  |  |
| Inclusion Criteria Entry IECAT = INCLUSION   |                    |  |  |                |                                     |  |  |
| 1.1 Inclusion Number:  |                    |  | <b>∩1</b>  |                |                                     |  |  |

|     | [Inclusion Number]   | 0 2 <b>IESPID</b><br>0 3<br>0 4  |
|-----|--|--|
| 1.2 | Cr terion Description:<br>[Criter on Descript on]                                  | V IETEST   |
| 1.3 | Cr terion met?<br>[Criter on met?]   | VES IEORRES<br>NO<br>Describe details if relevant<br>IEDESC in SUPPIE                          |
| 1.4 | Cr terion ID: (For Pfizer use<br>only)<br>[Criter on ID: (For Pfizer use<br>only)] | <ul> <li>IN01A00</li> <li>IN02A00 <i>IETESTCD</i></li> <li>IN03A00</li> <li>IN04A00</li> </ul> |

| Exclusion Criteria |   |  |                |                                     |  |  |
|--------------------|---|--|----------------|-------------------------------------|--|--|
| #                  | <b>Exclusion Number</b>                         | Criterion Description  | Criterion met? | Criterion ID: (For Pfizer use only) |  |  |
| 2.a                | 1   | Other medical or psychiatric condition incl. recent (within past year) or active suicidal deation/behavior/lab abnormal ty that may increase the risk of study participation                   |                | EX01A00                             |  |  |
| 2.b                | 2   | Known infection w th human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)   |                | EX02A00                             |  |  |
| 2.c                | 3   | History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)                                   |                | EX03A00                             |  |  |
| 2.d                | 4   | Receipt of medicat ons intended to prevent COVID-19  |                | EX04A00                             |  |  |
| 2.e                | 5   | Stages 1 and 2 only: Prev ous clinical or microbiolog cal diagnosis of COVID-19  |                | EX05A00                             |  |  |
| 2.f                | 8   | Immunocompromised indiv duals w th known or suspected immunodeficiency, as determined by history and/or laboratory/phys cal examination  |                | EX08A00                             |  |  |
| 2.g                | 10  | Bleeding diathesis or condition associated wth prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular inject on                                       |                | EX10A00                             |  |  |
| 2.h                | 11  | Women who are pregnant or breastfeeding  |                | EX11A00                             |  |  |
| 2.i                | 12  | Previous vaccinat on with any coronavirus vaccine  |                | EX12A00                             |  |  |
| 2.j                | 13  | Subjects who receive immunosuppressive therapy, such as cytotox c agents or systemic cort costeroids   |                | EX13A01                             |  |  |
| 2.k                | 15  | Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administrat on or planned receipt throughout the study  |                | EX14A01                             |  |  |
| 2.1                | 16  | Participation in other studies involving study intervention w thin 28 days pr or to study entry and/or during study participation  |                | EX15A01                             |  |  |
| 2.m                | 17  | Previous part cipation in other studies involving study intervent on containing lip d nanopart cles  |                | EX16A01                             |  |  |
| 2.n                | 22  | Investigator s te staff or Pfizer employees directly involved in the conduct of the study,<br>si <u>te staff otherwise supervised by</u> the investigator, and their respective family members |                | EX21A01                             |  |  |
| Exc                | usion Criteria Entr                             | , IECAT = EXCLUSION  |                | ·                                   |  |  |
| 2.1                | Exclusion Number:<br>[Exclusion Number]         |  |                |                                     |  |  |
| 2.2                | Cr terion Description<br>[Criter on Descript or | n]   |                |                                     |  |  |
| 2.3                | Cr terion met?<br>[Criter on met?]              | VES IEORRES<br>Describe details if relevant<br>IEDESC in SUPPIE  |                |                                     |  |  |





IE=Inclusion/Exclusion Criteria Not Met

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IE=Inclusion/Exclusion Criteria Not Met

| C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC NS) |
|---|
|---|

| Inc | inclusion Criteria  |  |  |  |  |  |  |
|-----|---|--|--|--|--|--|--|
| #   | Inclusion Number  | Criterion Description  | Criterion met? Criterion ID: (For Pfizer use only) |  |  |  |  |
| 1.a |   | Male or female part cipants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage) | IN01A00  |  |  |  |  |
| 1.b | 2   | Participants who are willing and able to comply w th all scheduled vis ts, vaccination plan, laboratory tests, lifestyle cons derat ons, and other study procedures                  | IN02A00  |  |  |  |  |
| 1.c | 1.c     3     Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study     IN03A00 |  | IN03A00  |  |  |  |  |
| 1.d |   | Capable of giving personal signed informed consent, which includes compliance with the<br>requirements and restr ctions listed in the ICD and in this protocol                       | IN04A00  |  |  |  |  |
| Inc | Inclusion Criteria Entry IECAT = INCLUSION  |  |  |  |  |  |  |

| 1.1 | Inclusion Number:<br>[Inclusion Number]  | 01<br>2<br><b>IESPID</b><br>03<br>04   |
|-----|--|--|
| 1.2 | Cr terion Description:<br>[Criter on Descript on]                                  | V IETEST   |
| 1.3 | Cr terion met?<br>[Criter on met?]   | VES IEORRES<br>NO<br>Describe details if relevant<br>IEDESC in SUPPIE                          |
| 1.4 | Cr terion ID: (For Pfizer use<br>only)<br>[Criter on ID: (For Pfizer use<br>only)] | <ul> <li>IN01A00</li> <li>IN02A00 <i>JETESTCD</i></li> <li>IN03A00</li> <li>IN04A00</li> </ul> |

| Exc | Exclusion Criteria                              |  |                |                                     |  |  |
|-----|---|--|----------------|-------------------------------------|--|--|
| #   | Exclusion Number                                | Criterion Description  | Criterion met? | Criterion ID: (For Pfizer use only) |  |  |
| 2.a | 1   | Other medical or psychiatric condition incl. recent (within past year) or active suicidal deation/behavior/lab abnormal ty that may increase the risk of study participation           |                | EX01A00                             |  |  |
| 2.b | 2   | Known infection w th human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)   |                | EX02A00                             |  |  |
| 2.c | 3   | History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)                           |                | EX03A00                             |  |  |
| 2.d | 4   | Receipt of medicat ons intended to prevent COVID-19  |                | EX04A00                             |  |  |
| 2.e | 5   | Stages 1 and 2 only: Prev ous clinical or microbiolog cal diagnosis of COVID-19  |                | EX05A00                             |  |  |
| 2.f | 8   | Immunocompromised indiv duals w th known or suspected immunodeficiency, as determined by history and/or laboratory/phys cal examination  |                | EX08A00                             |  |  |
| 2.g | 9   | Individuals with a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention  |                | EX09A00                             |  |  |
| 2.h | 10  | Bleeding diathesis or condition associated w th prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular inject on                              |                | EX10A00                             |  |  |
| 2.i | 11  | Women who are pregnant or breastfeeding  |                | EX11A00                             |  |  |
| 2.j | 12  | Previous vaccinat on with any coronavirus vaccine  |                | EX12A00                             |  |  |
| 2.k | 13  | Subjects who receive immunosuppressive therapy, such as cytotox c agents or systemic cort costeroids   |                | EX13A01                             |  |  |
| 2.1 | 15  | Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administrat on or planned receipt throughout the study                                      |                | EX14A01                             |  |  |
| 2.m | 16  | Participation in other studies involving study intervention w thin 28 days pr or to study entry and/or during study participation  |                | EX15A01                             |  |  |
| 2.n | 17  | Previous part cipation in other studies involving study intervent on containing lip d<br>nanopart cles   |                | EX16A01                             |  |  |
| 2.0 | 22  | Investigator s te staff or Pfizer employees directly involved in the conduct of the study,<br>site staff otherwise supervised by the investigator, and their respective family members |                | EX21A01                             |  |  |
| Exc | lusion Criteria Entr                            | IECAT = EXCLUSION  | ·              |                                     |  |  |
| 2.1 | Exclusion Number:<br>[Exclusion Number]         |  |                |                                     |  |  |
| 2.2 | Cr terion Description<br>[Criter on Descript or |  |                |                                     |  |  |
| 2.3 | Cr terion met?<br>[Criter on met?]              | YES IEORRES<br>Describe details if relevant  |                |                                     |  |  |

|     |  |                 | IE=Inclusion/Exclusion Criteria Not Met |
|-----|--|-----------------|---|
|     |  | <sup>◯</sup> NO |   |
| 2.4 | Cr terion ID: (For Pfizer use<br>only)<br>[Criter on ID: (For Pfizer use<br>only)] | IETESTCD        |   |

#### IE=Inclusion/Exclusion Criteria Not Met

| C4   | 591001: INCL   | USION/     | EXCLUSION CRITERIA (INC EXC NS)  |                |                                     |  |  |
|------|--|------------|--|----------------|-------------------------------------|--|--|
| Stud | Study eligibility requires subjects to meet all inclus on criteria (YES) and Not meet exclusion criteria (NO). |            |  |                |                                     |  |  |
| Inc  | Inclusion Criteria   |            |  |                |                                     |  |  |
| #    | Inclusion Number   |            | Criterion Description  | Criterion met? | Criterion ID: (For Pfizer use only) |  |  |
| 1.a  | 1  |            | ale part cipants between the ages of 18 and 55 years, inclusive, 65 and 85 sive, or 18 and 85 years, inclusive, at randomization (dependent upon study |                | IN01A00                             |  |  |
| 1.b  | 2  |            | who are willing and able to comply w th all scheduled vis ts, vaccination plan, tests, lifestyle cons derat ons, and other study procedures            |                | IN02A00                             |  |  |
| 1.c  | 3  |            | ticipants who are determined by medical history, physical examination, and ment of the investigator to be eligible for inclusion in the study          |                | IN03A00                             |  |  |
| 1.d  |  | requiremer | giving personal signed informed consent, which includes compliance with the ts and restr ctions listed in the ICD and in this protocol                 |                | IN04A00                             |  |  |
| Inc  | lusion Criteria Entr   | y IECAT :  | = INCLUSION  |                |                                     |  |  |
| 1.1  | Inclusion Number:<br>[Inclusion Number]  |            | 0 1<br>0 2<br>1<br>1<br>1<br>1<br>1<br>1<br>1<br>1<br>1<br>1<br>1<br>1<br>1  |                |                                     |  |  |
| 1.2  | 1.2 Cr terion Description:<br>[Criter on Descript on]  |            | <b>✓</b> IETEST  |                |                                     |  |  |
| 1.3  | 1.3 Cr terion met?<br>[Criter on met?]   |            | VES IEORRES<br>NO<br>Describe details if relevant<br>IEDESC in SUPPIE  |                |                                     |  |  |
|      | Cr terion ID: (For Pf<br>only)<br>[Criter on ID: (For P<br>only)]  |            | <ul> <li>IN01A00</li> <li>IN02A00 <i>JETESTCD</i></li> <li>IN03A00</li> <li>IN04A00</li> </ul>   |                |                                     |  |  |
| Exc  | Exclusion Criteria   |            |  |                |                                     |  |  |

| -   | Exclusion Criteria                              |  |  |  |  |  |  |
|-----|---|--|--|--|--|--|--|
| #   | Exclusion Number                                | Criterion Description  | Criterion met? Criterion ID: (For Pfizer use only) |  |  |  |  |
| 2.a | 1   | Other medical or psychiatric condition incl. recent (within past year) or active suicidal deation/behavior/lab abnormal ty that may increase the risk of study participation                             | EX01A00  |  |  |  |  |
| 2.b | 2   | Known infection w th human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)   | EX02A00  |  |  |  |  |
| 2.c | 3   | History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)   | EX03A00  |  |  |  |  |
| 2.d | 4   | Receipt of medicat ons intended to prevent COVID-19  | EX04A00  |  |  |  |  |
| 2.e | 5   | Stages 1 and 2 only: Prev ous clinical or microbiolog cal diagnosis of COVID-19  | EX05A00  |  |  |  |  |
| 2.f | 8   | Immunocompromised indiv duals w th known or suspected immunodeficiency, as determined by history and/or laboratory/phys cal examination  | EX08A00  |  |  |  |  |
| 2.g | 9   | Individuals with a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention  | EX09A00  |  |  |  |  |
| 2.h | 10  | Bleeding diathesis or condition associated wth prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular inject on   | EX10A00  |  |  |  |  |
| 2.i | 11  | Women who are pregnant or breastfeeding  | EX11A00  |  |  |  |  |
| 2.j | 12  | Previous vaccinat on with any coronavirus vaccine  | EX12A00  |  |  |  |  |
| 2.k | 13  | Individuals who receive immunosuppressive therapy, such as cytotoxic agents or<br>systemic corticosteroids. Inhaled/nebulized, Intra-art cular, intrabursal, or topical<br>cort costeroids are permitted | EX13A00  |  |  |  |  |
| 2.1 | 14  | Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administrat on or planned receipt throughout the study  | EX14A00  |  |  |  |  |
| 2.m | 15  | Participation in other studies involving study intervention w thin 28 days pr or to study entry and/or during study participation  | EX15A00  |  |  |  |  |
| 2.n | 16  | Previous part cipation in other studies involving study intervent on containing lip d nanopart cles  | EX16A00  |  |  |  |  |
| 2.0 | 21  | Investigator s te staff or Pfizer employees directly involved in the conduct of the study,<br>site staff otherwise supervised by the investigator, and their respective family members                   | EX21A00  |  |  |  |  |
| Exc | Exclusion Criteria Entry IECAT = EXCLUSION      |  |  |  |  |  |  |
| 2.1 | Exclusion Number:<br>[Exclusion Number]         |  |  |  |  |  |  |
| 2.2 | Cr terion Description<br>[Criter on Descript or |  |  |  |  |  |  |
| 2.3 | Cr terion met?<br>[Criter on met?]              | VES IEORRES<br>Describe details if relevant  |  |  |  |  |  |

|     |  |                 | IE=Inclusion/Exclusion Criteria Not Met |
|-----|--|-----------------|---|
|     |  | <sup>◯</sup> NO |   |
| 2.4 | Cr terion ID: (For Pfizer use<br>only)<br>[Criter on ID: (For Pfizer use<br>only)] | ✓ IETESTCD      |   |

### IE=Inclusion/Exclusion Criteria Not Met

#### C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC S)

| Inc | lusion Criteria   |  |  |
|-----|---|--|--|
| #   | Inclusion Number  | Criterion Description  | Criterion met? Criterion ID: (For Pfizer use only) |
| 1.a | 1   | Male or female part cipants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage) | IN01A00  |
| 1.b | 2   | Participants who are willing and able to comply w th all scheduled vis ts, vaccination plan, laboratory tests, lifestyle cons derat ons, and other study procedures                  | IN02A00  |
| 1.c | 1.c     3     Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study     IN03A00 |  | IN03A00  |
| 1.d |   | Capable of giving personal signed informed consent, which includes compliance with the<br>requirements and restr ctions listed in the ICD and in this protocol                       | IN04A00  |
| Inc | Inclusion Criteria Entry IECAT = INCLUSION  |  |  |

| 1.1 | Inclusion Number:<br>[Inclusion Number]  | 0 1<br>0 2<br>1<br>ESPID<br>0 3<br>0 4                                |
|-----|--|---|
| 1.2 | Cr terion Description:<br>[Criter on Descript on]                                  | IETEST  |
| 1.3 | Cr terion met?<br>[Criter on met?]   | VES IEORRES<br>NO<br>Describe details if relevant<br>IEDESC in SUPPIE |
| 1.4 | Cr terion ID: (For Pfizer use<br>only)<br>[Criter on ID: (For Pfizer use<br>only)] | IN01A00     IN02A00     IN03A00     IN04A00                           |

| Exc   | Exclusion Criteria |   |                                     |         |  |
|---|--------------------|---|-------------------------------------|---------|--|
| # Exclusion Number Criterion Description Criterion ID |                    |   | Criterion ID: (For Pfizer use only) |         |  |
| 2.a   | 1                  | Other medical or psychiatric condition incl. recent (within past year) or active suicidal deation/behavior/lab abnormal ty that may increase the risk of study participation                          |                                     | EX01A00 |  |
| 2.b   | 2                  | Known infection w th human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)  |                                     | EX02A00 |  |
| 2.c   | 3                  | History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)  |                                     | EX03A00 |  |
| 2.d   | 4                  | Receipt of medicat ons intended to prevent COVID-19   |                                     | EX04A00 |  |
| 2.e   | 5                  | Stages 1 and 2 only: Prev ous clinical or microbiolog cal diagnosis of COVID-19   |                                     | EX05A00 |  |
| 2.f   | 6                  | Sentinel participants in Stage 1 only: Individuals at high risk for severe COVID-19 (full details in protocol)  |                                     | EX06A01 |  |
| 2.g   | 7                  | Sentinel participants in Stage 1 only: Individuals currently working in occupations with high risk of exposure to SARS-CoV-2 (eg, healthcare worker, emergency response personnel)                    |                                     | EX07A00 |  |
| 2.h   | 8                  | Immunocompromised indiv duals w th known or suspected immunodeficiency, as determined by history and/or laboratory/phys cal examinat on   |                                     | EX08A00 |  |
| 2.i   | 9                  | Sentinel participants in Stage 1 only: Individuals with a history of autoimmune disease or<br>an active autoimmune disease requiring therapeut c intervention   |                                     | EX09A04 |  |
| 2.j   | 10                 | Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular inject on   |                                     | EX10A00 |  |
| 2.k   | 11                 | Women who are pregnant or breastfeeding   |                                     | EX11A00 |  |
| 2.1   | 12                 | Previous vaccinat on with any coronavirus vaccine   |                                     | EX12A00 |  |
| 2.m   | 13                 | Subjects who receive immunosuppressive therapy, such as cytotox c agents or systemic cort costeroids  |                                     | EX13A01 |  |
| 2.n   | 14                 | Sentinel participants in Stage 1 only: Regular receipt of inhaled/nebulized corticosteroids   |                                     | EX22A01 |  |
| 2.0   | 15                 | Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administrat on or planned receipt throughout the study   |                                     | EX14A01 |  |
| 2.p   | 16                 | Participation in other studies involving study intervention w thin 28 days pr or to study entry and/or during study participation   |                                     | EX15A01 |  |
| 2.q   | 17                 | Previous part cipation in other studies involving study intervent on containing lip d nanopart cles   |                                     | EX16A01 |  |
| 2.r   | 18                 | Sentinel part cipants in Stage 1 only: Positive serological test for SARS-CoV-2 IgM and/or IgG antibodies at the screening visit  |                                     | EX17A01 |  |
| 2.s   | 19                 | Sentinel part cipants in Stage 1 only: Screening hematology/blood chemistry lab >=Grade 1 abnormality. Except Bilirubin, other stable Grade1 abnormalities may be considered eligible by Investigator |                                     | EX18A01 |  |
| 2.t   | 20                 | Sentinel part cipants in Stage 1 only: Positive test for HIV, hepat tis B surface antigen   |                                     | EX19A01 |  |

## IE=Inclusion/Exclusion Criteria Not Met

|     |   | (HBsAg), hepat tis B core antibodies (HBc Abs), or hepatitis C virus antibodies (HCV Abs) at screening vis t   |         |
|-----|---|--|---------|
| 2.u | 21  | Sentinel participants in Stage 1 only: SARS-CoV-2 NAAT-positive nasal swab within 24 hours before receipt of study intervention  | EX20A01 |
| 2.v | 22  | 22 Investigator s te staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members EX21A01 |         |
| Exc | lusion Criteria Entr  | IECAT = EXCLUSION  |         |
| 2.1 | Exclusion Number:<br>[Exclusion Number]                             |  |         |
| 2.2 | Cr terion Description<br>[Criter on Descript of                     |  |         |
| 2.3 | Cr terion met?<br>[Criter on met?]                                  | VES IEORRES<br>Describe details if relevant<br>IEDESC in SUPPIE  |         |
| 2.4 | Cr terion ID: (For Pfi<br>only)<br>[Criter on ID: (For Pi<br>only)] |  |         |

#### IE=Inclusion/Exclusion Criteria Not Met

| C4591001: INCLUSION | /EXCLUSION CRITERIA ( | (INC EXC S) |   |
|---------------------|-----------------------|-------------|---|
|                     | EXCLOSION CITIENTA    |             | / |

| Inc   | nclusion Criteria    |  |  |  |  |
|---|----------------------|--|--|--|--|
| #   | Inclusion Number     | Criterion Description  | Criterion met? Criterion ID: (For Pfizer use only) |  |  |
| 1.a   | 1                    | Male or female part cipants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage) | IN01A00  |  |  |
| 1.b   | 2                    | Participants who are willing and able to comply w th all scheduled vis ts, vaccination plan, laboratory tests, lifestyle cons derat ons, and other study procedures                  | IN02A00  |  |  |
| 1.c   | 3                    | Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study                | IN03A00  |  |  |
| 1.d   | 4                    | Capable of giving personal signed informed consent, which includes compliance with the IN04A00 requirements and restrictions listed in the ICD and in this protocol                  |  |  |  |
| Inc   | lusion Criteria Entr | y IECAT = INCLUSION  |  |  |  |
| 1.1     Inclusion Number:<br>[Inclusion Number]     01<br>02       03<br>04 |                      |  |  |  |  |

| 1.2 | Cr terion Description:<br>[Criter on Descript on]                                  | ✓ IETEST   |
|-----|--|--|
| 1.3 | Cr terion met?<br>[Criter on met?]   | VES IEORRES<br>NO<br>Describe details if relevant<br>IEDESC in SUPPIE          |
| 1.4 | Cr terion ID: (For Pfizer use<br>only)<br>[Criter on ID: (For Pfizer use<br>only)] | <ul> <li>IN01A00</li> <li>IN02A00</li> <li>IN03A00</li> <li>IN04A00</li> </ul> |

| Exc  | Exclusion Criteria |  |         |  |  |
|--|--------------------|--|---------|--|--|
| # Exclusion Number Criterion Description Criterion met? Criterion ID: (For Pfizer use or |                    |  |         |  |  |
| 2.a  | 1                  | Other medical or psychiatric condition incl. recent (within past year) or active suicidal deation/behavior/lab abnormal ty that may increase the risk of study participation                             | EX01A00 |  |  |
| 2.b  | 2                  | Known infection w th human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)   | EX02A00 |  |  |
| 2.c  | 3                  | History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)   | EX03A00 |  |  |
| 2.d  | 4                  | Receipt of medicat ons intended to prevent COVID-19  | EX04A00 |  |  |
| 2.e  | 5                  | Stages 1 and 2 only: Prev ous clinical or microbiolog cal diagnosis of COVID-19  | EX05A00 |  |  |
| 2.f  | 6                  | Sentinel participants in Stage 1 only: Individuals at high risk for severe COVID-19  | EX06A00 |  |  |
| 2.g  | 7                  | Sentinel participants in Stage 1 only: Individuals currently working in occupations with high risk of exposure to SARS-CoV-2 (eg, healthcare worker, emergency response personnel)                       | EX07A00 |  |  |
| 2.h  | 8                  | Immunocompromised indiv duals w th known or suspected immunodeficiency, as determined by history and/or laboratory/phys cal examinat on  | EX08A00 |  |  |
| 2.i  | 9                  | Individuals with a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention  | EX09A00 |  |  |
| 2.j  | 10                 | Bleeding diathesis or condition associated w th prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular inject on  | EX10A00 |  |  |
| 2.k  | 11                 | Women who are pregnant or breastfeeding  | EX11A00 |  |  |
| 2.1  | 12                 | Previous vaccinat on with any coronavirus vaccine  | EX12A00 |  |  |
| 2.m  | 13                 | Individuals who receive immunosuppressive therapy, such as cytotoxic agents or<br>systemic corticosteroids. Inhaled/nebulized, Intra-art cular, intrabursal, or topical<br>cort costeroids are permitted | EX13A00 |  |  |
| 2.n  | 14                 | Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administrat on or planned receipt throughout the study  | EX14A00 |  |  |
| 2.0  | 15                 | Participation in other studies involving study intervention w thin 28 days pr or to study entry and/or during study participation  | EX15A00 |  |  |
| 2.p  | 16                 | Previous part cipation in other studies involving study intervent on containing lip d nanopart cles  | EX16A00 |  |  |
| 2.q  | 17                 | Sentinel part cipants in Stage 1 only: Positive serological test for SARS-CoV-2 IgM and/or IgG antibodies at the screening visit   | EX17A00 |  |  |
| 2.r  | 18                 | Sentinel part cipants in Stage 1 only: Screening hematology/blood chemistry lab >=Grade 1 abnormality. Except Bilirubin, other stable Grade1 abnormalities may be considered eligible by Investigator    | EX18A00 |  |  |
| 2.s  | 19                 | Sentinel part cipants in Stage 1 only: Positive test for HIV, hepat tis B surface antigen (HBsAg), hepat tis B core antibodies (HBc Abs), or hepatitis C virus antibodies (HCV Abs) at screening vis t   | EX19A00 |  |  |
|  |                    |  |         |  |  |

### IE=Inclusion/Exclusion Criteria Not Met

| 2.t | 20  | Sentinel participants in Stage 1 only: SARS-CoV-2 NAAT-positive nasal swab within 24 hours before receipt of study intervention   | EX20A00 |
|-----|---|---|---------|
| 2.u | 21  | Investigator s te staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members | EX21A00 |
| Exc | lusion Criteria Entr  | IECAT = EXCLUSION   |         |
| 2.1 | Exclusion Number:<br>[Exclusion Number]                             |   |         |
| 2.2 | Cr terion Description<br>[Criter on Descript of                     |   |         |
| 2.3 | Cr terion met?<br>[Criter on met?]                                  | • YES IEORRES<br>Describe details if relevant<br>IEDESC in SUPPIE   |         |
| 2.4 | Cr terion ID: (For Pfi<br>only)<br>[Criter on ID: (For Pr<br>only)] |   |         |

#### C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC S)

Study eligibility requires subjects to meet all inclus on criteria (YES) and Not meet exclusion criteria (NO).

| Inc  | lusion Criteria   |  |                |                                     |
|--|---|--|----------------|-------------------------------------|
| #  | Inclusion Number  | Criterion Description  | Criterion met? | Criterion ID: (For Pfizer use only) |
| 1.a  | 1   | Male or female part cipants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage) |                | IN01A00                             |
| 1.b  | b 2 Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures IN02A00 |  |                |                                     |
| 1.c  | 3   | Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study                |                | IN03A00                             |
| 1.d  | 4   | Capable of giving personal signed informed consent, which includes compliance with the requirements and restr ctions listed in the ICD and in this protocol                          |                | IN04A00                             |
| Inclusion Criteria Entry IECAT = INCLUSION |   |  |                |                                     |
| 1.1  | 1.1 Inclusion Number:   |  |                |                                     |

| 1.1 | Inclusion Number:  | $\bigcirc 1$ |
|-----|--------------------|--------------|
|     | [Inclusion Number] | 02           |

| 1.2 | Cr terion Description:<br>[Criter on Descript on]                                  | <b>IETEST</b> ■   |
|-----|--|---|
| 1.3 | Cr terion met?<br>[Criter on met?]   | VES IEORRES<br>NO<br>Describe details if relevant<br>IEDESC in SUPPIE         |
|     | Cr terion ID: (For Pfizer use<br>only)<br>[Criter on ID: (For Pfizer use<br>only)] | <ul> <li>IN01A00</li> <li>IN02A00 <i>JETESTCD</i></li> <li>IN03A00</li> </ul> |

O IN04A00

| #   | Exclusion Number | Criterion Description   | Criterion met? Criterion ID: (For Pfizer use only |
|-----|------------------|---|---|
| 2.a | 1                | Other medical or psychiatric condition incl. recent (within past year) or active suicidal deation/behavior/lab abnormal ty that may increase the risk of study participation                          | EX01A00   |
| 2.b | 2                | Known infection w th human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)  | EX02A00   |
| 2.c | 3                | History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)  | EX03A00   |
| 2.d | 4                | Receipt of medicat ons intended to prevent COVID-19   | EX04A00   |
| 2.e | 5                | Stages 1 and 2 only: Prev ous clinical or microbiolog cal diagnosis of COVID-19   | EX05A00   |
| 2.f | 6                | Sentinel participants in Stage 1 only: Individuals at high risk for severe COVID-19 (full details in protocol)  | EX06A01   |
| 2.g | 7                | Sentinel participants in Stage 1 only: Individuals currently working in occupations with high risk of exposure to SARS-CoV-2 (eg, healthcare worker, emergency response personnel)                    | EX07A00   |
| 2.h | 8                | Immunocompromised indiv duals w th known or suspected immunodeficiency, as determined by history and/or laboratory/phys cal examinat on   | EX08A00   |
| 2.i | 9                | Individuals w th a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention   | EX09A00   |
| 2.j | 10               | Bleeding diathesis or condition associated wth prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular inject on  | EX10A00   |
| 2.k | 11               | Women who are pregnant or breastfeeding   | EX11A00   |
| 2.1 | 12               | Previous vaccinat on with any coronavirus vaccine   | EX12A00   |
| 2.m | 13               | Subjects who receive immunosuppressive therapy, such as cytotox ${\bf c}$ agents or systemic cort costeroids  | EX13A01   |
| 2.n | 14               | Sentinel participants in Stage 1 only: Regular receipt of inhaled/nebulized corticosteroids   | EX22A01   |
| 2.0 | 15               | Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administrat on or planned receipt throughout the study   | EX14A01   |
| 2.p | 16               | Participation in other studies involving study intervention w thin 28 days pr or to study entry and/or during study participation   | EX15A01   |
| 2.q | 17               | Previous part cipation in other studies involving study intervent on containing lip d<br>nanopart cles  | EX16A01   |
| 2.r | 18               | Sentinel part cipants in Stage 1 only: Positive serological test for SARS-CoV-2 IgM and/or IgG antibodies at the screening visit  | EX17A01   |
| 2.s | 19               | Sentinel part cipants in Stage 1 only: Screening hematology/blood chemistry lab >=Grade 1 abnormality. Except Bilirubin, other stable Grade1 abnormalities may be considered eligible by Investigator | EX18A01   |
| 2.t | 20               | Sentinel part cipants in Stage 1 only: Positive test for HIV, hepat tis B surface antigen   | EX19A01   |

### IE=Inclusion/Exclusion Criteria Not Met

|     |   | (HBsAg), hepat tis B core antibodies (HBc Abs), or hepatitis C virus antibodies (HCV A at screening vis t   | bs)    |   |
|-----|---|---|--------|---|
| 2.u | 21  | Sentinel participants in Stage 1 only: SARS-CoV-2 NAAT-positive nasal swab within 24 hours before receipt of study intervention   | EX20A0 | 1 |
| 2.v | 22  | Investigator s te staff or Pfizer employees directly involved in the conduct of the study<br>site staff otherwise supervised by the investigator, and their respective family membe |        | 1 |
| Exc | lusion Criteria Entr  | y IECAT = EXCLUSION   |        |   |
| 2.1 | Exclusion Number:<br>[Exclusion Number]                             |   |        |   |
| 2.2 | Cr terion Description<br>[Criter on Descript of                     | n]  |        |   |
| 2.3 | Cr terion met?<br>[Criter on met?]                                  | VES IEORRES<br>Describe details if relevant<br>IEDESC in SUPPIE   |        |   |
| 2.4 | Cr terion ID: (For Pfi<br>only)<br>[Criter on ID: (For Pf<br>only)] |   |        |   |

| C                       | 4591001: CASEBOOK SI                       | GNATURE FORM (INVSIG) NOT SUBMITTED |  |  |
|-------------------------|--|-------------------------------------|--|--|
| Casebook Signature Form |  |                                     |  |  |
| 1.                      | Casebook Signature<br>[Casebook Signature] | Click Here to Enable                |  |  |

| ST        | UDYID  | LB=Laboratory Test   | t Results MB=Microbiology Specimen |  |  |  |
|-----------|--|--|------------------------------------|--|--|--|
| <b>C4</b> | 591001: CENTRAL LAB SAMPLE                                     | COLLECTION (LAB)   |                                    |  |  |  |
| Cen       | tral Lab Sample Collection                                     |  |                                    |  |  |  |
|           | Collection Date:<br>Collect on Date:]                          |  |                                    |  |  |  |
|           | Specimen Type:<br>Specimen Type] BLOOD LBSPEC MBSPEC           |  |                                    |  |  |  |
| Lab       | Test   |  |                                    |  |  |  |
| #         | Category for Lab Test  | Subcategory for Lab Test   | Lab Sub-Panel Collected            |  |  |  |
| 3.a       | CLINICAL CHEMISTRY   | BLOOD CHEMISTRY  |                                    |  |  |  |
| 3.b       | HEMATOLOGY   | DIFFERENTIAL   |                                    |  |  |  |
| Lab       | Test Entry   |  |                                    |  |  |  |
| 3.1       | Lab Panel:<br>[Category for Lab Test]                          | <pre>O HEMATOLOGY O CLINICAL CHEMISTRY</pre> <pre>     BCAT     MBCAT </pre> |                                    |  |  |  |
| 3.2       | Lab Sub-Panel:<br>[Subcategory for Lab Test]                   | O DIFFERENTIAL<br>O BLOOD CHEMISTRY  |                                    |  |  |  |
| 3.3       | Was the lab sub-panel collected?:<br>[Lab Sub-Panel Collected] | O YES<br>NO LBSCATYN in SUPPLB MBSCATYN in SUPPMB                            |                                    |  |  |  |

| รтเ                                  | IDYID   | LB=Laboratory Test  | Results MB=Microbiology Specimen |  |  |  |  |  |  |
|--------------------------------------|---|---|----------------------------------|--|--|--|--|--|--|
| <b>C4</b>                            | C4591001: CENTRAL LAB SAMPLE COLLECTION - BASELINE (LAB BSL)  |   |                                  |  |  |  |  |  |  |
| Cen                                  | tral Lab Sample Collection  |   |                                  |  |  |  |  |  |  |
|                                      | Collection Date:<br>Collect on Date:]   |   |                                  |  |  |  |  |  |  |
| 2. Specimen Type:<br>[Specimen Type] |   | OBLOOD  |                                  |  |  |  |  |  |  |
| Lab                                  | Test  |   |                                  |  |  |  |  |  |  |
| #                                    | Category for Lab Test   | Subcategory for Lab Test  | Lab Sub-Panel Collected          |  |  |  |  |  |  |
| 3.a                                  | CLINICAL CHEMISTRY  | BLOOD CHEMISTRY   |                                  |  |  |  |  |  |  |
| 3.b                                  | CLINICAL CHEMISTRY  | VIROLOGY  |                                  |  |  |  |  |  |  |
| 3.c                                  | HEMATOLOGY  | DIFFERENTIAL  |                                  |  |  |  |  |  |  |
| Lab                                  | Test Entry  |   |                                  |  |  |  |  |  |  |
| 3.1                                  | Lab Panel:<br>[Category for Lab Test]   | OHEMATOLOGY   |                                  |  |  |  |  |  |  |
| 3.2                                  | Lab Sub-Panel:<br>[Subcategory for Lab Test]  | <ul> <li>DIFFERENTIAL</li> <li>BLOOD CHEMISTRY</li> <li>VIROLOGY</li> </ul> |                                  |  |  |  |  |  |  |
| 3.3                                  | 3 Was the lab sub-panel collected?:<br>[Lab Sub-Panel Collected] OYES<br>[NO LBSCATYN in SUPPLB MBSCATYN in SUPPMB] |   |                                  |  |  |  |  |  |  |

### LB=Laboratory Test Results

| <b>ST</b> | LB=Laboratory Test Results  |   |               |         |            |            |              |  |  |  |
|-----------|---|---|---------------|---------|------------|------------|--------------|--|--|--|
| C4        | C4591001: LOCAL LABORATORY DATA - REPEATING CHEMISTRY (LAB CHEM) - Repeating Form |   |               |         |            |            |              |  |  |  |
| #         | Category for Lab Test   | Vendor Name                                 | Collection Da | te:     | Specimen 1 | Lab Result |              |  |  |  |
| 1         |   |   |               |         |            |            |              |  |  |  |
| La        | o Chemistry Details   |   |               |         |            |            |              |  |  |  |
| 1.        | Lab Panel:<br>[Category for Lab Test]   | CLINICAL CHEMISTRY                          | BCAT          |         |            |            |              |  |  |  |
| 2.        | Laboratory Name and Address<br>[Vendor Name]                                      | LBNAM                                       |               |         |            |            |              |  |  |  |
| 3.        | Collection Date:<br>[Collect on Date:]  | ✓ / ✓ / ✓                                   | LBDTC         |         |            |            |              |  |  |  |
| 4.        | Specimen Type:<br>[Specimen Type]   | BLOOD LBSPEC                                |               |         |            |            |              |  |  |  |
| La        | o Result  |   |               |         |            |            |              |  |  |  |
| #<br>✓    | Sponsor-Defined Identifier  | Tes   | st:           | Result: | Not Done:  | Lab        | Normal Range |  |  |  |
| 5.a       |   | C Reactive Protein_PX3                      | 29            |         |            |            |              |  |  |  |
| La        | b Result Entry  |   |               |         |            |            |              |  |  |  |
| 5.1       | Sponsor ID:<br>[Sponsor-Defined Identifier]                                       | LBSF  | PID           |         |            |            |              |  |  |  |
| 5.2       | Test:<br>[Test:]  | C Reactive Protein_PX                       | 329 LBTEST    |         |            |            |              |  |  |  |
| 5.3       | Result:<br>[Result:]  | LBORRES                                     |               |         |            |            |              |  |  |  |
| 5.4       | Not Done: [hidden]<br>[Not Done:]   | ONOT DONE                                   | -             |         |            |            |              |  |  |  |
| 5.5       | LNMT<br>[Lab Normal Range]  | Low<br>High<br>LBORNRHI<br>Un t<br>LBORRESU |               |         |            |            |              |  |  |  |

STUDYID LB=Laboratory Test Results C4591001: LOCAL LABORATORY DATA - REPEATING CHEMISTRY (LAB CHEM) - Repeating Form # **Category for Lab Test** Vendor Name **Collection Date:** Specimen Type Lab Result 1 Lab Chemistry Details CLINICAL CHEMISTRY 1. Lab Panel: [Category for Lab Test] 2. Laboratory Name and Address [Vendor Name] LBNAM 3. Collection Date: ✓ / ✓ / ~ LBDTC [Collect on Date:] 4. Specimen Type: ○ BLOOD LBSPEC [Specimen Type] Lab Result Sponsor-Defined Identifier Test: Result: Not Done: Lab Normal Range # ¥ C Reactive Protein\_PX329 5.a 5.b Alanine Aminotransferase\_PX30 Aspartate Aminotransferase\_PX28 5.c 5.d Alkaline Phosphatase\_PX35 5.e Bilirubin\_PX21 5.f Blood Urea Nitrogen\_PX47 5.g Creatinine\_PX48 Lab Result Entry 5.1 Sponsor ID: LBSPID [Sponsor-Defined Identifier] 5.2 Test: ~ LBTEST [Test:] 5.3 Result: LBORRES [Result:] 5.4 Not Done: NOT DONE LBSTAT [Not Done:] LNMT 5.5 Low [Lab Normal Range] LBORNRLO High

LBORNRHI

LBORRESU

Un t 🗸

| <b>S</b> 7 | <b>TUDYID</b>  |                    |             |                 | LB=            | Laboratory | Test Results |
|------------|--|--------------------|-------------|-----------------|----------------|------------|--------------|
| C4         | 591001: LOCAL LABORATO                                 | RY DATA - REPEATII | NG Hematolo | gy (LAB HEM)    | - Repeating Fo | orm        |              |
| #          | Category for Lab Test                                  | Vendor Name (DE    | RIVED)      | Collection Date | e: Speci       | men Type   | Lab Result   |
| 1          |  |                    |             |                 |                |            |              |
| Lat        | ooratory Data Hematology                               |                    |             |                 |                |            |              |
| 1.         | Lab Panel:<br>[Category for Lab Test]                  |                    | BCAT        |                 |                |            |              |
|            | Laboratory Name and Address<br>[Vendor Name (DERIVED)] | LBNAM              |             |                 |                |            |              |
|            | Collection Date:<br>[Collect on Date:]                 |                    |             | ]               |                |            |              |
| 4.         | Specimen Type:<br>[Specimen Type]                      | O BLOOD LBSPE      | C           |                 |                |            |              |
| Lat        | Result   | I                  |             |                 |                |            |              |
| #          | Sponsor-Defined Identifi                               | er                 | Test:       | Result:         | Not Done:      | Lab No     | rmal Range   |
| 5.a        |  | Hemoglobin_F       | PX1         |                 |                |            |              |
| 5.b        |  | Hematocrit_P       | X2          |                 |                |            |              |
| 5.c        |  | Erythrocytes_      | PX3         |                 |                |            |              |
| 5.d        |  | Platelets_PX5      |             |                 |                |            |              |
| 5.e        |  | Leukocytes_P       | X7          |                 |                |            |              |
| 5.f        |  | Neutrophils_P      | X608        |                 |                |            |              |
| 5.g        |  | Eosinophils_P      | X609        |                 |                |            |              |
| 5.h        |  | Monocytes_P>       | (612        |                 |                |            |              |
| 5.i        |  | Basophils_PX6      | 510         |                 |                |            |              |
| 5.j        |  | Lymphocytes_       | _PX611      |                 |                |            |              |
| Lal        | o Result Entry   |                    |             |                 |                |            |              |
| 5.1        | Sponsor ID:<br>[Sponsor-Defined Identifier]            |                    | LBSPID      |                 |                |            |              |
| 5.2        | Test:<br>[Test:]                                       |                    | Τ           |                 |                |            |              |
| 5.3        | Result:<br>[Result:]                                   | LBORRES            | ]           |                 |                |            |              |
| 5.4        | Not Done:<br>[Not Done:]                               |                    | BSTAT       |                 |                |            |              |
| 5.5        | LNMT<br>[Lab Normal Range]                             |                    | RHI         |                 |                |            |              |

#### LB=Laboratory Test Results

| C2  | C4591001: LAB URINALYSIS - PREGNANCY TEST (LAB PREG)             |                               |                               |         |           |  |  |  |
|-----|--|-------------------------------|-------------------------------|---------|-----------|--|--|--|
| La  | b Urinalysis   |                               |                               |         |           |  |  |  |
| 1.  | Lab Panel:<br>[Category for Lab Test]                            | OURINALYSIS LBCAT             |                               |         |           |  |  |  |
| 2.  | Lab Sub-Panel:<br>[Subcategory for Lab Test]                     | O PREGNA                      | ANCY LBSCAT                   |         |           |  |  |  |
| 3.  | Collection Date:<br>[Collect on Date:]                           | <b>~</b> /                    |                               |         |           |  |  |  |
| 4.  | Laboratory Name and Address (Derived)<br>[Vendor Name (DERIVED)] | LBNA                          | И                             |         |           |  |  |  |
| 5.  | Specimen Type:<br>[Specimen Type]                                | OURINE                        | LBSPEC                        |         |           |  |  |  |
| La  | b Result   |                               |                               |         |           |  |  |  |
| #   | Sponsor-Defined Identifier                                       |                               | Test:                         | Result: | Not Done: |  |  |  |
| 6.a | 1  |                               | Chor ogonadotropin Beta_PX113 |         |           |  |  |  |
| La  | b Result Entry   |                               |                               |         |           |  |  |  |
| 6.1 | Sponsor ID:<br>[Sponsor-Defined Identifier]                      |                               | LBSPID                        |         |           |  |  |  |
| 6.2 | Pest:<br>[Test:]   | Chor ogonadotropin Beta_PX113 |                               |         |           |  |  |  |
| 6.3 | Result:  | O NEGAT                       | IVE LBORRES                   |         |           |  |  |  |
| 6.4 | Not Done:<br>[Not Done:]   | NOT DONE LBSTAT               |                               |         |           |  |  |  |

|     | <u>UDYID</u><br>59100                                     |  | ΔΤΙΟ | ON ERROR (MED   | ERROR) - R                           | Repeating Form  | 1                              |                                 | p 12-70701                                | rse Events |
|-----|---|--|------|---|--------------------------------------|---|--------------------------------|---------------------------------|---|------------|
| - 1 |   |  |      | t Is the medication   | Study<br>Medication<br>Errors Action | Concomitant<br>Medication Given   | Non-Drug<br>Treatment<br>Given | Caused Study<br>Discontinuation | Medication Error<br>Associated With<br>AE |            |
| 1   |   |  |      |   |                                      |   |                                |                                 |   |            |
| 1.  | dication<br>Category<br>[Categor                          | /:<br>[y]  |      | MEDICATION ERROR  | AECAT                                |   |                                |                                 |   |            |
| 2.  | of Medic  | on Error (Type<br>ation Error):<br>: on Error]                         |      | AETERM  |                                      |   |                                |                                 |   |            |
| 3.  | error, re<br>incorrect<br>number<br>dispense<br>to the su | container  | ]    | A   | EIPKGID in S                         | UPPAE   |                                |                                 |   |            |
| 4.  | Start Da<br>[Start Da                                     |  |      | ✓/ ✓/ ✓   | AESTDTC                              |   |                                |                                 |   |            |
| 5.  | still ongo  | ned cat on erro  | , Õ  | YES<br>NO <b>AEENRTPT</b><br>End Date:<br>                            | = ONGOING                            |   | AST SUBJE(                     | CT ENCOUNTER                    | ]   |            |
| 6.  | with Stu  | ction Taken<br>dy Treatment:<br>1edication<br>ct on]                   | 00   | NO ACTION TAKEN<br>PERMANENTLY DISCO                                  |                                      | <sup>N</sup>  |                                |                                 |   |            |
| 7.  | Med cati  | oncomitant<br>on given?<br>n tant<br>on Given]                         | -    | NO AECONTRT   | AECMGIV in                           | SUPPAE  |                                |                                 |   |            |
| 8.  |   | on-Drug<br>nt given?<br>ug Treatment                                   | -    | NO AECONTRT   | AENDGIV in                           | SUPPAE  |                                |                                 |   |            |
| 9.  | cause th  |  |      | NO <b>AESUBJDC</b>  | in SUPPAE                            | Linked to relate  | ed DS record                   | i via RELREC                    |   |            |
| 10. | error ass<br>any adve<br>[Med cat                         | medication<br>sociated with<br>erse events?<br>on Error<br>ed With AE] |      | YES<br>AE ID:<br>AE ID:<br>AE ID:<br>AE ID:<br>AE ID:<br>AE ID:<br>NO | n SUPPAE                             | AEAENO in S<br>AEAENO in S<br>AEAENO in S<br>AEAENO in S<br>AEAENO in S | SUPPAE<br>SUPPAE<br>SUPPAE     |                                 |   |            |
| 11. | Number:<br>Only   | Adverse Event<br>: For Pfizer Use<br>Adverse Even                      |      | AEREFID   |                                      |   |                                |                                 |   |            |
| 12. | Compari<br>[hidden]<br>[Compar                            | son Term<br>ison Term]   |      | NOT SUBMITTEL   | •                                    |   |                                |                                 |   |            |
| 13. | [hidden]  | evel Term  |      | AELLT   |                                      |   |                                |                                 |   |            |
| 14. | Code [hi  | <b>.evel Term</b><br><i>dden]</i><br>Level Term                        |      | AEL   | LTCD                                 |   |                                |                                 |   |            |
| 15. | Term [hi  | ry-Derived<br>idden]<br>ary-Derived                                    |      | AEDECOD   |                                      |   |                                |                                 |   |            |

|     |   | AE=Adverse Events |
|-----|---|-------------------|
| 16. | Preferred Term Code<br>[hidden]<br>[Preferred Term Code]                            | AEPTCD            |
| 17. | High Level Term<br><i>[hidden]</i><br>[High Level Term]                             | AEHLT             |
| 18. | High Level Term Code<br>[hidden]<br>[High Level Term Code]                          | AEHLTCD           |
| 19. | High Level Group Term<br><i>[hidden]</i><br>[High Level Group<br>Term]              | AEHLGT            |
| 20. | High Level Group Term<br>Code [hidden]<br>[High Level Group Term<br>Code]           | AEHLGTCD          |
| 21. | Primary System Organ<br>Class [hidden]<br>[Primary System Organ<br>Class]           | AEBODSYS AESOC    |
| 22. | Primary System Organ<br>Class Code [hidden]<br>[Primary System Organ<br>Class Code] | AEBDSYCD AESOCCD  |

| MH=Medical Hi | story |
|---------------|-------|
|---------------|-------|

| C45  | 591001: GENERAL MEDICAL HISTORY (MEDHX) MHCAT=GENERAL MEDICAL HISTORY                     |                                    |  |                     |        |  |  |  |  |
|------|---|------------------------------------|--|---------------------|--------|--|--|--|--|
|      | Line/MH Number  |                                    | Ongoing                                |                     |        |  |  |  |  |
| 1.   |   |                                    |  |                     |        |  |  |  |  |
| Med  | ical History Details Entry  |                                    |  |                     |        |  |  |  |  |
| 1.1  | Line/MH Number:<br>[Line/MH Number]   |                                    | MHSPID                                 |                     |        |  |  |  |  |
| 1.2  | Disease/Syndrome/Surgery/Non-<br>Drug Allergies/Drug Allergies:<br>[Medical History Term] | MHTER                              | RM                                     |                     |        |  |  |  |  |
| 1.3  | Start Date:<br>[Start Date]   | /                                  |  |                     |        |  |  |  |  |
| 1.4  | Ongoing:<br>[Ongoing]   | OYES M<br>ONO<br>End Date<br>↓ ✓ / | ······································ | = LAST SUBJECT ENCC | JUNTER |  |  |  |  |
| 1.5  | Comparison Term [hidden]<br>[Comparison Term]   | NOT SL                             | IBMITTED                               |                     |        |  |  |  |  |
| 1.6  | Lowest Level Term [hidden]<br>[Lowest Level Term]   | MHLLT                              |  |                     |        |  |  |  |  |
| 1.7  | Lowest Level Term Code<br>[hidden]<br>[Lowest Level Term Code]                            |                                    | MHLLTCD                                |                     |        |  |  |  |  |
| 1.8  | Dict onary Derived Term<br>[hidden]<br>[Dictionary Derived Term]                          | MHDEC                              | OD                                     |                     |        |  |  |  |  |
| 1.9  | Preferred Term Code [hidden]<br>[Preferred Term Code]                                     |                                    | MHPTCD                                 |                     |        |  |  |  |  |
| 1.10 | High Level Term [hidden]<br>[High Level Term]   | MHHLT                              | ]                                      |                     |        |  |  |  |  |
| 1.11 | High Level Term Code [hidden]<br>[High Level Term Code]                                   |                                    | MHHLTCD                                |                     |        |  |  |  |  |
| 1.12 | High Level Group Term [hidden]<br>[High Level Group Term]                                 | MHHLG                              | Τ                                      |                     |        |  |  |  |  |
| 1.13 | High Level Group Term Code<br>[hidden]<br>[High Level Group Term Code]                    |                                    | MHHLGTCD                               |                     |        |  |  |  |  |
| 1.14 | Primary System Organ Class<br>[hidden]<br>[Primary System Organ Class]                    | MHBOD                              | SYS MHSOC                              |                     |        |  |  |  |  |
| 1.15 | Primary System Organ Class<br>Code [hidden]<br>[Primary System Organ Class<br>Code]       |                                    | MHBDSYCD MHSOCCD                       |                     |        |  |  |  |  |

# STUDYID LB=Laboratory Test Results C4591001: OXYGENATION PARAMETERS (OXYGEN) - Repeating Form LBCAT= OXYGENATION PARAMETERS # Date Time of Assessment 1 Arterial Blood Gases PaO2 Fi02 (Fraction of Inhaled Oxygen) 1 LBSCAT= BLOOD CHEMISTRY Oxygenation Parameters 1. Date Time of Assessment: [Date Time of Assessment] Image: Comparison of Assessment

|   | 😧 : 🔽 24-hour clock          |
|---|------------------------------|
| Arterial Blood Gases PaO2<br>(mmHg):<br>[Arterial Blood Gases PaO2]             | LBORRES when LBTESTCD = PO2  |
| FiO2 (Fract on of Inhaled<br>Oxygen):<br>[FiO2 (Fraction of Inhaled<br>Oxygen)] | LBORRES when LBTESTCD = FIO2 |

PE=Physical Examination

| ST  | UDYID   | Ē   | PE=Physical Examination         |
|-----|---|---|---------------------------------|
| C4  | 591001: PHYSICAL EX                             | AMINATION (PHYS EXAM) PECAT=PHYSICAL EXAMINATION  |                                 |
|     | sical Examination                               |   |                                 |
|     | Exam Date:<br>[Exam Date]                       |   |                                 |
| Phy | sical Examination Result                        |   |                                 |
| #   |   | Body System Examined  | Result                          |
| 2.a | GENERAL APPEARANCE                              |   |                                 |
| 2.b | SKIN  |   |                                 |
| 2.c | HEAD  |   |                                 |
| 2.d | EYES  |   |                                 |
| 2.e | EARS  |   |                                 |
| 2.f | NOSE  |   |                                 |
| 2.g | THROAT  |   |                                 |
| 2.h | HEART   |   |                                 |
| 2.i | LUNGS   |   |                                 |
| 2.j | ABDOMEN   |   |                                 |
| 2.k | MUSCULOSKELETAL                                 |   |                                 |
| 2.1 | EXTREMITIES                                     |   |                                 |
| 2.m | NEUROLOGICAL                                    |   |                                 |
| 2.n | LYMPH NODES                                     |   |                                 |
| Phy | sical Examination Result Entr                   | γ   |                                 |
| 2.1 | Body System Examined:<br>[Body System Examined] | PETEST  |                                 |
| 2.2 | Result:<br>[Result]                             | NORMAL PEORRES If abnormal findings, specify: (If clinically signif cant, record on the Medical History or Adve Are there clinically signif cant findings? YES PECLSIG in SUPPPE NO NOT DONE PESTAT | erse Event CRF as appropriate). |

| S   | STUDYID IS=Immunogenicity Specimen Assessment CO=Comments  |  |  |  |  |  |  |  |
|-----|--|--|--|--|--|--|--|--|
| C   | C4591001: ELECTRONIC SAMPLE TRACKING - PRIOR COVID-19 INFECTION (PRIORCOV19) //SCAT=SEROLOGY   |  |  |  |  |  |  |  |
| Ele | Electronic Sample Tracking   |  |  |  |  |  |  |  |
| 1.  | Data Origin<br>[Data Origin]   | OSITE ETRKDOR in SUPPIS  |  |  |  |  |  |  |
| 2.  | Sample Type<br>[Sample Type]   | SERUM ISSPEC   |  |  |  |  |  |  |
| 3.  | Sample Collected?<br>[Sample Collected]  | NO       COVAL when COREF=SAMPLE COLLECTED         YES       Date of Collect on:         ♥ / ♥ / ♥ / ♥ / ♥ ISDTC CODTC |  |  |  |  |  |  |
| 4.  | If no sample was collected or<br>sample was not collected<br>according to protocol, please<br>provide reason:<br>[Reason sample not collected] | COVAL when RDOMAIN = IS  |  |  |  |  |  |  |
|     |  | Sample ID  |  |  |  |  |  |  |
| 5.  | 5.   |  |  |  |  |  |  |  |
| AI  | Aliquot Entry  |  |  |  |  |  |  |  |
| Ple | ase enter barcode for each aliquo  | t.   |  |  |  |  |  |  |
| 5.  | L Sample ID<br>[Sample ID]   | NOT SUBMITTED  |  |  |  |  |  |  |

### CM=Concomitant Medications

| ST  | STUDYID CM=Concomitant Medications   |  |                          |                            |                       |                     |              |                   |       | ations        |         |
|-----|--|--|--------------------------|----------------------------|-----------------------|---------------------|--------------|-------------------|-------|---------------|---------|
| C4  | 591001: CONCO  | OMITANT MED  | ICATIONS -               | PROHIBITE                  | D (PROHIB C           | M) - Repeat         | ting Fo      | rm                |       |               |         |
| #   | Sponsor-Defined<br>Identifier  | Category for<br>Medication   |                          | ledications Pre-<br>cified | Name of<br>Medication | Dose<br>Description | Dose<br>Unit | Dose<br>Frequency | Route | Start<br>Date | Ongoing |
| 1   |  |  |                          |                            |                       |                     |              |                   |       |               |         |
| Сог | comitant Medication  | าร   |                          |                            |                       |                     |              |                   |       |               |         |
| 1.  | What is the medicatio<br>[Sponsor-Defined Ide  |  | CMS                      | SPID                       |                       |                     |              |                   |       |               |         |
| 2.  | Category:<br>[Category for Medicat   | ion]   | CORTIC                   |                            | SUPPRESSIVE THE       | RAPY                |              |                   |       |               |         |
| 3.  | Concomitant Medicati<br>[Concom tant Medicat   |  |                          | OT SUBMITTE                | ED .                  |                     |              |                   |       |               |         |
| 4.  | Med cation:  |  | CMTR                     | 7                          |                       |                     |              |                   |       |               |         |
|     | Prov de the complete<br>(including salt form, v<br>generic name is unkn<br>proprietary name. Inc<br>in the Med cat on text<br>route, use, formulatio<br>[Name of Medication] | where applicable). W<br>own, enter the full tr<br>clude clarifying inforr<br>(e.g., Ingredient(s)<br>n). | here<br>ade or<br>nation |                            |                       |                     |              |                   |       |               |         |
| 5.  | Dose:<br>[Dose Description]  |  | CMD                      | OSE CMDO                   | STXT                  |                     |              |                   |       |               |         |
| 6.  | Dose Unit:<br>[Dose Unit]  |  |                          | MDOSU                      |                       |                     |              |                   |       |               |         |
| 7.  | Dose Frequency:<br>[Dose Frequency]  |  |                          | MDOSFRQ                    |                       |                     |              |                   |       |               |         |
| 8.  | Route:<br>[Route]  |  |                          | MROUTE                     |                       |                     |              |                   |       |               |         |
| 9.  | Start Date:<br>[Start Date]  |  | /                        | ⊻/ ⊻(                      | CMSTDTC               |                     |              |                   |       |               |         |
| 10. | Ongoing?<br>[Ongoing]  |  | O YES<br>NO<br>End Da    |                            |                       | MENTPT= LA          | AST SU       | BJECT ENC         | OUNT  | ER            |         |
| 11. | Comparison Term [hic<br>[Comparison Term]  | dden]  | NOTS                     | UBMITTED                   |                       |                     |              |                   |       |               |         |
| 12. | Standardized Med cat<br>derived. [hidden]<br>[Standardized Med ca  |  |                          | COD                        |                       |                     |              |                   |       |               |         |
| 13. | Standardized Med cat<br>derived [hidden]<br>[Standardized Med ca   |  |                          | C                          | MCODE in SU           | РРСМ                |              |                   |       |               |         |

| ST   | TUDYID PR=Procedures           |  |   |                |            |          |  |  |  |
|--|--------------------------------|--|---|----------------|------------|----------|--|--|--|
| C4   | 591001: I                      | RADIATION TREATMENT  | (PROHIB ND) - Repeating Form  |                |            |          |  |  |  |
| #  | Category                       | Treatment Identifier   | Con Non-Drug Treatments Pre-specified   | Treatment      | Start Date | Ongoing? |  |  |  |
| 1  |                                |  |   |                |            |          |  |  |  |
| Rac  | liation Treat                  | ment   |   |                |            |          |  |  |  |
| 1.   | Category:<br>[Category]        |  | RADIATION THERAPY     PRCAT   |                |            |          |  |  |  |
| 2.   | What is the t<br>[Treatment I  | reatment Identifier?<br>dentifier]   | PRSPID  |                |            |          |  |  |  |
| 3.   |                                | Non-drug Treatment Pre-specified:<br>ug Treatments Pre-specified]  | O YES PRPRESP   |                |            |          |  |  |  |
| 4.   | 4. Treatment:<br>[Treatment]   |  | PRTRT   |                |            |          |  |  |  |
| 5.   | Start Date:<br>[Start Date]    |  |   |                |            |          |  |  |  |
| 6.   | Ongoing?<br>[Ongoing?]         |  | YES     PRENRTPT= ONGOING     PRENTPT       NO     End Date:     Image: Comparison of the second secon | E LAST SUBJECT | ENCOUNTER  | ]        |  |  |  |
| 7. Comparison Term [hidden]<br>[Comparison Term] |                                |  | NOT SUBMITTED   |                |            |          |  |  |  |
| 8.   | Lowest Level<br>[Lowest Leve   | Term [hidden]<br>I Term]   | PRLLT in SUPPPR   |                |            |          |  |  |  |
| 9.   | Lowest Level                   | Term Code [hidden]<br>I Term Code]   | PRLLTCD in SUPPPR   |                |            |          |  |  |  |
| 10.  |                                | erived Term [hidden]<br>erived Term]   | PRDECOD   |                |            |          |  |  |  |
| 11.  | Preferred Ter<br>[Preferred Te | r <b>m Code [<i>hidden</i>]</b><br>rrm Code]   | PRPTCD in SUPPPR  |                |            |          |  |  |  |
| 12.  | High Level Te<br>[High Level T |  | PRHLT in SUPPPR   |                |            |          |  |  |  |
| 13.  | High Level Te<br>[High Level T | erm Code [hidden]<br><sup>[</sup> erm Code]  | PRHLTCD in SUPPPR   |                |            |          |  |  |  |
| 14.  | High Level G<br>[High Level G  | r <b>oup Term [<i>hidden</i>]</b><br>Group Term]   | PRHLGT in SUPPPR  |                |            |          |  |  |  |
| 15.  |                                | roup Term Code [hidden]<br>Group Term Code]  | PRHLGTCD in SUPPPR  |                |            |          |  |  |  |
| 16.  |                                | <b>em Organ Class [hidden]</b><br>tem Organ Class]   | PRBODSYS in SUPPPR PRSOC in SUP   | PPR            |            |          |  |  |  |
| 17.  |                                | rimary System Organ Class Code [hidden]<br>rimary System Organ Class Code]  PRBDSYCD in SUPPPR PRSOCCD in SUPPPR |   |                |            |          |  |  |  |

### VS=Vital Signs C4591001: VITAL SIGNS - PULSE OX ROOM AIR (PULSE OX) - Repeating Form VSCAT=GENERAL VITAL SIGNS

| <b>U</b> 4 | S91001: VITAL SIGNS                               | - PULSE UX ROOM AIR (PULSE U | x) - Repeating Form recentled that older |  |  |
|------------|---|------------------------------|--|--|--|
| #          | Date:   |                              | Vital Signs Details                      |  |  |
| 1          |   |                              |  |  |  |
| Vita       | al Signs  |                              |  |  |  |
|            | Date:<br>[Date:]                                  |                              |  |  |  |
| Vita       | al Signs Details                                  |                              |  |  |  |
| #<br>✓     | Re  | ecord Identifier:            | Oxygen Saturation                        |  |  |
| 2.a        | 1   |                              |  |  |  |
| Vita       | al Signs Details Entry                            |                              |  |  |  |
| 2.1        | Record Identifier:<br>[Record Identifier:]        | O <sup>1</sup> VSSPID        |  |  |  |
| 2.2        | SP02 Pulse Oximetry %         [Oxygen Saturation] |                              |  |  |  |

## STUDYID DS=Disposition C4591001: RANDOMIZATION (RAND) DSCAT=PROTOCOL MILESTONE Disposition 1. Randomizat on Date : Image: Ima

| [Randomization Date :]                              |                    |  |
|---|--------------------|--|
| <br>Randomizat on Number:<br>[Randomization Number] | DSREFID            |  |
| Randomizat on Group:<br>[Randomization Group]       | DSRANGRP in SUPPDS |  |

### C4591001: REACTOGENICITY DIARY (REAC DIARY)

| R  | eactogenicity Diary                                     | REACTOFL='Y' in SUPPDM when non-missing  |
|----|---|--|
| 1. | Select appropriate response -                           | O YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT <b>of vaccination start date</b> |
|    | Reactogen c ty diary collection<br>[Trigger Response 9] | ONO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT <b>REACTOFL='N' in SUPPDM</b>  |

DM=Demographics

| ST       | UDYID   |  | FA=F   | Findings About Events or Interventions |  |  |  |  |
|----------|---|--|--|--|--|--|--|--|
|          |   |  |  | -                                      |  |  |  |  |
|          | C4591001: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT (REACTION) Inplanned Assessment Of Local Reaction FACAT=REACTOGENICITY -UNPLANNED ASSESSMENT  |  |  |  |  |  |  |  |
| <u> </u> | CISR Category [hidden] UNPLANNED ASSESSMENT OF LOCAL REACTION/SYSTEMIC EVENT NOT SUBMITTED  |  |  |  |  |  |  |  |
|          | [CISR Category]   | ategory]   |  |  |  |  |  |  |
|          | Date of Assessment:<br>[Date of Assessment]   |  | ADTC   |  |  |  |  |  |
|          | Injection Site Location<br>[Injection S te Location]  | O DELTOID MUSCLE   | DELTOID MUSCLE FALOC   |  |  |  |  |  |
|          | Injection Site Body S de:<br>[Injection S te Body Side]   |  |  |  |  |  |  |  |
| Rea      | action  |  |  |  |  |  |  |  |
| #        |   | ction:   | R  | eaction Present:                       |  |  |  |  |
| 5.a      |   |  |  |  |  |  |  |  |
|          | SWELLING  |  |  |  |  |  |  |  |
| Rea      | action Entry  |  |  |  |  |  |  |  |
| 5.1      | Reaction:<br>[React on:]  | <ul> <li>REDNESS</li> <li>SWELLING</li> </ul>                    |  |  |  |  |  |  |
|          | Present:       YES       FAORRES when FATESTCD=OCCUR         Maximum Diameter (cm):       FAORRES when FATESTCD=MAXDIAM         Minimum Diameter (cm):       FAORRES when FATESTCD=MINDIAM         Meets Grade 4 Reaction Cr teria:       YES         NO       NO |  |  |  |  |  |  |  |
| Syr      | nptom   |  |  |  |  |  |  |  |
| #        |   | Symptom:   |  | Symptom Present:                       |  |  |  |  |
| 6.a      | PAIN AT INJECTION SITE  |  |  |  |  |  |  |  |
| 6.b      |   |  |  |  |  |  |  |  |
| 6.c      |   |  |  |  |  |  |  |  |
| 6.d      |   |  |  |  |  |  |  |  |
| 6.e      | DIARRHEA<br>NEW OR WORSENED MUSCLE  | DATN   |  |  |  |  |  |  |
| 6.f      |   |  |  |  |  |  |  |  |
| <u> </u> | CHILLS  |  |  |  |  |  |  |  |
|          |   |  |  |  |  |  |  |  |
| <u> </u> | Symptom:<br>[Symptom:] [Symptom:]   |  |  |  |  |  |  |  |
| 6.2      | Symptom Present:<br>[Symptom Present:]  | Symptom Grade:<br>1<br>2<br>3<br>4<br>Event related to Study Tre | n FATESTCD=OCCUR<br>nen FATESTCD=SEV<br>eament?<br>when FATESTCD=REL |  |  |  |  |  |

| ST  | UDYID   |   |            |             |            | PR=P       | rocedures |  |
|-----|---|---|------------|-------------|------------|------------|-----------|--|
| _   | 591001: RESPIRATORY TREATME   | NT (RESP TX) - Repea  | atina Forn | PRCAT=GENE  | RAL NON-DI |            |           |  |
| #   |   | Non-Drug Treatments Pre-sp  |            | Treatment   | Treatment  | Start Date | Ongoing?  |  |
| 1   |   |   |            |             |            |            |           |  |
| Res | spiratory Treatment   |   |            |             | 1          | 1          | 1         |  |
| 1.  | What is the treatment Identifier?<br>[Treatment Identifier]                             | PRSPID  |            |             |            |            |           |  |
| 2.  | Concomitant Non-drug Treatment Pre-specified<br>[Con Non-Drug Treatments Pre-specified] | OYES PRPRESP  |            |             |            |            |           |  |
| 3.  | Treatment:<br>[Treatment]   | NON-INVASIVE POSITIVE PRESSURE VENTILATION CPAP PRTRT MECHANICAL VENTILATION EXTRACORPOREAL MEMBRANE OXYGENATION HIGH FLOW OXYGEN THERAPY |            |             |            |            |           |  |
| 4.  | Treatment:<br>[Treatment]   | PRTRT   |            |             |            |            |           |  |
| 5.  | Start Date:<br>[Start Date]   |   | STDTC      |             |            |            |           |  |
| 6.  | Ongoing?<br>[Ongoing?]  | YES     PRENRTPT= OI       NO     End Date:       ♥ /     ♥ /   | NGOING     | PRENTPT= LA | ST SUBJECT | ENCOUNTE   | R         |  |
| 7.  | Comparison Term [hidden]<br>[Comparison Term]   | NOT SUBMITTED   |            |             |            |            |           |  |
| 8.  | Lowest Level Term [hidden]<br>[Lowest Level Term]                                       | PRLLT in SUPPPR   |            |             |            |            |           |  |
| 9.  | Lowest Level Term Code [hidden]<br>[Lowest Level Term Code]                             | PRLLTC  | D in SUPP  | PPR         |            |            |           |  |
| 10. | D ctionary Derived Term [hidden]<br>[D ctionary Derived Term]                           | PRDECOD   |            |             |            |            |           |  |
| 11. | Preferred Term Code [hidden]<br>[Preferred Term Code]                                   | PRPTCI  | ) in SUPPI | PR          |            |            |           |  |
| 12. | High Level Term [hidden]<br>[High Level Term]   | PRHLT in SUPPPR   |            |             |            |            |           |  |
| 13. | High Level Term Code [hidden]<br>[High Level Term Code]                                 | PRHLTC  | CD in SUPI | PPR         |            |            |           |  |
| 14. | High Level Group Term [hidden]<br>[High Level Group Term]                               | PRHLGT in SUPPPR  | ]          |             |            |            |           |  |
| 15. | High Level Group Term Code [hidden]<br>[High Level Group Term Code]                     | PRHLG   | TCD in SU  | PPPR        |            |            |           |  |
| 16. | Primary System Organ Class [hidden]<br>[Primary System Organ Class]                     | PRBODSYS in SUPP  | PR PRSO    | C in SUPPPR |            |            |           |  |
| 17. | Primary System Organ Class Code [hidden]<br>[Primary System Organ Class Code]           | PRBDS   | YCD in SU  | IPPPR PRSO  | CCD in SUP | PPR        |           |  |

PR-Procedures

| <b>S</b> 7 | TUDYID PR=Procedure  |         |  |                    |             |                   |             | Procedures |            |
|------------|--|---------|--|--------------------|-------------|-------------------|-------------|------------|------------|
| C4         | 591001: RESPIRATORY  | TREATME | NT (RESP T                                       | X) - Repeating     | g Form 🦻    | RCAT=GENE         | RAL NON-DI  | RUG TREAT  | MENT       |
| #          | Treatment Identifier   | Con N   | on-Drug Treat                                    | ments Pre-specifie | ed          | Treatment         | Treatment   | Start Date | Ongoing?   |
| 1          |  |         |  |                    |             |                   |             |            |            |
|            | spiratory Treatment  |         |  |                    |             |                   |             |            |            |
| 1.         | What is the treatment Identifier?<br>[Treatment Identifier]      |         | PRSPID   |                    |             |                   |             |            |            |
| 2.         | Concomitant Non-drug Treatment<br>[Con Non-Drug Treatments Pre-s |         | OYES PRPR  | RESP               |             |                   |             |            |            |
| 3.         | Treatment:<br>[Treatment]  |         | O INTUBATION<br>NON-INVASI<br>CPAP<br>OXYGEN THE | IVE POSITIVE PRESS | SURE VENTIL | ATION <b>PRTR</b> | Γ           |            |            |
| 4.         | Treatment:<br>[Treatment]  |         | PRTRT  |                    |             |                   |             |            |            |
| 5.         | Start Date:<br>[Start Date]                                      |         |  | / PRST             | DTC         |                   |             |            |            |
| 6.         | Ongoing?<br>[Ongoing?]   |         | OYES<br>NO<br>End Date:<br>↓ ↓                   | ENRTPT= ONG        | OING PI     | RENTPT= LA        | ST SUBJEC1  | ENCOUNTE   | <u>:</u> R |
| 7.         | Comparison Term [hidden]<br>[Comparison Term]                    |         | NOT SUBI   | MITTED             |             |                   |             |            |            |
| 8.         | Lowest Level Term [hidden]<br>[Lowest Level Term]                |         | PRLLT in   | SUPPPR             |             |                   |             |            |            |
| 9.         | Lowest Level Term Code [hidden]<br>[Lowest Level Term Code]      | 1       |  | PRLLTCD i          | in SUPPP    | R                 |             |            |            |
| 10.        | D ctionary Derived Term [hidden]<br>[D ctionary Derived Term]    | 1       | PRDECOD  |                    |             |                   |             |            |            |
| 11.        | Preferred Term Code [hidden]<br>[Preferred Term Code]            |         |  | PRPTCD in          | SUPPPR      | 2                 |             |            |            |
| 12.        | High Level Term [hidden]<br>[High Level Term]                    |         | PRHLT in   | SUPPPR             |             |                   |             |            |            |
| 13.        | High Level Term Code [hidden]<br>[High Level Term Code]          |         |  | PRHLTCD            | in SUPPP    | PR .              |             |            |            |
| 14.        | High Level Group Term [hidden]<br>[High Level Group Term]        |         | PRHLGT   | in SUPPPR          |             |                   |             |            |            |
| 15.        | High Level Group Term Code [hia<br>[High Level Group Term Code]  | lden]   |  | PRHLGTC            | D in SUPF   | PPR               |             |            |            |
| 16.        | Primary System Organ Class [hid<br>[Primary System Organ Class]  | den]    | PRBODS   | YS in SUPPPR       | PRSOC       | in SUPPPR         |             |            |            |
| 17.        | Primary System Organ Class Cod                                   |         |  | PRBDSYC            | D in SUP    | PPR PRSC          | OCCD in SUP | PPR        |            |

### C4591001: FURTHER VACCINATION CONFIRMATION (REVAX CONF)

| Further Vaccination Confirmation   |  |  |  |  |  |  |
|--|--|--|--|--|--|--|
| part cipant willing to return for       Participant is:         Vaccination 3?       eligible per local         [Trigger Response 1]       eligible per othe         eligible and NOT       eligible and NOT | to return for Vaccinat on 3<br>national recommendations and confirmed to have received only placebo at Vaccination 1/2<br>protocol allowance(s) and confirmed to have received only placebo at Vaccination 1/2<br>confirmed to have received only placebo at Vaccination 1/2<br>illing to return for Vaccination 3 OR otherwise not eligible |  |  |  |  |  |

### STUDYID DS=Disposition C4591001: INFORMED CONSENT - FURTHER VACCINATION (REVAX CONS) DSCAT=PROTOCOL MILESTONE Informed Consent - Further Vaccination Informed Consent - Further Vaccination

| 1 | Consent Was:   | OBTAINED                      | DSSTDTC when            |  |
|---|----------------|-------------------------------|-------------------------|--|
|   | [Consent Was:] | Date Written Consent Obtained | DSTERM/DSDECOD=INFORMED |  |
|   |                |                               | CONSENT OBTAINED        |  |

| ST  | TUDYID   | IE=Inclusion/Exclusion Criteria Not Met |  |  |
|-----|--|---|--|--|
| C4  | 4591001: INCLUSION/EXCLUSION CRITERIA - FURTH                              | HER VACCINATION (REVAX IE)              |  |  |
|     | Criteri  | rion Description                        |  |  |
| 1.  |  |   |  |  |
| Inc | nclusion Criteria Not Met Entry  |   |  |  |
| 1.1 | 1 Description of Inclusion<br>Cr terion Not Met<br>[Criter on Descript on] | V                                       |  |  |
|     | Criteri  | rion Description                        |  |  |
| 2.  |  |   |  |  |
| Exe | xclusion Criteria Met Entry  |   |  |  |
| 2.1 | 1 Description of Exclusion<br>Cr terion Met<br>[Criter on Descript on]     | Y                                       |  |  |

| S  | TUDYID   | MB=Microbiology Specimen CO=Comments   |
|----|--|--|
| С  | 4591001: ELECTRONIC  | SAMPLE TRACKING - REPEAT SWAB (RSWAB) MBCAT=VIROLOGY   |
| E  | ectronic Sample Tracking   |  |
| 1. | Data Origin<br>[Data Origin]   | OSITE ETRKDOR in SUPPMB  |
| 2. | Sample Type<br>[Sample Type]   | ○ NASAL_SWAB ○ NASAL_SWAB_SELF MBSPEC  |
| 3. | Sample Collected?<br>[Sample Collected]  | NO       NOT SUBMITTED         YES       Date of Collect on:         ▼ /       ▼ /         ▼ /       ▼ / |
| 4. | If no sample was collected or<br>sample was not collected<br>according to protocol, please<br>provide reason:<br>[Reason sample not collected] | COVAL when RDOMAIN = MB  |

Sample ID

### Aliquot Entry

5.

ΡI

| Plea | Please enter barcode for each aliquot. |               |  |  |
|------|--|---------------|--|--|
| 5.1  | Sample ID                              | NOT SUBMITTED |  |  |
|      | [Sample ID]                            |               |  |  |

| S   | TUDYID   | IS=Immunogenicity Specimen Assessment CO=Comments  |  |  |  |
|-----|--|--|--|--|--|
| C   | C4591001: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY (SAMP TRK)   |  |  |  |  |
| Ele | ectronic Sample Tracking   |  |  |  |  |
| 1.  | Data Origin<br>[Data Origin]   | OSITE ETRKDOR in SUPPIS  |  |  |  |
| 2.  | Sample Type<br>[Sample Type]   | O SERUM ISSPEC   |  |  |  |
| 3.  | Sample Collected?<br>[Sample Collected]  | NO<br>YES       COVAL when COREF=SAMPLE COLLECTED         Date of Collect on:       Image: Control in the second |  |  |  |
| 4.  | If no sample was collected or<br>sample was not collected<br>according to protocol, please<br>provide reason:<br>[Reason sample not collected] | COVAL when RDOMAIN = IS  |  |  |  |
|     |  | Sample ID  |  |  |  |
| 5.  |  |  |  |  |  |
| AI  | Aliquot Entry  |  |  |  |  |
| Ple | Please enter barcode for each aliquot.   |  |  |  |  |
| 5.  | 1 Sample ID<br>[Sample ID]   | NOT SUBMITTED  |  |  |  |

| C  | C4591001: INFORM SCREENING (SCREEN) NOT SUBMITTED |  |  |
|----|---|--|--|
| In | InForm Screening                                  |  |  |
| 1. | InForm Initials [hidden]<br>[InForm Initials]     |  |  |
| 2. | Birth Date:<br>[Birth Year]                       |  |  |

| S   | MB=Microbiology Specimen         CO=Comments   |  |  |  |  |
|-----|--|--|--|--|--|
| C   | C4591001: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF (SELF SWAB) MBCAT=VIROLOGY  |  |  |  |  |
| Ele | ectronic Sample Tracking   |  |  |  |  |
| 1.  | Data Origin<br>[Data Origin]   | OSITE ETRKDOR in SUPPMB  |  |  |  |
| 2.  | Sample Type<br>[Sample Type]   | ○ NASAL_SWAB_SELF MBSPEC   |  |  |  |
| 3.  | Sample Collected?<br>[Sample Collected]  | NO       NOT SUBMITTED         YES       Date of Collect on:         ▼ /       ▼ /         ▼ /       ▼ /         ▼ /       ▼ / |  |  |  |
| 4.  | If no sample was collected or<br>sample was not collected<br>according to protocol, please<br>provide reason:<br>[Reason sample not collected] | COVAL when RDOMAIN = MB  |  |  |  |
|     | Sample ID  |  |  |  |  |

5.

Aliquot Entry

5.1 Sample ID [Sample ID]

Please enter barcode for each aliquot.

NOT SUBMITTED

#### Annotated Study Book - C4591001

| STU      | Original version   | : VERSION 1: USED PRIOR TO JULY 6, 2020<br>ERSION 2: USED AFTER JULY 6, 2020<br>ERSION 2: USED AFTER JULY 6, 2020 | t<br>ons CE=Clinical Events |  |  |
|----------|--|---|-----------------------------|--|--|
| C45      | C4591001: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 (SOD) FACAT=EFFICACY CECAT=EFFICACY                   |   |                             |  |  |
| Sign     | igns and Symptoms FASCAT=RESPIRATORY ILLNESS CESCAT=SIGNS AND SYMPTOMS OF DISEASE                        |   |                             |  |  |
|          | ate of Assessment:<br>Date of assessment]  |   |                             |  |  |
|          | ate of First Symptom Started:<br>First Symptom Started Date]   | ✓ / ✓ FAORRES when FATESTCD=FSYMDATE CESTD  | TC                          |  |  |
|          | ymptoms Ongoing?<br>Symptoms Ongoing]  | O YES FAORRES when FATESTCD=SYMONGO CEENRTPT= ONGOI   | NG CEENTPT= ONGOING         |  |  |
|          |  | Date of Last Symptom Resolved:  |                             |  |  |
| Svm      | ptoms  |   |                             |  |  |
| #        | Event Pre-specified  | Symptoms  | Symptom Present             |  |  |
| ✓<br>4.a | YES  | FEVER   |                             |  |  |
| 4.b      | YES  | NEW OR INCREASED COUGH  |                             |  |  |
| 4.c      | YES  | NEW OR INCREASED SHORTNESS OF BREATH  |                             |  |  |
| 4.d      | YES  | CHILLS  |                             |  |  |
| 4.e      | YES  | NEW OR INCREASED MUSCLE PAIN  |                             |  |  |
| 4.f      | YES  | NEW LOSS OF TASTE OR SMELL  |                             |  |  |
| 4.g      | YES  | NEW OR INCREASED SORE THROAT  |                             |  |  |
| 4.h      | YES  | DIARRHEA  |                             |  |  |
| 4.i      | YES  | VOMITING  |                             |  |  |
| <u> </u> | ptoms Entry  |   |                             |  |  |
|          | Event Pre-specified: [hidden]<br>[Event Pre-specified]   | VES NOT SUBMITTED   |                             |  |  |
|          | Symptoms:<br>[Symptoms]  |   |                             |  |  |
| 4.3      | Was symptom present?<br>[Symptom Present]  | O YES<br>NO ► FAORRES when FATESTCD=OCCUR   |                             |  |  |
|          |  | Symptoms - Other  |                             |  |  |
| 5.<br> ✔ |  |   |                             |  |  |
|          | ptoms - Other Entry  |   |                             |  |  |
| 5.1      | Symptoms - Other Text:<br>[Symptoms - Other]   | NOT SUBMITTED   |                             |  |  |
| 5.2      | Comparison Term: [hidden]<br>[Comparison Term]   |   |                             |  |  |
|          |  |   |                             |  |  |
|          |  |   |                             |  |  |
| 5.3      | Lowest Level Term [hidden]<br>[Lowest Level Term]  | NOT SUBMITTED   |                             |  |  |
| 5.4      | Lowest Level Term Code<br>[hidden]<br>[Lowest Level Term Code]   | NOT SUBMITTED   |                             |  |  |
| 5.5      | Dict onary Derived Term<br>[hidden]<br>[Dictionary Derived Term]   | FAOBJ   |                             |  |  |
| 5.6      | Preferred Term Code [hidden]<br>[Preferred Term Code]  | NOT SUBMITTED   |                             |  |  |
| 5.7      | High Level Term [hidden]<br>[High Level Term]  | NOT SUBMITTED   |                             |  |  |
| 5.8      | High Level Term Code<br>[hidden]<br>[High Level Term Code]   | NOT SUBMITTED   |                             |  |  |
| 5.9      | High Level Group Term<br>[hidden]<br>[High Level Group Term]   | NOT SUBMITTED   |                             |  |  |
| 5.10     | High Level Group Term Code<br>[hidden]<br>[High Level Group Term Code]                                   | NOT SUBMITTED   |                             |  |  |
| 5.11     | Primary System Organ Class<br>[hidden]<br>[Primary System Organ Class]                                   | NOT SUBMITTED   |                             |  |  |
| 5.12     | Primary System Organ Class<br>Primary System Organ Class<br>Code [hidden]<br>[Primary System Organ Class | NOT SUBMITTED   |                             |  |  |

Code]

FA=Findings About Events or Interventions

#### Annotated Study Book - C4591001

090177e196f3882d\Final\Final On: 04-May-2021 20:47 (GMT)

| STL      | Original version   | : VERSION 1: USED PRIOR TO JULY 6, 2020<br>ERSION 2: USED AFTER JULY 6, 2020<br>EVents or Interventio   | t<br>ons CE=Clinical Events |
|----------|--|---|-----------------------------|
| C4!      |  |   | ECAT=EFFICACY               |
|          |  |   |                             |
|          | ate of Assessment:   |   | ASE                         |
|          | Date of assessment]  |   |                             |
| ] [      | ate of First Symptom Started:<br>First Symptom Started Date]               | ▼ / ▼ / ▼ FAORRES when FATESTCD=FSYMDATE CESTD  | TC                          |
|          | ymptoms Ongoing?<br>Symptoms Ongoing]                                      | OYES FAORRES when FATESTCD=SYMONGO CEENRTPT= ONGOIN   | G CEENTPT= ONGOING          |
|          |  | NO     Image: Second control of Lord control control of Lord control contro contro control contro control control control control control c | AT CURRENT VISIT            |
| - Cyrm   | ptoms  | PAORRES WIEI PATESTODELSTINDATE   |                             |
| 3ym<br># | Event Pre-specified  | Symptoms  | Symptom Present             |
| V        |  | - ,   | -,                          |
| 4.a      | YES  | FEVER   |                             |
| 4.b      | YES  | LOSS OF TASTE/SMELL   |                             |
| 4.c      | YES  | NEW OR INCREASED COUGH  |                             |
| 4.d      | YES  | NEW OR INCREASED NASAL CONGESTION   |                             |
| 4.e      | YES  | NEW OR INCREASED NASAL DISCHARGE  |                             |
| 4.f      | YES  | NEW OR INCREASED SHORTNESS OF BREATH  |                             |
| 4.g      | YES  | NEW OR INCREASED SORE THROAT  |                             |
| 4.h      | YES  | NEW OR INCREASED SPUTUM PRODUCTION  |                             |
| 4.i      | YES  | NEW OR INCREASED WHEEZING   |                             |
| Sym      | ptoms Entry  |   |                             |
| 4.1      | Event Pre-specified: [hidden]<br>[Event Pre-specified]                     | O YES NOT SUBMITTED   |                             |
| 4.2      | Symptoms:<br>[Symptoms]  | FAOBJ CETERM  |                             |
| 4.3      | Was symptom present?<br>[Symptom Present]                                  | ● YES<br>● NO FAORRES when FATESTCD=OCCUR   |                             |
|          |  | Symptoms - Other  |                             |
| 5.       |  |   |                             |
|          |  |   |                             |
| <u> </u> | ptoms - Other Entry  |   |                             |
| 5.1      | Symptoms - Other Text:<br>[Symptoms - Other]                               | NOT SUBMITTED   |                             |
| 5.2      | Comparison Term: [hidden]<br>[Comparison Term]                             | NOT SUBMITTED   |                             |
| 5.3      | Lowest Level Term [hidden]<br>[Lowest Level Term]                          | NOT SUBMITTED   |                             |
| 5.4      | Lowest Level Term Code<br>[hidden]<br>[Lowest Level Term Code]             | NOT SUBMITTED   |                             |
| 5.5      | Dict onary Derived Term<br>[hidden]<br>[Dictionary Derived Term]           | FAOBJ   |                             |
| 5.6      | Preferred Term Code [hidden]<br>[Preferred Term Code]                      | NOT SUBMITTED   |                             |
| 5.7      | High Level Term [hidden]<br>[High Level Term]                              | NOT SUBMITTED   |                             |
| 5.8      | High Level Term Code<br>[hidden]<br>[High Level Term Code]                 | NOT SUBMITTED   |                             |
| 5.9      | High Level Group Term<br>[hidden]<br>[High Level Group Term]               | NOT SUBMITTED   |                             |
| 5.10     | High Level Group Term Code<br>[hidden]<br>[High Level Group Term Code]     | NOT SUBMITTED   |                             |
| 5.11     | Primary System Organ Class<br>[hidden]<br>[Primary System Organ Class]     | NOT SUBMITTED   |                             |
| 5.12     | Primary System Organ Class<br>Orde [hidden]<br>[Primary System Organ Class | NOT SUBMITTED   |                             |

Code]

FA=Findings About Events or Interventions

| C  | C4591001: STRATIFICATION (STRAT) NOT SUBMITTED                                    |   |
|----|---|---|
| St | ratification  |   |
| 1. | Select appropriate response -<br>Randomizat on Stage<br>[Trigger Response 3]      | ○Non-Sentinel Stage 1   |
| 2. | Select appropriate response -<br>Randomizat on Age Group<br>[Trigger Response 4]  | <ul> <li>○ Age 18 to 55</li> <li>○ Age 65 to 85</li> </ul>            |
| 3. | Select appropriate response -<br>Randomizat on Dose<br>[Trigger Response 5]       | <ul> <li>10 mcg</li> <li>20 mcg</li> <li>30 mcg</li> </ul>            |
| 4. | Select appropriate response -<br>Randomizat on Dose Group<br>[Trigger Response 8] | 0 21 Day<br>0 60 Day  |
| 5. | Select appropriate response -<br>BNT Number<br>[Trigger Response 7]               | (BNT162b1 or PBO)         (BNT162b2 or PBO)         (BNT162b3 or PBO) |

| С  | C4591001: STRATIFICATION (STRAT) NOT SUBMITTED                                   |   |  |
|----|--|---|--|
| St | tratification  |   |  |
| 1. | Select appropriate response -<br>Randomizat on Stage<br>[Trigger Response 3]     | O Stage 2   |  |
| 2. | Select appropriate response -<br>Randomizat on Age Group<br>[Trigger Response 4] | <ul> <li>○ Age 18 to 55</li> <li>○ Age 56 to 85</li> </ul>  |  |
| 3. | Select appropriate response -<br>Randomizat on Dose<br>[Trigger Response 5]      | <ul> <li>10 mcg</li> <li>20 mcg</li> <li>30 mcg</li> </ul>  |  |
| 4. | Select appropriate response -<br>BNT Number<br>[Trigger Response 7]              | <ul> <li>○ (BNT162b1 or PBO)</li> <li>○ (BNT162b2 or PBO)</li> <li>○ (BNT162b3 or PBO)</li> </ul> |  |

### C4591001: STRATIFICATION (STRAT) NOT SUBMITTED

| C  | C4591001: STRATIFICATION (STRAT) NOT SUBMITTED  |  |  |
|----|---|--|--|
| St | ratification  |  |  |
| 1. | Select appropriate response -<br>Randomizat on Stage<br>[Trigger Response 3]                  | O Stage 1<br>O Stage 2   |  |
| 2. | Select appropriate response -<br>Randomizat on Age Group<br>[Trigger Response 4]              | <ul> <li>Age 18 to 55</li> <li>Age 56 to 85</li> <li>Age 65 to 85</li> </ul>   |  |
| 3. | Select appropriate response -<br>Randomizat on Dose<br>[Trigger Response 5]                   | Low dose level (3mcg)         Medium dose level (10mcg)         High dose level (30mcg)         Low dose level (10mcg)         Medium dose level (30mcg)         High dose level (100mcg)         Low dose level (0.1mcg)         Medium dose level (0.3mcg)         High dose level (10mcg)         Medium dose level (0.3mcg)         Medium dose level (0.3mcg)         High dose level (1mcg)         Mid-High dose level (50mcg)         Low-Mid dose level (20mcg) |  |
| 4. | Select appropriate response -<br>Randomizat on Dose Group<br>[hidden]<br>[Trigger Response 6] | <ul> <li>21 Day 2-dose group</li> <li>60 Day 2-dose group</li> <li>1-dose group</li> </ul>   |  |
| 5. | Select appropriate response -<br>Randomizat on Dose Group<br>[Trigger Response 8]             | 0 21 Day<br>0 60 Day   |  |
| 6. | Select appropriate response -<br>BNT Number<br>[Trigger Response 7]                           | <ul> <li>(BNT162a1 or PBO)</li> <li>(BNT162b1 or PBO)</li> <li>(BNT162b2 or PBO)</li> <li>(BNT162c2 or PBO)</li> <li>(BNT162b3 or PBO)</li> </ul>  |  |

| C  | C4591001: SUBJECT STATUS (SUB STATU) NOT SUBMITTED |  |  |  |  |  |  |  |
|----|--|--|--|--|--|--|--|--|
| Su | Subject Status                                     |  |  |  |  |  |  |  |
|    | Subject Status<br>[Subject Status]                 |  |  |  |  |  |  |  |
| 2. | Subject Status Date<br>[Status Date]               |  |  |  |  |  |  |  |

### STUDYID DS=Disposition C4591001: INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE (SURV CONS) DSCAT=PROTOCOL MILESTONE

| I | Informed Consent - Asymptomatic Surveillance |                               |   |  |  |  |  |
|---|--|-------------------------------|---|--|--|--|--|
| 1 | Consent Was:<br>[Consent Was:]               | Date Written Consent Obtained | DSSTDTC when<br>DSTERM/DSDECOD=INFORMED<br>CONSENT OBTAINED |  |  |  |  |

| <b>S</b> 1 | TUDYID   | MB=Microbiology Specimen CO=Comments   |  |  |  |  |  |  |
|------------|--|--|--|--|--|--|--|--|
| C          | C4591001: ELECTRONIC SAMPLE TRACKING - NASAL SWAB (SWAB PFE) MBCAT=VIROLOGY  |  |  |  |  |  |  |  |
| El         | ectronic Sample Tracking   |  |  |  |  |  |  |  |
| 1.         | Data Origin<br>[Data Origin]   | OSITE ETRKDOR in SUPPMB  |  |  |  |  |  |  |
| 2.         | Sample Type<br>[Sample Type]   | ONASAL_SWAB MBSPEC   |  |  |  |  |  |  |
| 3.         | Sample Collected?<br>[Sample Collected]  | NO       NOT SUBMITTED         YES       Date of Collect on:         V       V         V       V |  |  |  |  |  |  |
| 4.         | If no sample was collected or<br>sample was not collected<br>according to protocol, please<br>provide reason:<br>[Reason sample not collected] | COVAL when RDOMAIN = MB  |  |  |  |  |  |  |
|            |  | Sample ID  |  |  |  |  |  |  |

5.

Aliquot Entry

5.1 Sample ID [Sample ID]

Please enter barcode for each aliquot.

NOT SUBMITTED

| S  | <b>STUDYID</b> MB=Microbiology Specimen DI=Device Identifiers CO=Comments                   |          |   |  |   |                            |             |            |        |          |
|----|---|----------|---|--|---|----------------------------|-------------|------------|--------|----------|
| C  | 4591001: MICROBIOLOGY SPECIMEN (SWAB SITE) - Repeating Form MBCAT=CONFIRMATION OF INFECTION |          |   |  |   |                            |             |            |        |          |
| #  | Date of Collection  | Specimen | Туре  | Specimen Collect                                       | tion Location                                 | Assay Code and Description | Device Type | Trade Name | Result | Comments |
| 1  |   |          |   |  |   |                            |             |            |        |          |
| Mi | crobiology Specimen   | 1        |   |  |   |                            |             |            |        |          |
| 1. | Actual Date of Collecti<br>[Date of Collection]   | ion:     | *   | / 🖌 / 🖌  | <b>MBDTC</b>                                  |                            |             |            |        |          |
| 2. | Specimen Type:<br>[Specimen Type]   |          | ⊖SWA  | ABBED MATERIAL   | BSPEC   |                            |             |            |        |          |
| 3. | B. Specimen Collection Location:<br>[Specimen Collection Location]                          |          |   |  |   |                            |             |            |        |          |
| 4. | Assay Code and Descr<br>[Assay Code and Desc  |          | ⊖ SEVI  | SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2 <b>MBTEST</b> |   |                            |             |            |        |          |
| 5. | Device Type:<br>[Device Type]   |          | ⊖ SAR:  | S-COV-2 DIAGNOST                                       | DIAGNOSTIC TEST DIVAL when DIPARMCD = DEVTYPE |                            |             |            |        |          |
| 6. | 5. Trade Name:<br>[Trade Name]  |          | CEPHEID XPERT XPRESS SARS-COV-2 TEST DIVAL when DIPARMCD = TRADENAM |  |   |                            |             |            |        |          |
| 7. | [Result]  |          |   |  |   |                            |             |            |        |          |
| 8. | Comments/Findings/D<br>[Comments:]  | Details: | COV   | AL when RDO  | MAIN = MB                                     | l                          |             |            |        |          |

Annotated Study Book - C4591001

| ST  | JDYID  | CE=Clinical Events FA=Findings About Events or Interventions AE=Adverse Events  |  |  |  |  |  |
|-----|--|---|--|--|--|--|--|
| C4  | C4591001: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES (SYMPRDATE CECAT=REACTOGENICIT   |   |  |  |  |  |  |
|     | cination Symptoms Diary - Sy   |   |  |  |  |  |  |
| 1.  | Were medications to treat<br>fever/pain given on the last day<br>the Subject Diary was<br>completed?<br>[Fever/Pain Medication on Last<br>Diary Day]   | YES<br>Ongoing?       FAORRES         YES<br>NO       FAENRTPT= ONGOING         FAENRTPT= ONGOING       FAENTPT= ONGOING RELATIVE TO LAST DAY OF<br>DIARY PERIOD         Stop Date:       Image: Comparison of the second seco |  |  |  |  |  |
| #   | Symptom:   | Were fever or systemic symptoms present on the last day the Subject Diary was completed?  |  |  |  |  |  |
| 2.a | FEVER  | CESCAT=SYSTEMIC FASCAT=SYSTEMIC AESCAT=SYSTEMIC   |  |  |  |  |  |
| 2.b | FATIGUE  |   |  |  |  |  |  |
| 2.c | HEADACHE   |   |  |  |  |  |  |
| 2.d | CHILLS   |   |  |  |  |  |  |
| 2.e | VOMITING   |   |  |  |  |  |  |
| 2.f | DIARRHEA   |   |  |  |  |  |  |
| 2.g | NEW OR WORSENED MUSCLE P   | AIN   |  |  |  |  |  |
| 2.h | NEW OR WORSENED JOINT PAI  | N   |  |  |  |  |  |
| 2.1 | Symptom:<br>[Symptom:]   |   |  |  |  |  |  |
| 2.2 | Were fever or system c<br>symptoms present on the last<br>day the Subject Diary was<br>completed?<br>[Were fever or systemic<br>symptoms present on the last<br>day the Subject Diary was<br>completed?] | YES       NOT SUBMITTED         Ongoing       Ongoing         YES       CEENRTPT=         NO       ONGOING         Stop Date:       DAY OF DIARY PERIOD         NO       RCENDTC in SUPPCE  |  |  |  |  |  |
|     | Injection Site Location:<br>[Injection S te Location:]   | O DELTOID MUSCLE CELOC AELOC  |  |  |  |  |  |
|     | Injection Site Body S de:<br>[Injection S te Body Side:]   | OLEFT CELAT AELAT   |  |  |  |  |  |
| #   | Injection Site Reaction:   | Were injection site reactions present on the last day the Subject Diary was completed?  |  |  |  |  |  |
| 5.a | REDNESS  | CESCAT=ADMINISTRATION SITE FASCAT=ADMINISTRATION SITE   |  |  |  |  |  |
| 5.b | SWELLING   | AESCAT=ADMINISTRATION SITE  |  |  |  |  |  |
| 5.c | PAIN AT INJECTION SITE   |   |  |  |  |  |  |
| 5.1 | Injection Site React on:<br>[Injection Site Reaction:]   | O REDNESS       CETERM FAOBJ       AETERM         O SWELLING       PAIN AT INJECTION SITE   |  |  |  |  |  |
| 5.2 | Were injection s te reactions<br>present on the last day the<br>Subject Diary was completed?<br>[Were inject on site reactions<br>present on the last day the<br>Subject Diary was completed?]           | YES       NOT SUBMITTED       AEENTPT=         Ongoing       CEENRTPT=       CEENTPT= ONGOING       ONGNXVIS in       AEENRTPT         YES       ONG       RELATIVE TO LAST       SUPPCE       ONGOING       RELATIVE TO LAST         NO       Date:       DAY OF DIARY PERIOD       ONGNXVIS in       AEENRTPT       ONGOING         NO       RCENDTC in SUPPCE       DAY OF DIARY       PERIOD  |  |  |  |  |  |

|    | TUDYID  | PR=Procedures   |                     |  |
|----|---|---|---------------------|--|
| C  | 4591001: TRANSFUSI                            |   |                     |  |
| #  |   | ransfusion Type   | Date of Transfusion |  |
| 1  |   |   |                     |  |
| 1. | Transfus on Type:<br>[Transfus on Type]       | <ul> <li>PACKED RBC</li> <li>PLATELETS</li> <li>WHOLE BLOOD</li> <li>PLASMA</li> <li>OTHER</li> <li>Specify:</li> </ul> |                     |  |
| 2. | Date of Transfus on:<br>[Date of Transfusion] |   |                     |  |

| C4591   | C4591001: TREATMENT UNBLINDED (TRN UNBLN)DSCAT=OTHER EVENT   |  |  |  |  |  |  |
|---------|--|--|--|--|--|--|--|
| Treatme | Treatment Unblinded  |  |  |  |  |  |  |
|         | Date Treatment Unblinded :     Image: Constraint of the second seco |  |  |  |  |  |  |
|         | ary Reason for Unblinding:<br>ary Reason for Unblinding]   | SUBJECT SAFETY CONCERN DSTERM     OTHER     If other, specify:     ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION |  |  |  |  |  |

| С                     | 4591001: UNPLANNED           | VISIT (UNPL) NOT SUBMITTED |  |  |  |
|-----------------------|------------------------------|----------------------------|--|--|--|
| Unplanned Assessments |                              |                            |  |  |  |
| 1.                    | Assessments<br>[Assessments] |                            |  |  |  |

| S7               | TUDYID EX=Exposure EC=Exposure as Collected  |   |  |  |  |  |  |
|------------------|--|---|--|--|--|--|--|
| C4               | 591001: VA   | CCINATION (VACIN TRT) EXCAT=INVESTIGATIONAL ECCAT=INVESTIGATIONAL ECSCAT=VACCINATION  |  |  |  |  |  |
| <b>Vac</b><br>1. | Was there a  | EXSCAT=VACCINATION     PRODUCT       OYES     EXTDV in SUPPEX   |  |  |  |  |  |
|                  | temporary<br>delay of<br>vaccinat on?<br>[Temporary<br>Delay of<br>Vaccination]  | Date of First Delay:  |  |  |  |  |  |
| 2.               | Treatment<br>Name<br>[Treatment<br>Name]   |   |  |  |  |  |  |
| 3.               | Formulat on:<br>[Formulat on:]   | OINJECTION EXDOSFRM ECDOSFRM  |  |  |  |  |  |
| 4.               | Dose Date<br>Time:<br>[Dose Date<br>Time:]   | Image: Second state of the second s |  |  |  |  |  |
| 5.               | Anatomical<br>Locat on:<br>[Anatomical<br>Locat on:]   | ODELTOID MUSCLE EXLOC ECLOC   |  |  |  |  |  |
| 6.               | Body Side:<br>[Body S de:]   | OLEFT EXLAT ECLAT   |  |  |  |  |  |
| 7.               | Route:<br>[Route:]   |   |  |  |  |  |  |
| 8.               | Planned Dose:<br>[Planned Dose]  | ECDOSE  |  |  |  |  |  |
| 9.               | Planned Dose<br>Unit:<br>[Planned Dose<br>Unit]  | Oug <u>ECDOSU</u>   |  |  |  |  |  |
| 10.              | Actual Dose:<br>[Actual Dose:]   | EXDOSE ECDOSE   |  |  |  |  |  |
| 11.              | Unit:<br>[Unit:]   |   |  |  |  |  |  |
| 12.              | Was the Actual<br>Dose adjusted<br>from planned?<br>[Dose Adjusted<br>From Planned]  | YES       EXDOSADJ in SUPPEX       ECDOSADJ in SUPPEC         What was the reason the dose was adjusted?       EXADJ when more than one selected, EXADJ=MULTIPLE and individual responses are EXADJ1, EXADJ2, etc. in SUPPEX       ECADJ when more than one selected, ECADJ=MULTIPLE and individual responses are EXADJ1, EXADJ2, etc. in SUPPEX         OTHER SPECIFY       If other, specify:       ECDOSAJO in SUPPEX         EXDOSAJO in SUPPEX       ECDOSAJO in SUPPEC  |  |  |  |  |  |
| 13.              | Timeframe<br>Subject Was<br>Observed<br>[Timeframe<br>Subject Was<br>Observed]   | THE PROTOCOL SPECIFIED OBSERVATION PERIOD EXOBSVT in SUPPEX ECOBSVT in SUPPEC   |  |  |  |  |  |
| 14.              | Was the<br>subject<br>observed for at<br>least the<br>protocol<br>specified<br>observation<br>period after<br>investigational<br>product<br>administration?<br>[Observed Post<br>Dose For<br>Specified Time] | YES       EXOBSV in SUPPEX         NO       If No, specify reason:         EXOBSVD in SUPPEX       ECOBSVD in SUPPEC  |  |  |  |  |  |
| 15.              | Comparison<br>Term [hidden]<br>[Comparison<br>Term]  | NOT SUBMITTED   |  |  |  |  |  |
| 16.              | Standardized<br>Med cation<br>Name -   | EXDECOD in SUPPEX ECDECOD in SUPPEC   |  |  |  |  |  |

|     |  |                               | EX=Exposure EC=Exposure as Collected |
|-----|--|-------------------------------|--------------------------------------|
|     | D ctionary<br>Derived.<br>[hidden]<br>[Standardized<br>Med cation<br>Name]   |                               |                                      |
| 17. | Standardized<br>Med cation<br>Code -<br>D ctionary<br>Derived<br>[ <i>hidden</i> ]<br>[Standardized<br>Med cation<br>Code] | EXCD in SUPPEX ECCD in SUPPEC |                                      |

| <b>S</b> 7       | STUDYID EX=Exposure EC=Exposure as Collected   |  |   |  |          |   |  |
|------------------|--|--|---|--|----------|---|--|
| C4               | 591001: VA   | CCINATION (VACIN TRT) EXCAT=INVES  | TIGATIONAL  | ECCAT=INVESTIG   | ATIONAL  | ECSCAT=VACCINATION  |  |
| <b>Vac</b><br>1. | Was there a<br>temporary<br>delay of<br>vaccinat on?<br>[Temporary<br>Delay of<br>Vaccination]   | EXSCAT=VACCINATION       PRODUCT         YES       EXTDV in SUPPEX       ECTDV in SUPPEX         Date of First Delay:       Image: Construction       Image: FDDTC in SUPPEX         Reason(s) for Temporary Delay of Vaccination       Image: FEVER OR ACUTE ILLNESS       Image: Construction Construction         RECENT SYSTEMIC CORTICOSTEROID TREATMENT       Image: Construction Construction       Image: Construction Construction         ANTICIPATED NON-STUDY VACCINATION       Image: Construction Construction       Image: Construction Construction  | FDDTC in SU<br>EXADJ when<br>selected, EX<br>and individu | PRODUCT<br>JPPEC<br>n more than one<br>XADJ=MULTIPLE<br>ial responses are<br>ADJ2, etc. in | selected | when more than one<br>ECADJ=MULTIPLE<br>vidual responses are<br>ECADJ2, etc. in |  |
| 2.               | Treatment<br>Name<br>[Treatment<br>Name]   | EXTRT ECTRT  |   |  |          |   |  |
| 3.               | Formulat on:<br>[Formulat on:]   | OINJECTION EXDOSFRM ECDOSFRM   |   |  |          |   |  |
| 4.               | Dose Date<br>Time:<br>[Dose Date<br>Time:]   | Image: Construction of the second | ECSTDTC   | ECENDTC  |          |   |  |
| 5.               | Anatomical<br>Locat on:<br>[Anatomical<br>Locat on:]   | ODELTOID MUSCLE EXLOC ECLOC  |   |  |          |   |  |
| 6.               | Body Side:<br>[Body S de:]   | OLEFT<br>ORIGHT EXLAT ECLAT  |   |  |          |   |  |
| 7.               | Route:<br>[Route:]   | OINTRAMUSCULAR EXROUTE ECROUTE   |   |  |          |   |  |
| 8.               | Container<br>Number:<br>[hidden]<br>[PAC / K t<br>Number:]   | NOT SUBMITTED  |   |  |          |   |  |
| 9.               | Actual Dose:<br>[Actual Dose:]   | EXDOSE ECDOSE  |   |  |          |   |  |
| 10.              | Unit:<br>[Unit:]   | O <sup>mL</sup> <sub>Oug</sub> EXDOSU ECDOSU   |   |  |          |   |  |
| 11.              | Timeframe<br>Subject Was<br>Observed<br>[Timeframe<br>Subject Was<br>Observed]   | THE PROTOCOL SPECIFIED OBSERVATION PERIOD     EXOBSVT in SUPPEX ECOBSVT in SUPPEX  | IPPEC   |  |          |   |  |
| 12.              | Was the<br>subject<br>observed for at<br>least the<br>protocol<br>specified<br>observation<br>period after<br>investigational<br>product<br>administration?<br>[Observed Post<br>Dose For<br>Specified Time] | YES EXOBSV in SUPPEX ECOBSV in S     NO     If No, specify reason:     EXOBSVD in SUPPEX ECOBSVD in S  |   |  |          |   |  |
| 13.              | Comparison<br>Term [hidden]<br>[Comparison<br>Term]  | NOT SUBMITTED  |   |  |          |   |  |
| 14.              | Standardized<br>Med cation<br>Name -<br>D ctionary<br>Derived.<br>[ <i>hidden</i> ]<br>[Standardized<br>Med cation<br>Name]  | EXDECOD in SUPPEX ECDECOD in SUPPEX  | JPPEC   |  |          |   |  |
| 15.              | Standardized<br>Med cation<br>Code -<br>D ctionary<br>Derived<br>[hidden]  | EXCD in SUPPEX ECO   | CD in SUPPEC  | 2  |          |   |  |

| 1             |
|---------------|
| [Standardized |
| Med cation    |
| Codel         |

EX=Exposure EC=Exposure as Collected

| S  | TUDYID  |          |                |                      |                     | СМ     | =Concomit     | ant Medi   | cations |
|----|---|----------|----------------|----------------------|---------------------|--------|---------------|------------|---------|
| C  | 4591001: CONCOMITAN   | T MEDIC  | ATIONS - VA    | SOPRESSORS (VA       | SOPRESS) - Rep      | eating | Form          |            |         |
| #  | Sponsor-Defined Identifier  | Category | for Medication | Concomitant Medica   | tions Pre-specified | Name   | of Medication | Start Date | Ongoing |
| 1  |   |          |                |                      |                     | (      | CMSCAT=VA     | SOPRESS    | SORS    |
| Co | ncomitant Medications   |          |                |                      |                     |        | AGENTS        |            |         |
| 1. | What is the medication identifier?<br>[Sponsor-Defined Identifier]    |          | CMSPID         |                      |                     | _      |               |            |         |
| 2. | Category:<br>[Category for Med cat on]                                |          | O GENERAL CO   | NCOMITANT MEDICATION | S CMCAT             |        |               |            |         |
| 3. | Concomitant Medications Pre-spec<br>[Concomitant Medications Pre-spec |          | ONO NOT S      | UBMITTED             |                     |        |               |            |         |
| 4. | Medication:<br>Provide the complete gener c drug                      | name     | CMTRT          |                      |                     |        |               |            |         |

| 4. | Provide the complete gener c drug name<br>(including salt form, where applicable). Where<br>generic name is unknown, enter the full trade<br>or proprietary name. Include clarifying<br>information in the Med cat on text (e.g.,<br>Ingredient(s), route, use, formulation).<br>[Name of Medication] | CMTRT  |
|----|---|--|
| 5. | Start Date:<br>[Start Date]   |  |
| 6. | Ongoing?<br>[Ongoing]   | O YES       CMENRTPT= ONGOING       CMENTPT= LAST SUBJECT ENCOUNTER         End Date:       Image: |
| 7. | Comparison Term [hidden]<br>[Comparison Term]   | NOT SUBMITTED  |
| 8. | Standardized Medicat on Name - Dict onary derived. [hidden] [Standardized Med cat on Name]  | CMDECOD  |
| 9. | Standardized Med cat on Code - Dictionary<br>derived [hidden]<br>[Standardized Med cat on Code]   | CMCODE in SUPPCM   |

| <b>S</b> 7 | UDYID  |   |                  |                  | VS=Vital Signs        |  |  |  |
|------------|--|---|------------------|------------------|-----------------------|--|--|--|
| C4         | C4591001: VITAL SIGNS - TEMP (VITAL TEMP) VSCAT=REACTOGENICITY - UNPLANNED TEMPERATURE |   |                  |                  |                       |  |  |  |
| Vita       | al Signs   |   |                  | VSSCAT=SYSTEMIC  |                       |  |  |  |
|            | Date:<br>[Date:]   | ✓ /   |                  |                  |                       |  |  |  |
| Vita       | al Signs Details   |   |                  |                  |                       |  |  |  |
| #          | Record Identifier:   |   | Temperature      | Temperature Unit | Temperature Location: |  |  |  |
| 2.a        | 1  |   |                  |                  |                       |  |  |  |
| Vita       | al Signs Details Entry   |   |                  |                  |                       |  |  |  |
| 2.1        | Record Identifier:<br>[Record Identifier:]   |   | PID              |                  |                       |  |  |  |
| 2.2        | Temperature:<br>[Temperature]  |   | VSORRES when V   | STESTCD =TEMP    |                       |  |  |  |
| 2.3        | Unit:<br>[Temperature Unit]  |   | ORRESU when VSTE | STCD = TEMP      |                       |  |  |  |
| 2.4        | Temperature Location:<br>[Temperature Location:]                                       | ORAL CA<br>EAR<br>RECTUM<br>AXILLA<br>FOREHEA | VSLOC when       | /STESTCD = TEMP  |                       |  |  |  |

# STUDYID

| ST   | UDYID  |   |                             |                   | VS=Vital Signs        |  |  |  |  |
|------|--|---|-----------------------------|-------------------|-----------------------|--|--|--|--|
| C4   | 4591001: VITAL SIGNS - BASELINE (VITALS BSL) VSCAT=GENERAL VITAL SIGNS |   |                             |                   |                       |  |  |  |  |
|      | al Signs   |   |                             |                   |                       |  |  |  |  |
|      | Date:<br>[Date:]   | <b>v</b> /                                      |                             |                   |                       |  |  |  |  |
|      | Weight:<br>[Weight]  |   | VSORRES when V              | /STESTCD = WEIGHT |                       |  |  |  |  |
|      | <b>Un t:</b><br>[Weight Unit]  | Okg<br>OLB <b>VSO</b>                           | RRESU when VSTE             | STCD = WEIGHT     |                       |  |  |  |  |
|      | Height:<br>[Height]  |   | VSORRES when V              | STESTCD = HEIGHT  |                       |  |  |  |  |
|      | <b>Un t:</b><br>[Height Un t]  | Orm<br>On VSORRESU when VSTESTCD = HEIGHT       |                             |                   |                       |  |  |  |  |
|      | Body Mass Index:<br>[Body Mass Index]                                  |   | VSORRES when VSTESTCD = BMI |                   |                       |  |  |  |  |
| Vita | al Signs Details   |   |                             |                   |                       |  |  |  |  |
| #    | Record Identifier:   |   | Temperature                 | Temperature Unit  | Temperature Location: |  |  |  |  |
| 7.a  | 1  |   |                             |                   |                       |  |  |  |  |
| Vita | al Signs Details Entry   |   |                             |                   |                       |  |  |  |  |
| 7.1  | Record Identifier:<br>[Record Identifier:]                             | <sup>O1</sup> VSSPI                             | D                           |                   |                       |  |  |  |  |
| 7.2  | Temperature:<br>[Temperature]  |   | SORRES when VS              | STESTCD = TEMP    |                       |  |  |  |  |
| 7.3  | Unit:<br>[Temperature Unit]  | OC<br>F <b>VSOF</b>                             | RESU when VSTE              | STCD = TEMP       |                       |  |  |  |  |
| 7.4  | Temperature Location:<br>[Temperature Location:]                       | ORAL CAV<br>EAR<br>RECTUM<br>AXILLA<br>FOREHEAL | VSLOC when VS               | TESTCD = TEMP     |                       |  |  |  |  |

# STUDYID

VS=Vital Signs

| C4   | C4591001: VITAL SIGNS - BASELINE (VITALS BSL) VSCAT=GENERAL VITAL SIGNS |                     |  |                       |           |            |             |        |
|------|---|---------------------|--|-----------------------|-----------|------------|-------------|--------|
| Vita | al Signs  |                     |  |                       |           |            |             |        |
|      | Date:<br>[Date:]  | ✓ /                 |  |                       |           |            |             |        |
|      | Weight:<br>[Weight]   |                     | VSORRES when VS                            | TESTCD = WEIGHT       |           |            |             |        |
|      | <b>Un t:</b><br>[Weight Unit]   |                     | RESU when VSTES                            | TCD = WEIGHT          |           |            |             |        |
|      | Height:<br>[Height]   |                     | VSORRES when VS                            | TESTCD = HEIGHT       |           |            |             |        |
|      | <b>Un t:</b><br>[Height Un t]   | ocm<br>oin VSOR     | RESU when VSTES                            | TCD = HEIGHT          |           |            |             |        |
|      | Body Mass Index:<br>[Body Mass Index]                                   |                     | VSORRES when VS1                           | ESTCD = BMI           |           |            |             |        |
| Vita | al Signs Details  |                     |  |                       |           |            |             |        |
| #    | Record Identifier:  | Temperature         | Temperature Unit                           | Temperature Location: | Systolic: | Diastolic: | BP Position | Pulse: |
| 7.a  | 1   |                     |  |                       |           |            | SITTING     |        |
| Vit  | al Signs Details Entry  |                     |  |                       |           |            |             |        |
| 7.1  | Record Identifier:<br>[Record Identifier:]                              |                     | D  |                       |           |            |             |        |
| 7.2  | Temperature:<br>[Temperature]   |                     | SORRES when VST                            | ESTCD = TEMP          |           |            |             |        |
| 7.3  | Unit:<br>[Temperature Unit]   | OC<br>F <b>VSOR</b> | RESU when VSTES                            | TCD = TEMP            |           |            |             |        |
| 7.4  | Temperature Location:<br>[Temperature Location:]                        |                     |  |                       |           |            |             |        |
| 7.5  | Systol c:<br>[Systolic:]  | VSO                 | VSORRES when VSTESTCD = SYSBP              |                       |           |            |             |        |
| 7.6  | Diastol c:<br>[Diastol c:]  | VSC                 | VSORRES when VSTESTCD = DIABP              |                       |           |            |             |        |
| 7.7  | BP Posit on:<br>[BP Position]   |                     | SITTING VSPOS when VSTESTCD = DIABP, SYSBP |                       |           |            |             |        |
| 7.8  | Pulse:<br>[Pulse:]  | VSO                 | RRES when VSTES                            | TCD = PULSE           |           |            |             |        |

VS=Vital Signs

| ST     | UDYID   |            |                               |   | VS=Vital Signs             |  |  |  |
|--------|---|------------|-------------------------------|---|----------------------------|--|--|--|
| C4     | 591001: VITAL SIGN  | NS - COVI  | D (VITALS C                   | COV) - Repeating Form VSCAT=GENERAL     | VITAL SIGNS                |  |  |  |
| #      | Date:   |            |                               | Vital Signs Details                     |                            |  |  |  |
| 1      |   |            |                               |   |                            |  |  |  |
| Vita   | al Signs  |            |                               |   |                            |  |  |  |
| 1 1    | Date:<br>[Date:]  | <b>v</b> / |                               | VSDTC                                   |                            |  |  |  |
| Vita   | al Signs Details  |            |                               |   |                            |  |  |  |
| #<br>✓ | Record Identifier:  | Systolic:  | Diastolic:                    | Respiratory Rate in respirations/minute | Heart Rate in beats/minute |  |  |  |
| 2.a    | 1   |            |                               |   |                            |  |  |  |
| Vit    | al Signs Details Entry  |            |                               |   |                            |  |  |  |
| 2.1    | Record Identifier:<br>[Record Identifier:]  | O ¹ VS     | SPID                          |   |                            |  |  |  |
| 2.2    | Systol c:<br>[Systolic:]  |            | VSORRES wh                    | nen VSTESTCD = SYSBP                    |                            |  |  |  |
| 2.3    | Diastol c:<br>[Diastol c:]  |            | VSORRES when VSTESTCD = DIABP |   |                            |  |  |  |
| 2.4    | Respiratory Rate in<br>respirations/minute:<br>[Respiratory Rate in<br>respirations/minute] |            | VSORRES when VSTESTCD = RESP  |   |                            |  |  |  |
| 2.5    | Heart Rate in beats/minute:<br>[Heart Rate in beats/minute]                                 |            | VSORRES wh                    | hen VSTESTCD = HR                       |                            |  |  |  |

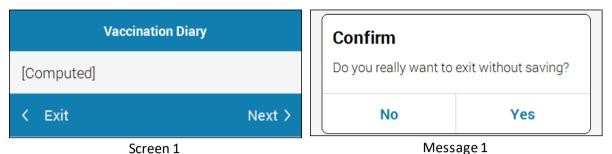
#### C4591001: VITAL SIGNS (VITALS FUP) VSCAT=GENERAL VITAL SIGNS Vital Signs 1. Date: ✓ / **~** / 4 VSDTC [Date:] Vital Signs Details **Record Identifier:** Temperature Temperature Unit Diastolic: **BP** Position Pulse: # **Temperature Location:** Systolic: 2.a 1 SITTING Vital Signs Details Entry 2.1 Record Identifier: [Record Identifier:] 2.2 Temperature: VSORRES when VSTESTCD = TEMP [Temperature] 2.3 Unit: ⊖ F VSORRESU when VSTESTCD = TEMP [Temperature Unit] ОC O ORAL CAVITY VSLOC when VSTESTCD = TEMP 2.4 Temperature Location: [Temperature Location:] O EAR ○ RECTUM ○ AXILLA ○ FOREHEAD VSORRES when VSTESTCD = SYSBP 2.5 Systol c: [Systolic:] 2.6 Diastol c: VSORRES when VSTESTCD = DIABP [Diastol c:] **SITTING** VSPOS when VSTESTCD = DIABP, SYSBP BP Posit on: 2.7 [BP Position] VSORRES when VSTESTCD = PULSE 2.8 Pulse: [Pulse:]

| STUDYID   | DS=Disposition                                       |
|---|--|
| C4591001: WITHDRAWAL OF CONSENT                                   | (WOC) DSCAT=OTHER EVENT                              |
| Withdrawal Of Consent   |  |
| 1. Withdrawal of Consent Date :<br>[Withdrawal of Consent Date :] | DSSTDTC when DSTERM/DSDECOD=WITHDRAWAL<br>OF CONSENT |

22-JUN-2020 Version 2

VSCAT=REACTOGENICITY VSSCAT=SYSTEMIC

# 3 Form: Vaccination Diary



[Computed] Text will display "Hello, welcome to the vaccination diary. You will be answering the following questions about how you have been feeling since your vaccination on {1}. You will answer these questions for {2} day(s)."

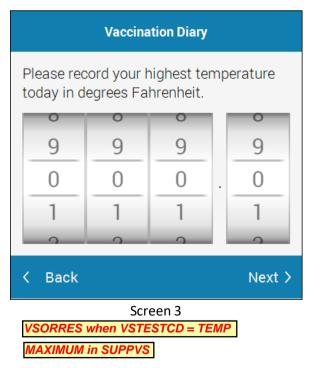
{1} Will display a date

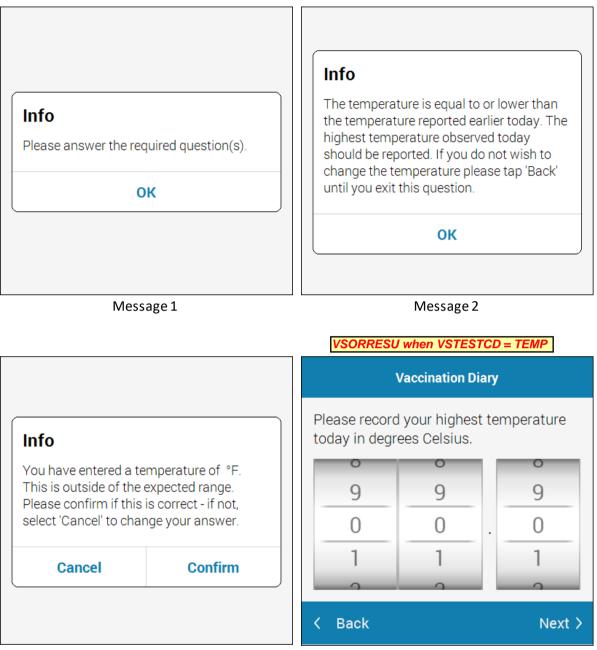
{2} Will display a number of days.

Example: Hello, welcome to the vaccination diary. You will be answering the following questions about how you have been feeling since your vaccination on Mar-27-2020. You will answer these questions for 7 day(s).



## VSORRESU when VSTESTCD = TEMP





Message 3

Screen 4

VSORRES when VSTESTCD = TEMP MAXIMUM in SUPPVS A-1426-0086 / C4591001-Post-12-July-2020 STUDYID App Subject Facing Screen Report English (USA) enUS FACAT=REACTOGENICITY 22-JUN-2020 Version 2

|   |  |  | Vaco                       | cination Diary                                  |
|---|--|--|----------------------------|---|
| Info  |  |  | Please confirm y<br>today: | our highest temperature                         |
| You have entered a temperature of °C.   |  |  | [Computed]                 |   |
| This is outside of the expected range.<br>Please confirm if this is correct - if not,<br>select 'Cancel' to change your answer. |  |  | < Back                     | Next >  |
|   |  |  |                            | Screen 5  |
| Cancel Confirm  |  |  |                            | display the temperature<br>Screen 3 or Screen 4 |
|   |  |  |                            |   |

Message 3

Info
Please contact your study doctor as soon
as possible.

OK
Message 1
Vaccination Diary
Today, have you had any redness at the
injection site?
Ves
No
Next >

Screen 6 FAORRES when FATESTCD = OCCUR and FAOBJ = REDNESS

FASCAT = ADMINISTRATION SITE

## A-1426-0086 / C4591001-Post-12-July-2020

App Subject Facing Screen Report English (USA) enUS

22-JUN-2020 Version 2

#### FASCAT = ADMINISTRATION SITE

FAORRES when FATESTCD = DIAMETER and FAOBJ = REDNESS

# Info

The value you reported is the same as previously reported. If you do not wish to change the response please tap 'Back' until you exit this question.

ОК

Message 2

| measuring device for redness. |   |  |  |
|-------------------------------|---|--|--|
| 0                             | 0 |  |  |
| 9                             | 9 |  |  |
| 0                             | 0 |  |  |
| 1                             | 1 |  |  |
|                               |   |  |  |

Vaccination Diary

Please tap on the number from the and the second second

If your redness was greater than 21, please select 21.

#### < Back Next >



## Vaccination Diary Please confirm the number from the measuring device for redness: Info [Computed] The measurement is equal to or lower than that reported earlier today. The highest measurement observed today should be < Back reported. If you do not wish to change the measurement please tap 'Back' until you Screen 8 exit this question. Screen 7. ОК

Message 2

Next >

[Computed] will display the number selected on

|  |              | FA=Findings Abou   | ut Events or Interventions                                     |
|--|--------------|--|--|
| A-1426-0086 /<br>C4591001-Post-12-July-2020<br>FASCAT = ADMINISTRATION SI<br>FAORRES when FATESTCD = C<br>FAOBJ = SWELLING | English (I   | ing Screen Report<br>JSA) enUS<br><i>FASCAT = ADMINISTR</i><br><i>FAORRES when FATE</i><br><i>FAOBJ = SWELLING</i> | 22-JUN-2020<br>Version 2<br>RATION SITE<br>STCD = DIAMETER and |
| Vaccination Diary  |              | Vaccinat   | ion Diary  |
| Today, have you had any swe<br>injection site?   | lling at the | Please select the nur<br>measuring device for  |  |
| Vac  | 0            | 0  | 0  |
| Yes  | 0            | 9  | 9  |
| No   | $\bigcirc$   | 0  | 0  |
|  |              | 1  | 1  |
| < Back   | Next >       |  |  |
| Screen 9   |              | If your swelling was g<br>please select 21.  | greater than 21,   |
|  |              | < Back   | Next >   |



FASCAT = ADMINISTRATION SITE

| Vaccination Diary   | Vaccination Diary   |
|---|---|
| Please confirm the number from the measuring device for swelling: | Today, have you had any pain at the injection site?                 |
| [Computed]  | Yes   |
| < Back Next >   | No  |
| Screen 11   |   |
| [Computed] will display the number selected on Screen 10.         | < Back Next >   |
| Scieen 10.  | Screen 12   |
|   | FAORRES when FATESTCD = OCCUR and<br>FAOBJ = PAIN AT INJECTION SITE |

|   |          | FA=Findings About   | Events or Interventions |
|---|----------|---|-------------------------|
| A-1426-0086 /<br>C4591001-Post-12-July-2020               |          | ng Screen Report<br>JSA) enUS<br><i>FASCAT = ADMINIST</i><br><i>FAORRES when FATES</i><br><i>FAOBJ = PAIN AT INJE</i> | STCD = SEV and          |
| Vaccination Dia   | ry       | Vaccinatio  | n Diary                 |
| Pain at the injection site<br>Mild = Does not interfere w |          | Please indicate whethe<br>injection site was:   | er the pain at the      |
| Moderate = Interferes with                                | activity | Mild  | 0                       |
| Severe = Prevents daily act                               | ivity    | Moderate  | 0                       |
| < Back  | Next >   | Severe  | 0                       |
| Screen 13   |          |   |                         |
|   |          | < Back  | Next >                  |
|   |          | Screen  | 14                      |
|   |          |   |                         |
|   |          |   |                         |

| Info<br>Severe = Prevents da<br>correct tap 'Yes' to g<br>change your answer | o forward or 'No' to | Info<br>The severity is equal to or lower than the<br>severity reported earlier today. The most<br>severe symptom observed today should be<br>reported. If you do not wish to change the<br>severity please tap 'Back' until you exit this<br>question. |
|--|----------------------|---|
| No   | Yes                  |   |
|  |                      | ОК  |
|  |                      |   |
| Mes  | sage 2               | Message 4   |

|   | FA=Findings About Events   | s or Interventions                               |
|---|--|--|
|   |  | 22-JUN-2020<br>Version 2<br><b>D = OCCUR and</b> |
| Vaccination Diary   | Vaccination Dia  | ry   |
| Did you go to the ER or were you hospitalized for this reaction?  | Today, have you experience<br>(tiredness)?   | ed fatigue                                       |
| Yes   | O Yes  | $\bigcirc$                                       |
| No  | No   | 0  |
| K Back No.  | ext > < Back   | Next >   |
|   |  |  |
| Screen 15   | Screen 16  |  |
| Screen 15<br>FASCAT = S   | FAORRES when FATESTCD  | = SEV and  |
|   | FAORRES when FATESTCD  |  |
| FASCAT = S  | FAORRES when FATESTCD<br>FAOBJ = FATIGUE         Vaccination Dia         Please indicate whether the<br>(tiredness) was:                               | ry   |
| FASCAT = 5         Vaccination Diary         Fatigue (tiredness) definitions:         Mild = Does not interfere with activity         Moderate = Some interference with   | FAORRES when FATESTCD<br>FAOBJ = FATIGUE         Vaccination Dia         Please indicate whether the<br>(tiredness) was:                               | ry   |
| FASCAT = S         Vaccination Diary         Fatigue (tiredness) definitions:         Mild = Does not interfere with activity   | FAORRES when FATESTCD<br>FAOBJ = FATIGUE         Vaccination Dia         Please indicate whether the<br>(tiredness) was:         Mild         Moderate | ry   |
| FASCAT = S         Vaccination Diary         Fatigue (tiredness) definitions:         Mild = Does not interfere with activity         Moderate = Some interference with activity         Severe = Prevents daily routine activity | FAORRES when FATESTCD<br>FAOBJ = FATIGUE         Vaccination Dia         Please indicate whether the<br>(tiredness) was:         Mild         Moderate | ry   |

Screen 18

|   |                   | FA=Findings About Ever                                      | nts or Interventions  |
|---|-------------------|---|-----------------------|
| -1426-0086 /<br>4591001-Post-12-July-202                  | •••••             | icing Screen Report<br>(USA) enUS                           | 22-JUN-202<br>Version |
|   | FASCAT = SYSTEMIC | FAORRES when FATESTO<br>FAOBJ = HOSPITALIZED I<br>(FATIGUE) |                       |
|   |                   | Vaccinatio  | n Diary               |
| Info  |                   | Did you go to the ER or<br>hospitalized for this re         | •                     |
| Severe = Prevents daily r<br>this is correct tap 'Yes' to | o go forward or   | Yes   | 0                     |
| 'No' to change your answ                                  | ver.              | No  | 0                     |
| No  | Yes               | < Back  | Next >                |
|   |                   | Screen  | 19                    |
| Messag<br>ORRES when FATESTCD =                           | = OCCUR and       |   |                       |
| OBJ = HEADACHE  |                   | AT = SYSTEMIC   |                       |
| Vaccination   | i Diary           | Vaccinatio  | n Diary               |
| Today, have you experi                                    | enced headache?   | Headache definition   | S:                    |
| Yes   | 0                 | Mild = Does not interfe                                     | re with activity      |
|   |                   | Moderate = Some inter                                       | ference with          |
| No  | $\bigcirc$        | activity  |                       |
| No<br>K Back  | ○<br>Next >       | Severe = Prevents daily                                     | routine activity      |

Screen 21

|  |                       | FA=Findings About   | Events or Interventions                       |
|--|-----------------------|---|---|
| A-1426-0086 /<br>C4591001-Post-12-July-2020  |                       | ing Screen Report<br>USA) enUS  | 22-JUN-2020<br>Version 2                      |
| FASCAT = SYSTEMIC<br>FAORRES when FATESTCD<br>FAOBJ = HEADACHE   | = SEV and             | FASCAT = SYSTEMIC<br>FAORRES when FATES<br>FAOBJ = HOSPITALIZE  | TCD = OCCUR and                               |
| Vaccination Di   | ary                   | Vaccinatio  | n Diary                                       |
| Please indicate whether th<br>was:   | e headache            | Did you go to the ER of<br>hospitalized for this re   | _   |
| Mild   | 0                     | Yes   | 0   |
| Moderate   | 0                     | No  | 0   |
| Severe   | 0                     | < Back  | Next >  |
|  |                       |   |   |
| < Back   | Next >                | Screen  | 23  |
| K Back           Screen 22           FAORRES when FATESTO           FAOBJ = VOMITING                         |                       | Screen  | 23  |
| Screen 22  | CD = OCCUR and        |   |   |
| Screen 22<br>FAORRES when FATESTO<br>FAOBJ = VOMITING  | CD = OCCUR and<br>ary | FASCAT = SYSTEMIC   | n Diary                                       |
| Screen 22<br>FAORRES when FATESTO<br>FAOBJ = VOMITING<br>Vaccination Di                                      | CD = OCCUR and<br>ary | FASCAT = SYSTEMIC<br>Vaccinatio<br>Vomiting definitions<br>Mild = 1 to 2 times in 2                         | <b>n Diary</b><br>:<br>24 hours               |
| Screen 22<br>FAORRES when FATESTO<br>FAOBJ = VOMITING<br>Vaccination Di<br>Today, have you experience        | CD = OCCUR and<br>ary | FASCAT = SYSTEMIC<br>Vaccinatio<br>Vomiting definitions   | n Diary<br>:<br>24 hours<br>twice in 24 hours |
| Screen 22<br>FAORRES when FATESTO<br>FAOBJ = VOMITING<br>Vaccination Di<br>Today, have you experience<br>Yes | CD = OCCUR and<br>ary | FASCAT = SYSTEMIC<br>Vaccinatio<br>Vomiting definitions<br>Mild = 1 to 2 times in 2<br>Moderate = More than | n Diary<br>:<br>24 hours<br>twice in 24 hours |

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| FAORRES when FATESTCD = SEV and<br>FAOBJ = VOMITING | FAS        | CAT = SYSTEMIC                                       |                  |
|---|------------|--|------------------|
| Vaccination Diary                                   |            |  |                  |
| Please indicate whether the vomiting was:           |            | Info   |                  |
| Mild  | $\bigcirc$ | Severe = Requires intra<br>this is correct tap 'Yes' | to go forward or |
| Moderate  | $\bigcirc$ | 'No' to change your an                               | swer.            |
| Severe  | 0          | No   | Yes              |
| K Back Ne   | xt >       |  |                  |

Screen 26

Message 2

| Vaccination Diary  |        | Vaccinat  | ion Diary          |
|--|--------|---|--------------------|
| Did you go to the ER or were you hospitalized for this reaction?       | L      | Today, have you expe                                  | erienced diarrhea? |
|  | 0      | Yes   | $\bigcirc$         |
| Yes  | 0      | No  | 0                  |
| No   | 0      |   |                    |
| < Back   | Next > | < Back  | Next >             |
| Server 27  |        | Scree   | en 28              |
| Screen 27 FAORRES when FATESTCD = OCCUR and                            |        | FAORRES when FATESTCD = OCCUR and<br>FAOBJ = DIARRHEA |                    |
| FAORRES When FATESTCD = OCCUR and<br>FAOBJ = HOSPITALIZED FOR VOMITING |        | FASCAT = S  | YSTEMIC            |
| FASCAT = SYSTEMIC  |        |   |                    |

| A-1426-0086 /<br>C4591001-Post-12-July-2                                     |                   | FA=Findings About Events or Inter<br>cing Screen Report<br>(USA) enUS<br>FASCAT = SYSTEMIC<br>FAORRES when FATESTCD = SEV a<br>FAOBJ = DIARRHEA | 22-JUN-2020<br>Version 2 |
|--|-------------------|---|--------------------------|
| Vaccina  | tion Diary        | Vaccination Diary   |                          |
| Diarrhea definition  | IS:               | Please indicate whether the diar  | rhea was:                |
| Mild = 2 to 3 loose st   | tools in 24 hours | Mild  | 0                        |
| Moderate = 4 to 5 loo<br>hours   | ose stools in 24  | Moderate  | 0                        |
| Severe = 6 or more lo<br>hours   | pose stools in 24 | Severe  | 0                        |
| < Back   | Next >            | < Back  | Next >                   |
| Scree  | en 29             | Screen 30   |                          |
|  | FASCAT = SYSTEMIC | FAORRES when FATESTCD = OCCUR<br>FAOBJ = HOSPITALIZED FOR DIARRI  |                          |
|  |                   | Vaccination Diary   |                          |
| Info   |                   | Did you go to the ER or were you hospitalized for this reaction?  | L                        |
| Severe = 6 or more lo<br>hours. If this is correct<br>forward or 'No' to cha | t tap 'Yes' to go | Yes   | $\bigcirc$               |
|  |                   | No  | $\bigcirc$               |
| No   | Yes               | < Back  | Next >                   |
|  |                   | Screen 31   |                          |
| Mess   | sage 2            |   |                          |

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| FAORRES when FATESTCD = OC<br>FAOBJ = CHILLS   | CCUR and    | FASCAT = SYSTEMIC   |   |
|--|-------------|---|---|
| Vaccination Diary  |             | Vaccinati   | on Diary  |
| Today, have you experienced chills         Yes         No         < Back         Screen 32 | s? O Next > | Chills definitions:<br>Mild = Does not interf<br>Moderate = Some inter<br>activity<br>Severe = Prevents dai | erference with<br>ly routine activity<br>Next > |
| FASCAT = SYSTEMIC<br>FAORRES when FATESTCD = S<br>FAOBJ = CHILLS                           | SEV and     | Scree   | n 33  |
| Vaccination Diary  |             | Vaccinati   | on Diary  |
| Please indicate whether the chills   | were:       | Did you go to the ER of hospitalized for this re  | -   |
| Mild   | 0           | Yes   | 0   |
| Moderate   | 0           | No  | 0   |
| Severe   | $\bigcirc$  |   |   |
| < Back   | ○<br>Next > | < Back<br>Scree   | Next >  |

FASCAT = SYSTEMIC

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| FAORRES when FATESTCD = OCCUR and<br>FAOBJ = MUSCLE PAIN                            | ASCAT = SYSTEMIC   |
|---|--|
| Vaccination Diary   | Vaccination Diary  |
| Today, have you had new or worsened muscle pain (other than at the injection site)? | Muscle pain definitions:<br>Mild = No interference with activity                               |
| Yes   | Moderate = Some interference with<br>activity  |
| No  | Severe = Prevents daily routine activity   |
| ≺ Back Next >   | K Back Next > Screen 37  |
| Screen 36   | FASCAT = SYSTEMIC<br>FAORRES when FATESTCD = OCCUR and<br>FAOBJ = HOSPITALIZED FOR MUSCLE PAIN |
| Vaccination Diary   | Vaccination Diary  |
| Please indicate whether the new or worsened muscle pain was:                        | Did you go to the ER or were you hospitalized for this reaction?                               |
| Mild  | Yes  |
| Moderate O  | No   |
| Severe O  | < Back Next >  |

Next >

Screen 39

Back

Screen 38 FAORRES when FATESTCD = SEV and FAOBJ = MUSCLE PAIN

FASCAT = SYSTEMIC

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#### FAORRES when FATESTCD = OCCUR and FAOBJ = JOINT PAIN

| Vaccination Diary                                   |            | Vaccination Diary   |
|---|------------|---|
| Today, have you had any new or worsened joint pain? |            | Joint pain definitions:<br>Mild = No interference with activity |
| Yes   | $\bigcirc$ | Moderate = Some interference with<br>activity                   |
| No  | $\bigcirc$ | Severe = Prevents daily routine activity                        |
| < Back  | Next >     | < Back Next >   |

Screen 40

Screen 41

| Vaccination Diary  |            | Vaccination Diary  |            |
|--|------------|--|------------|
| Please indicate whether the new of worsened joint pain was:        | r          | Did you go to the ER or were yo<br>hospitalized for this reaction?       | DU         |
| Mild   | $\bigcirc$ | Yes  | $\bigcirc$ |
| Moderate   | $\bigcirc$ | No   | $\bigcirc$ |
| Severe   | 0          | K Back   | Next >     |
| < Back   | Next >     | Screen 43<br>FAORRES when FATESTCD = OC<br>FAOR L = HOSPITAL IZED FOR 10 |            |
| Screen 42<br>FAORRES when FATESTCD = SEV and<br>FAOBJ = JOINT PAIN |            | FAOBJ = HOSPITALIZED FOR JOINT PAIN<br>FASCAT = SYSTEMIC                 |            |
| FASCAT = SYSTEMIC  |            |  |            |

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| FAORRES when FATESTCD = MEDTFVPN and<br>FAOBJ = MEDICATIONS  |        | FASCAT = MEDICATION   | S GIVEN |
|--|--------|---|---------|
| Vaccination Diary  |        |   |         |
| Today, have you taken any medication to treat fever or pain? |        | Info  |         |
| Yes  | 0      | You have reported taking medication to treat fever or pain. Is your answer correct? |         |
| No   | 0      | No  | Yes     |
| < Back   | Next > |   |         |
| Screen 44  |        | Message 2   |         |

| Vaccination Diary  | Vaccination Diary  |  |
|--|--|--|
| Thank you! You have now completed the<br>diary for today. Please save your<br>answers by selecting ' <b>Save</b> '. If you wish<br>to change your answers, select ' <b>Back</b> '. | Thank you! You have now updated the<br>diary for today. Please save your<br>answers by selecting ' <b>Save</b> '. If you wish<br>to change your answers, select ' <b>Back</b> '. |  |
| If your symptoms worsen today, please<br>select ' <b>Update Symptoms</b> ' from the<br>main menu to update your symptoms.  | If your symptoms worsen again today,<br>please select ' <b>Update Symptoms</b> ' from<br>the main menu to update your<br>symptoms.   |  |
| [Computed]   | [Computed]   |  |
| Save   | Save   |  |
| < Back   | < Back   |  |
| Screen 45  |  |  |
|  | Screen 46  |  |
| [Computed] will display "Please continue to fill<br>out your diary for the next {1} day(s)."   | [Computed] will display "Please continue to fill<br>out your diary for the next {1} day(s)."<br>Where {1} = a number of days   |  |
| Where {1} = a number of days   |  |  |
| Example: Please continue to fill out your diary  |  |  |

Example: Please continue to fill out your diary for the next 4 day(s).

for the next 4 day(s).