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

Visits

SCR

- MAIN INFORMED CONSENT
- DEMOGRAPHY
- DATE OF VISIT
- INCLUSION/EXCLUSION CRITERIA (INC EXC S)
- INCLUSION/EXCLUSION CRITERIA (INC EXC S)
- INCLUSION/EXCLUSION CRITERIA (INC EXC S)
- INCLUSION/EXCLUSION CRITERIA (INC EXC)
- DISPOSITION - SCREENING
- GENERAL MEDICAL HISTORY
- CONCOMITANT MEDICATIONS - BASELINE
- PHYSICAL EXAMINATION
- VITAL SIGNS - BASELINE
- ELECTRONIC SAMPLE TRACKING - PRIOR COVID-19 INFECTION
- MICROBIOLOGY SPECIMEN (COV19 SITE)
- CENTRAL LAB SAMPLE COLLECTION – BASELINE
- LAB URINALYSIS - PREGNANCY TEST

V1_DAY1_VAX1_S

- DATE OF VISIT
- PHYSICAL EXAMINATION
- VITAL SIGNS
- LAB URINALYSIS - PREGNANCY TEST
- ELECTRONIC SAMPLE TRACKING - 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

MICROBIOLOGY SPECIMEN (SWAB SITE)
CENTRAL LAB SAMPLE COLLECTION
ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
VACCINATION
VACCINATION DIARY

V5_WEEK1_POSTVAX2_S
DATE OF VISIT
PHYSICAL EXAMINATION
VITAL SIGNS
CENTRAL LAB SAMPLE COLLECTION
ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

V6_WEEK2_POSTVAX2_S
DATE OF VISIT
VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES
PHYSICAL EXAMINATION
VITAL SIGNS
ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
VACCINATION DIARY

V7_MONTH1_S
DATE OF VISIT
ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

V4_WEEK3_VAX2_S_R
DATE OF VISIT
VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES
PHYSICAL EXAMINATION
VITAL SIGNS
LAB URINALYSIS - PREGNANCY TEST
ELECTRONIC SAMPLE TRACKING - NASAL SWAB
MICROBIOLOGY SPECIMEN (SWAB SITE)
CENTRAL LAB SAMPLE COLLECTION
ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
VACCINATION
VACCINATION DIARY

V5_WEEK1_POSTVAX2_S_R
DATE OF VISIT
PHYSICAL EXAMINATION
VITAL SIGNS
CENTRAL LAB SAMPLE COLLECTION
ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

V6_WEEK2_POSTVAX2_S_R
DATE OF VISIT
VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES
PHYSICAL EXAMINATION
VITAL SIGNS
ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
VACCINATION DIARY

V7_MONTH1_S_R
DATE OF VISIT

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 (INC EXC NS)

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 (INC EXC)
  - 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_COVID_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_COVID_CONVA
- DATE OF VISIT - ILLNESS CONVALESCENT
- ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
- VACCINATION DIARY

POT_COVID_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

UNPLANNED_VACCINATION
- DATE OF VISIT

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

DATE OF VISIT
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)
ELECTRONIC SAMPLE 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
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
INFORMED CONSENT - FURTHER VACCINATION
DISPOSITION - SCREENING FOR FURTHER VACCINATION
INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

EC=EXPOSURE AS COLLECTED

VACCINATION
VACCINATION

EX=EXPOSURE

VACCINATION
VACCINATION

FA=FINDINGS ABOUT EVENTS OR INTERVENTIONS

VACCINATION DIARY
VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES
SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
HEALTH CARE UTILIZATION
UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT

HO=HEALTHCARE ENCOUNTERS

HEALTH CARE UTILIZATION
HOSPITALIZATION DETAILS

IE=INCLUSION/EXCLUSION CRITERIA NOT MET

INCLUSION/EXCLUSION CRITERIA (INC EXC S)
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 (REVAX IE)

IS=IMMUNOGENICITY SPECIMEN ASSESSMENTS

ELECTRONIC SAMPLE TRACKING - PRIOR COVID-19 INFECTION
ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

LB=LABORATORY TEST RESULTS

CENTRAL LAB SAMPLE COLLECTION - BASELINE
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

STUDYID

AE=Adverse Events

C4591001: ADVERSE EVENT REPORT (AE) - Repeating Form

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Toxicity Grade	Serious	Is AE a Result of a Medication Error	Relationship to Study Treatment	Action Taken with Study Treatment	Concomitant Medication Given	Non-Drug Treatment Given	Outcome	Caused Study Discontinuation	Serious Adverse Event Number
1															

Adverse Event Report

1.	Category: [Category]	○ ADVERSE EVENT AECAT
2.	AE ID: [AE Identifier]	AESPID
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms) [Adverse Event]	AETERM
4.	Start Date Time: [Start Date]	/ / AESTDTC : *24-hour clock*
5.	Is the adverse event still ongoing? [Is the Adverse Event Still Ongoing]	○ YES AEENRTPT= ONGOING AEENTPT= LAST SUBJECT ENCOUNTER ○ NO End Date Time: / / AEENDTC : *24-hour clock*
6.	Toxicity Grade: [Toxicity Grade]	○ 1 AETOXGR ○ 2 ○ 3 ○ 4
7.	Is the adverse event ser ous? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hosp talization or prolongat on of existing hosp talization; Persistent or signif cant disabil ty/incapac ty; Congenital anomaly/birth defect; Important med cal event (i.e. may jeopardize subject and may require med cal/surgical intervention to prevent above outcomes). [Serious]	○ YES AESER Is this ser ous event associated with congenital anomaly or birth defect? ○ YES AESCONG ○ NO Did this serious event result in death? ○ YES AESDTH ○ NO Did this serious event require or prolong hospitalization? ○ YES AESHOSP ○ NO Did this serious event result in persistent or significant disabil ty/incapac ty? ○ YES AESDISAB ○ NO Is this ser ous event life threatening? ○ YES AESLIFE ○ NO Other med cally important ser ous event ○ YES AESMIE ○ NO ○ NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log. [Is AE a Result of a Medication Error]	○ YES AEMERES in SUPPAE ○ NO
9.	Is this event related to study treatment: [Relat onship to Study Treatment]	○ NOT RELATED AEREL If Not Related to study treatment(s), this event is due to: ○ CONCOMITANT DRUG TREATMENT AERELNST ○ CONCOMITANT NON-DRUG TREATMENT ○ OTHER If Other, specify: AERELTXT in SUPPAE ○ RELATED
10.	Latest Action Taken with Study	○ DRUG WITHDRAWN AEACN NOT APPLICABLE

AE=Adverse Events

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

STUDYID

LB=Laboratory Test Results

C4591001: LABORATORY DATA - HEMATOLOGY (CD4)

Laboratory Data Hematology

1.	Lab Panel: [Category for Lab Test]	○ HEMATOLOGY LBCAT
2.	Laboratory Name and Address [Vendor Name (DERIVED)]	LBNAM
3.	Collection Date: [Collect on Date:]	/ / LBDTC
4.	Specimen Type: [Specimen Type]	○ BLOOD LBSPEC

Lab Result

#	Sponsor-Defined Identifier	Test:	Result:	Not Done:	Lab Normal Range
5.a		CD4_PX4722			

Lab Result Entry

5.1	Sponsor ID: [Sponsor-Defined Identifier]	LBSPID
5.2	Test: [Test:]	○ CD4_PX4722 LBTEST
5.3	Result: [Result:]	LBORRES
5.4	Not Done: *[hidden]* [Not Done:]	○ NOT DONE LBSTAT
5.5	LNMT [Lab Normal Range]	Low LBORNRLO High LBORNRHI Un t ○ 10^3/mm3 LBORRESU ○ /uL ○ %

C4591001: COHORT SELECTION (COHORT SEL) NOT SUBMITTED		
Cohort Selection		
DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.		
1.	Select appropriate response - Protocol version [Trigger Response 1]	
2.	Select appropriate response - What cohort does the subject belong to? [Trigger Response 10]	◯ STAGE 1 SENTINEL COHORTS ◯ STAGE 1 NONSENTINEL COHORTS ◯ STAGE 2 COHORTS ◯ STAGE 3 COHORTS

STUDYID

CM=Concomitant Medications

C4591001: CONCOMITANT MEDICATIONS - BASELINE (CONMED BSL) - Repeating Form

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Dose Unit	Dose Frequency	Route	Start Date
1									

Concomitant Medications

1.	What is the medication dentifier? [Sponsor-Defined Identifier]	CMSPID
2.	Category: [Category for Medication]	○ GENERAL CONCOMITANT MEDICATIONS CMCAT
3.	Concomitant Medications Pre-specified: [Concom tant Medications Pre-specified]	○ NO NOT SUBMITTED
4.	Med cation: Prov de the complete gener c drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Med cat on text (e.g., Ingredient(s), route, use, formulation). [Name of Medication]	CMTRT
5.	Dose: [Dose Description]	CMDOSE CMDOSTXT
6.	Dose Unit: [Dose Unit]	CMDOSU
7.	Dose Frequency: [Dose Frequency]	CMDOSFRQ
8.	Route: [Route]	CMROUTE
9.	Start Date: [Start Date]	/ / CMSTDTC
10.	Comparison Term *[hidden]* [Comparison Term]	NOT SUBMITTED
11.	Standardized Med cat on Name - Dict onary derived. *[hidden]* [Standardized Med cat on Name]	CMDECOD
12.	Standardized Med cat on Code - D ctionary derived *[hidden]* [Standardized Med cat on Code]	CMCODE in SUPPCM

STUDYID

CM=Concomitant Medications

C4591001: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS (CONMED VAX) - Repeating Form

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date
1					

Concomitant Medications

1.	What is the medication identifier? [Sponsor-Defined Identifier]	CMSPID
2.	Category: [Category for Med cat on]	VACCINATIONS CMCAT
3.	Concomitant Medications Pre-specified: [Concomitant Medications Pre-specified]	NO NOT SUBMITTED
4.	Medication: Provide the complete gener c drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Med cat on text (e.g., Ingredient(s), route, use, formulation). [Name of Medication]	CMTRT
5.	Date: [Start Date]	/ / CMSTDTC
6.	Comparison Term *[hidden]* [Comparison Term]	NOT SUBMITTED
7.	Standardized Medicat on Name - Dict onary derived. *[hidden]* [Standardized Med cat on Name]	CMDECOD
8.	Standardized Med cat on Code - Dictionary derived *[hidden]* [Standardized Med cat on Code]	CMCODE in SUPPCM

STUDYID

DS=Disposition

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

Informed Consent

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

STUDYID

SV=Subject Visits

C4591001: CONTACT OUTCOME - MONTH 1 (CONTACT 1M)

Contact Outcome

1.	Follow-Up Contact Category *[hidden]* [Follow Up Contact Category]	◯ CONTACT OUTCOME NOT SUBMITTED
2.	Contact Type: [Type of Contact/Visit]	◯ CLINIC VISIT ◯ TELEHEALTH VISIT SVREFID
3.	Was contact made? [Was Contact Made]	◯ YES NOT SUBMITTED Date of Contact: / / SVSTDTC SVENDTC when UNPLANNED VISITS ◯ NO If No, why? NOT SUBMITTED
4.	Comments: [Comments/Findings/Details]	NOT SUBMITTED

STUDYID

SV=Subject Visits

C4591001: CONTACT OUTCOME - MONTH 6 (CONTACT 6M)

Contact Outcome

1.	Follow-Up Contact Category *[hidden]* [Follow Up Contact Category]	○ CONTACT OUTCOME NOT SUBMITTED
2.	Contact Type: [Type of Contact/Visit]	○ CLINIC VISIT SVREFID ○ TELEHEALTH VISIT
3.	Was contact made? [Was Contact Made]	○ YES NOT SUBMITTED Date of Contact: / / SVSTDTC SVENDTC when UNPLANNED VISITS ○ NO If No, why? NOT SUBMITTED
4.	Comments: [Comments/Findings/Details]	NOT SUBMITTED

STUDYID

SV=Subject Visits

C4591001: CONTACT OUTCOME (CONTACT SV)

Contact Outcome

1.	Follow-Up Contact Category *[hidden]* [Follow Up Contact Category]	◯ CONTACT OUTCOME NOT SUBMITTED
2.	Contact Type: [Type of Contact/Visit]	◯ TELEPHONE VISIT SVREFID
3.	Was contact made? [Was Contact Made]	◯ YES NOT SUBMITTED Date of Contact: / / SVSTDTC ◯ NO If No, why? NOT SUBMITTED
4.	Comments: [Comments/Findings/Details]	NOT SUBMITTED

STUDYID

SV=Subject Visits

C4591001: CONTACT OUTCOME - UNPLANNED (CONTACT UV)

Contact Outcome

1.	Follow-Up Contact Category *[hidden]* [Follow Up Contact Category]	◯ CONTACT OUTCOME NOT SUBMITTED
2.	Contact Type: [Type of Contact/Visit]	◯ TELEPHONE VISIT SVREFID
3.	Was contact made? [Was Contact Made]	◯ YES Date of Contact: NOT SUBMITTED / / 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 REQUIRED, DATA ENTRY ERROR IN E-DIARY ◯ VISIT NOT REQUIRED, INVESTIGATOR DECISION ◯ NO If No, why? NOT SUBMITTED
4.	Comments: [Comments/Findings/Details]	NOT SUBMITTED

STUDYID | MB=Microbiology Specimen | DI=Device Identifiers | CO=Comments

C4591001: MICROBIOLOGY SPECIMEN (COV19 SITE) - Repeating Form MBCAT=CONFIRMATION OF INFECTION

#	Date of Collection	Specimen Type	Assay Code and Description	Device Type	Result	Comments:
1						

Microbiology Specimen

1.	Actual Date of Collection: [Date of Collection]	/ / MBDTC
2.	Specimen Type: [Specimen Type]	SERUM BLOOD PLASMA MBSPEC
3.	Assay Code and Description: [Assay Code and Description]	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2 MBTEST
4.	Device Type: [Device Type]	SARS-COV-2 DIAGNOSTIC TEST DIVAL when DIPARMCD = DEVTYPE
5.	Test Result: [Result]	POSITIVE NEGATIVE INDETERMINATE MBORRES when MBTESTCD = SARSCOV2
6.	Comments/Findings/Details: [Comments:]	COVAL when RDOMAIN = MB

STUDYID

MB=Microbiology Specimen | DI=Device Identifiers | CO=Comments

C4591001: MICROBIOLOGY SPECIMEN (COVID TEST) - Repeating Form MBCAT=CONFIRMATION OF INFECTION

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Trade Name	Result	Comments:	Trade Name Other, Specify
1									

Microbiology Specimen

1.	Actual Date of Collection: [Date of Collection]	/ / MBDTC
2.	Specimen Type: [Specimen Type]	SWABBED MATERIAL RESPIRATORY SECRETIONS MBSPEC
3.	Specimen Collection Location: [Specimen Collection Location]	NASOPHARYNX LOWER RESPIRATORY SYSTEM THROAT MBLOC
4.	Assay Code and Description: [Assay Code and Description]	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2 MBTEST
5.	Device Type: [Device Type]	SARS-COV-2 DIAGNOSTIC TEST DIVAL when DIPARMCD = DEVTYPE
6.	Trade Name: [Trade Name]	DIVAL when DIPARMCD = TRADENAM
7.	Test Result: [Result]	POSITIVE NEGATIVE INDETERMINATE MBORRES when MBTESTCD = SARSCOV2
8.	Comments/Findings/Details: [Comments:]	COVAL when RDOMAIN = MB
9.	Trade Name Other, Specify: [Trade Name Other, Specify]	SUPPMB in TRADEOTH

STUDYID

DD=Death Details

C4591001: DEATH DETAILS CODED (DEATH DTL) DDCAT = DEATH DETAILS CODED

Death Details

1.	Date of Collect on / Notification of Death: [Date of Collect on / Notif cat on of Death]	/ / DDDTC

	Cause of Death Status	Cause of Death
2.		

Cause of Death Entry

2.1	Cause of Death Status: [Cause of Death Status]	PRIMARY CAUSE OF DEATH SECONDARY CAUSE OF DEATH DDTEST
2.2	Cause of Death: [Cause of Death]	DDORRES
2.3	Comparison Term *[hidden]* [Comparison Term]	NOT SUBMITTED
2.4	Lowest Level Term *[hidden]* [Lowest Level Term]	NOT SUBMITTED
2.5	Lowest Level Term Code *[hidden]* [Lowest Level Term Code]	NOT SUBMITTED
2.6	Dict onary-Derived Term *[hidden]* [Dictionary-Derived Term]	DDSTRESC
2.7	Preferred Term Code *[hidden]* [Preferred Term Code]	NOT SUBMITTED
2.8	High Level Term *[hidden]* [High Level Term]	NOT SUBMITTED
2.9	High Level Term Code *[hidden]* [High Level Term Code]	NOT SUBMITTED
2.10	High Level Group Term *[hidden]* [High Level Group Term]	NOT SUBMITTED
2.11	High Level Group Term Code *[hidden]* [High Level Group Term Code]	NOT SUBMITTED
2.12	Primary System Organ Class *[hidden]* [Primary System Organ Class]	NOT SUBMITTED
2.13	Primary System Organ Class Code *[hidden]* [Primary System Organ Class Code]	NOT SUBMITTED

STUDYID

DM=Demographics

C4591001: DEMOGRAPHY (DEMOG)

Demography

1.	Subject ID [Subject ID]	SUBJID
2.	Birth Date: [Birth Date]	/ / BRTHDTC
3.	Sex: [Sex]	FEMALE MALE SEX
4.	Ethnicity: [Ethnicity]	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN NOT REPORTED ETHNIC
5.	Race: (Check X all that apply): [Race Of Subject]	BLACK OR AFRICAN AMERICAN AMERICAN INDIAN OR ALASKA NATIVE ASIAN NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER WHITE NOT REPORTED RACE, when more than one selected, RACE=MULTIPLE and individual responses are RACE1, RACE2, etc. in SUPPDM
6.	Racial Designation: [Racial Designat on]	JAPANESE OTHER RACIALD in SUPPDM

STUDYID | Linked to related AE record via RELREC | DS=Disposition

C4591001: DISPOSITION - FOLLOW-UP (DISP FUP) DSCAT = DISPOSITION EVENT

Disposition - Follow-Up

1.	Date of Complet on/Discontinuation/Death : [Date of Completion/Discontinuation/Death :]	/ / DSSTDTC
2.	Phase of Disposition: [Disposition Phase]	FOLLOW-UP DSPHASE in SUPPDS
3.	Status: [Status]	DSDECOD
4.	Specify Status: [Specify Status]	DSTERM

STUDYID

Linked to related AE record via RELREC

DS=Disposition

C4591001: DISPOSITION - SCREENING FOR FURTHER VACCINATION (DISP RESCR) DSCAT = DISPOSITION EVENT

Disposition - Screening for Further Vaccination

1.	Date of Complet on/Discontinuation/Death : [Date of Completion/Discontinuation/Death :]	/ / DSSTDTC
2.	Phase of Disposition: [Disposition Phase]	REPEAT SCREENING 1 DSPHASE in SUPPDS
3.	Status: [Status]	DSDECOD
4.	Specify Status: [Specify Status]	DSTERM

STUDYID

Linked to related AE record via RELREC

DS=Disposition

C4591001: DISPOSITION - SCREENING (DISP SCR) DSCAT = DISPOSITION EVENT

Disposition - Screening

1.	Date of Complet on/Discontinuation/Death [Date of Completion/Discontinuation/Death]	/ / DSSTDTC
2.	Phase of Disposition: [Disposition Phase]	○ SCREENING DSPHASE in SUPPDS
3.	Status: [Status]	DSDECOD
4.	Specify Status: [Specify Status]	DSTERM

STUDYID

Linked to related AE record via RELREC

DS=Disposition

C4591001: DISPOSITION - TREATMENT (DISP TRT) DSCAT = DISPOSITION EVENT

Disposition - Treatment

1.	Date of Complet on/Discontinuation/Death : [Date of Completion/Discontinuation/Death :]	/ / DSSTDTC
2.	Phase of Disposition: [Disposition Phase]	○ VACCINATION DSPHASE in SUPPDS ○ OPEN LABEL TREATMENT
3.	Status: [Status]	DSDECOD
4.	Specify Status: [Specify Status]	DSTERM

STUDYID

SV=Subject Visits

C4591001: DATE OF VISIT (DOV)		
Date of Visit		
1.	Date of Visit [Date of Visit]	/ / SVSTDTC SVENDTC when UNPLANNED VISITS
2.	Erroneous Visit [Visit Error]	ERRONEOUS VISIT NOT SUBMITTED

STUDYID

SV=Subject Visits

C4591001: DATE OF VISIT - ILLNESS CONVALESCENT (DOV CONV)		
Date of Visit		
1.	Date of Visit [Date of Visit]	/ / SVSTDTC
2.	Erroneous Visit [Visit Error]	ERRONEOUS VISIT NOT SUBMITTED
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit: [COVID-19 Illness Vis t]	VISIT

STUDYID

SV=Subject Visits

C4591001: DATE OF VISIT - ILLNESS ONSET (DOV ILL)		
Date of Visit		
1.	Date of Visit [Date of Visit]	/ / SVSTDTC
2.	Erroneous Visit [Visit Error]	ERRONEOUS VISIT NOT SUBMITTED
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit: [COVID-19 Illness Vis t]	VISIT

STUDYID

SV=Subject Visits

C4591001: DATE OF VISIT - ASYMPTOMATIC SURVEILLANCE (DOV SURV)		
Date of Visit		
1.	Date of Visit [Date of Visit]	/ / SVSTDTC SVENDTC when UNPLANNED VISITS
2.	Erroneous Visit [Visit Error]	ERRONEOUS VISIT NOT SUBMITTED
COVID-19 Surveillance Visit		
3.	COVID-19 Surveillance Vis t: [COVID-19 Surveillance Visit]	NOT SUBMITTED

STUDYID

SV=Subject Visits

C4591001: DATE OF VISIT - REPEAT SWAB (DOV SWAB)		
Date of Visit		
1.	Date of Visit [Date of Visit]	/ / SVSTDTC
2.	Erroneous Visit [Visit Error]	ERRONEOUS VISIT NOT SUBMITTED
COVID-19 Repeat Swab		
3.	COVID-19 Repeat Swab: [COVID-19 Repeat Swab]	VISIT

C4591001: INFORM ENROLLMENT (ENROLL) NOT SUBMITTED		
InForm Enrollment		
1.	Subject ID [Subject ID]	

C4591001: HIV STATUS (HIV) NOT SUBMITTED		
HIV Status		
1.	Select appropriate response - What is the subject HIV status? [Trigger Response 2]	◯ The subject is known to be HIV POSITIVE ◯ The subject is NOT known to be HIV POSITIVE

STUDYID

LB=Laboratory Test Results

C4591001: LAB CHEMISTRY (HIV RNA)

Lab Chemistry Details

1.	Lab Panel: [Category for Lab Test]	○CLINICAL CHEMISTRY LBCAT
2.	Laboratory Name and Address [Vendor Name]	LBNAM
3.	Collection Date: [Collect on Date:]	/ / LBDTC
4.	Specimen Type: [Specimen Type]	○BLOOD LBSPEC

Lab Result

#	Sponsor-Defined Identifier	Test:	Result:	Not Done:	Lab Normal Range
5.a		HIV RNA (Ultrasensitive)			

Lab Result Entry

5.1	Sponsor ID: [Sponsor-Defined Identifier]	LBSPID
5.2	Test: [Test:]	○HIV RNA (Ultrasens tive) LBTEST
5.3	Result: [Result:]	LBORRES
5.4	Not Done: *[hidden]* [Not Done:]	○NOT DONE LBSTAT
5.5	LNMT [Lab Normal Range]	Low LBORNRLO High LBORNRHI Un t ○/mL LBORRESU

STUDYID

HO=Healthcare Encounters | FA=Findings About Events or Interventions

C4591001: HEALTH CARE UTILIZATION (HLTHCARE)

HOCAT=HEALTHCARE UTILIZATION ASSESSMENT | FACAT=HEALTHCARE UTILIZATION

Health Care Utilization

1.	Evaluation Interval: *[hidden]* [Evaluation Interval]	◯ SINCE THE START OF THE RESPIRATORY ILLNESS EPISODE HOEVINTX | FAEVINTX
2.	Disease Name: *[hidden]* [Disease Name]	◯ RESPIRATORY ILLNESS HCUIDIS in SUPPHO

Health Care Utilization

# ✔	Pre-Specified	Type of Practitioner	Occurrence 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	

Health Care Utilization Entry

3.1	Pre-Specified: *[hidden]* [Pre-Specified]	◯ YES HOPRESP
3.2	Physician or Healthcare Professional: [Type of Practitioner]	◯ SPECIALIST HOTERM ◯ EMERGENCY ROOM ◯ PRIMARY CARE PHYSICIAN ◯ URGENT CARE ◯ TELEPHONE CONSULTATION ◯ OTHER
3.3	Occurrence of Visits or Contacts: [Occurrence of Vis ts or Contacts]	◯ YES HOOCCUR Number of Vis ts or Contacts: [ ] FAORRES when FATESTCD=NUMBER ◯ NO

Health Care Utilization Other

4.	Other Type of Pract tioner Specify: [Other Type of Pract t oner Specify]	HOTERM

Health Care Utilization

5.	Has the subject been hospitalized due to potential COVID-19 illness? [Been Hospitalized]	◯ YES HCUHSP in SUPPHO Has the subject been in intensive care due to potential COVID-19 illness? ◯ YES HCUICU in SUPPHO ◯ NO ◯ NO

STUDYID

HO=Healthcare Encounters

C4591001: HOSPITALIZATION DETAILS (HOSP) - Repeating Form

#	Hospitalization Category	Hospitalization Term	Admission Date	Ongoing
1				

Hospitalization Details

1.	Hosp talization Category: [Hospitalization Category]	◯ HOSPITALIZATION STATUS HOCAT
2.	Hosp talization Term: [Hospitalization Term]	◯ ICU HOTERM ◯ HOSPITAL
3.	Admission Date: [Admission Date]	/ / HOSTDTC
4.	Ongoing? [Ongoing]	◯ YES HOENRTPT= ONGOING HOENTPT= ONGOING AT CURRENT VISIT ◯ NO Discharge Date: / / HOENDTC

STUDYID

CE=Clinical Events

C4591001: ILLNESS DETAILS (ILL POTEN) CECAT = EFFICACY

Illness Details

1.	Category of Clinical Event: [Category of Clin cal Event:]	○ POTENTIAL COVID-19 ILLNESS NOT SUBMITTED
2.	Was a diagnosis obtained for Potential COVID-19 Illness? [Diagnosis Obtained]	○ YES Respiratory Illness Diagnosis: CETERM Date of Diagnosis: / / CEDTC ○ NO NOT SUBMITTED
3.	Toxicity Grade: [Toxicity Grade]	○ 0 ○ 1 CETOXGR ○ 2 ○ 3 ○ 4 ○ 5
4.	Comparison Term: *[hidden]* [Comparison Term]	NOT SUBMITTED
5.	Lowest Level Term *[hidden]* [Lowest Level Term]	CELLT
6.	Lowest Level Term Code *[hidden]* [Lowest Level Term Code]	CELLTCD
7.	D ctionary Derived Term *[hidden]* [D ctionary Derived Term]	CEDECOD
8.	Preferred Term Code *[hidden]* [Preferred Term Code]	CEPTCD
9.	High Level Term *[hidden]* [High Level Term]	CEHLT
10.	High Level Term Code *[hidden]* [High Level Term Code]	CEHLTCD
11.	High Level Group Term *[hidden]* [High Level Group Term]	CEHLGT
12.	High Level Group Term Code *[hidden]* [High Level Group Term Code]	CEHLGTCD
13.	Primary System Organ Class *[hidden]* [Primary System Organ Class]	CEBODSYS CESOC
14.	Primary System Organ Class Code *[hidden]* [Primary System Organ Class Code]	CEBDSYCD CESOCCD

STUDYID

CE=Clinical Events

C4591001: ILLNESS DETAILS - SEVERE (ILL SEVERE)

Illness Details

1.	Category of Clinical Event: [Category of Clin cal Event:]	○ SEVERE COVID-19 ILLNESS CECAT
2.	Subcategory of Clin cal Event: [Subcategory of Clin cal Event]	○ SIGNIFICANT ACUTE RENAL DYSFUNCTION ○ SIGNIFICANT ACUTE HEPATIC DYSFUNCTION CESCAT ○ SIGNIFICANT ACUTE NEUROLOGIC DYSFUNCTION
3.	Was a diagnosis obtained? [Diagnosis Obtained]	○ YES Diagnosis: CETERM Start Date: / / CESTDTC Ongoing?: ○ YES CEENRTPT= ONGOING/BEFORE CEENTPT= LAST SUBJECT ENCOUNTER ○ NO End Date: / / CEENDTC ○ NO NOT SUBMITTED
4.	Toxicity Grade: [Toxicity Grade]	○ 1 ○ 2 ○ 3 CETOXGR ○ 4 ○ 5
5.	Comparison Term: *[hidden]* [Comparison Term]	NOT SUBMITTED
6.	Lowest Level Term *[hidden]* [Lowest Level Term]	CELLT
7.	Lowest Level Term Code *[hidden]* [Lowest Level Term Code]	CELLTCD
8.	D ctionary Derived Term *[hidden]* [D ctionary Derived Term]	CEDECOD
9.	Preferred Term Code *[hidden]* [Preferred Term Code]	CEPTCD
10.	High Level Term *[hidden]* [High Level Term]	CEHLT
11.	High Level Term Code *[hidden]* [High Level Term Code]	CEHLTCD
12.	High Level Group Term *[hidden]* [High Level Group Term]	CEHLGT
13.	High Level Group Term Code *[hidden]* [High Level Group Term Code]	CEHLGTCD
14.	Primary System Organ Class *[hidden]* [Primary System Organ Class]	CEBODSYS CESOC
15.	Primary System Organ Class Code *[hidden]* [Primary System Organ Class Code]	CEBDSYCD CESOCCD

STUDYID

CE=Clinical Events

C4591001: ILLNESS DETAILS - SEVERE (ILL SEVERE) - Repeating Form

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade
1				

Illness Details

1.	Category of Clinical Event: [Category of Clin cal Event:]	○ SEVERE COVID-19 ILLNESS CECAT
2.	Subcategory of Clin cal Event: [Subcategory of Clin cal Event]	○ SIGNIFICANT ACUTE RENAL DYSFUNCTION ○ SIGNIFICANT ACUTE HEPATIC DYSFUNCTION CESCAT ○ SIGNIFICANT ACUTE NEUROLOGIC DYSFUNCTION
3.	Was a diagnosis obtained? [Diagnosis Obtained]	○ YES Diagnosis: CETERM Start Date: / / CESTDTC Ongoing?: ○ YES CEENRTPT= ONGOING/BEFORE CEENTPT= LAST SUBJECT ENCOUNTER ○ NO End Date: / / CEENDTC ○ NO NOT SUBMITTED
4.	Toxicity Grade: [Toxicity Grade]	○ 1 ○ 2 ○ 3 CETOXGR ○ 4 ○ 5
5.	Comparison Term: *[hidden]* [Comparison Term]	NOT SUBMITTED
6.	Lowest Level Term *[hidden]* [Lowest Level Term]	CELLT
7.	Lowest Level Term Code *[hidden]* [Lowest Level Term Code]	CELLTCD
8.	D ctionary Derived Term *[hidden]* [D ctionary Derived Term]	CEDECOD
9.	Preferred Term Code *[hidden]* [Preferred Term Code]	CEPTCD
10.	High Level Term *[hidden]* [High Level Term]	CEHLT
11.	High Level Term Code *[hidden]* [High Level Term Code]	CEHLTCD
12.	High Level Group Term *[hidden]* [High Level Group Term]	CEHLGT
13.	High Level Group Term Code *[hidden]* [High Level Group Term Code]	CEHLGTCD
14.	Primary System Organ Class *[hidden]* [Primary System Organ Class]	CEBODSYS CESOC
15.	Primary System Organ Class Code *[hidden]* [Primary System Organ Class Code]	CEBDSYCD CESOCCD

STUDYID

MO=Morphology

C4591001: IMAGING (IMAGING) - Repeating Form MOCAT=CLINICAL ASSESSMENT OF RADIOGRAPHS - IMAGING

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment
1				

Imaging

1.	Date of Assessment: [Date of Assessment]	/ / MODTC
2.	Locat on of Assessment: [Location of Assessment]	○ CHEST ○ HEAD MOLOC ○ OTHER If other, specify: LOCOTH in SUPPMO
3.	Type of Imaging Exam: [Imaging Method]	○ CT SCAN ○ X-RAY MOMETHOD ○ ULTRASOUND ○ MRI ○ OTHER If other, specify: METHOTH in SUPPMO
4.	Assessment: MOTEST [Overall Assessment]	○ ABNORMAL MOORRES If abnormal, specify findings: ASPECIFY IN SUPPMO ○ INDETERMINATE ○ NORMAL MOORRES ○ UNKNOWN ○ NOT EVALUABLE

STUDYID

IE=Inclusion/Exclusion Criteria Not Met

C4591001: INCLUSION/EXCLUSION CRITERIA (IN EX STG3)

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

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

Inclusion Criteria Entry IECAT = INCLUSION

1.1	Inclusion Number: [Inclusion Number]	◯ 1 ◯ 2 IESPID ◯ 3 ◯ 4
1.2	Cr terion Description: [Criter on Descript on]	IETEST
1.3	Cr terion met? [Criter on met?]	◯ YES IEORRES ◯ NO Describe details if relevant IEDESC in SUPPIE
1.4	Cr terion ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	◯ IN01A00 ◯ IN02A00 IETESTCD ◯ IN03A00 ◯ IN04A00

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	8	Immunocompromised indiv duals w th 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 w th 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 systemic corticosteroids. Inhaled/nebulized, Intra-art cular, intrabursal, or topical 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.l	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, site staff otherwise supervised by the investigator, and their respective family members		EX21A00

Exclusion Criteria Entry IECAT = EXCLUSION

2.1	Exclusion Number: [Exclusion Number]	IESPID
2.2	Cr terion Description: [Criter on Descript on]	IETEST
2.3	Cr terion met? [Criter on met?]	◯ YES IEORRES Describe details if relevant IEDESC in SUPPIE

IE=Inclusion/Exclusion Criteria Not Met

		○ NO
2.4	Cr terion ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	IETESTCD

STUDYID

IE=Inclusion/Exclusion Criteria Not Met

C4591001: INCLUSION/EXCLUSION CRITERIA (IN EX STG3)

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

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

Inclusion Criteria Entry IECAT = INCLUSION

1.1	Inclusion Number: [Inclusion Number]	○ 1 ○ 2 ○ 3 ○ 4 IESPID
1.2	Cr terion Description: [Criter on Descript on]	IETEST
1.3	Cr terion met? [Criter on met?]	○ YES IEORRES ○ NO Describe details if relevant IEDESC in SUPPIE
1.4	Cr terion ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	○ IN01A00 ○ IN02A00 ○ IN03A00 ○ IN04A00 IETESTCD

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	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.l	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, site staff otherwise supervised by the investigator, and their respective family members		EX21A01

Exclusion Criteria Entry IECAT = EXCLUSION

2.1	Exclusion Number: [Exclusion Number]	IESPID
2.2	Cr terion Description: [Criter on Descript on]	IETEST
2.3	Cr terion met? [Criter on met?]	○ YES IEORRES Describe details if relevant IEDESC in SUPPIE ○ NO
2.4	Cr terion ID: (For Pfizer use	IETESTCD

IE=Inclusion/Exclusion Criteria Not Met

	only) [Criter on ID: (For Pfizer use only)]	

STUDYID

IE=Inclusion/Exclusion Criteria Not Met

C4591001: INCLUSION/EXCLUSION CRITERIA (IN EX STG3)

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

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

Inclusion Criteria Entry IECAT = INCLUSION

1.1	Inclusion Number: [Inclusion Number]	◯ 1 ◯ 2 IESPID ◯ 3 ◯ 4
1.2	Cr terion Description: [Criter on Descript on]	IETEST
1.3	Cr terion met? [Criter on met?]	◯ YES IEORRES ◯ NO Describe details if relevant IEDESC in SUPPIE
1.4	Cr terion ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	◯ IN01A00 ◯ IN02A00 IETESTCD ◯ IN03A00 ◯ IN04A00

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	8	Immunocompromised indiv duals w th 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 w th 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.l	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, site staff otherwise supervised by the investigator, and their respective family members		EX21A01

Exclusion Criteria Entry IECAT = EXCLUSION

2.1	Exclusion Number: [Exclusion Number]	IESPID
2.2	Cr terion Description: [Criter on Descript on]	IETEST
2.3	Cr terion met? [Criter on met?]	◯ YES IEORRES Describe details if relevant IEDESC in SUPPIE

IE=Inclusion/Exclusion Criteria Not Met

		○ NO
2.4	Cr terion ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	IETESTCD

STUDYID

IE=Inclusion/Exclusion Criteria Not Met

C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC)

	Criterion Description
1.	

Inclusion Criteria Not Met Entry

1.1	Description of Inclusion Cr terion Not Met [Criter on Descript on]	IETEST when IEORRES=N

	Criterion Description
2.	

Exclusion Criteria Met Entry

2.1	Description of Exclusion Cr terion Met [Criter on Descript on]	IETEST when IEORRES=Y

STUDYID

IE=Inclusion/Exclusion Criteria Not Met

C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC NS)

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

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

Inclusion Criteria Entry IECAT = INCLUSION

1.1	Inclusion Number: [Inclusion Number]	◯ 1 ◯ 2 ◯ 3 ◯ 4 IESPID
1.2	Cr terion Description: [Criter on Descript on]	IETEST
1.3	Cr terion met? [Criter on met?]	◯ YES IEORRES ◯ NO Describe details if relevant IEDESC in SUPPIE
1.4	Cr terion ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	◯ IN01A00 ◯ IN02A00 IETESTCD ◯ IN03A00 ◯ IN04A00

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	10	Bleeding diathesis or condition associated w th 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.l	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, site staff otherwise supervised by the investigator, and their respective family members		EX21A01

Exclusion Criteria Entry IECAT = EXCLUSION

2.1	Exclusion Number: [Exclusion Number]	IESPID
2.2	Cr terion Description: [Criter on Descript on]	IETEST
2.3	Cr terion met? [Criter on met?]	◯ YES IEORRES Describe details if relevant IEDESC in SUPPIE ◯ NO

IE=Inclusion/Exclusion Criteria Not Met

2.4	Cr terion ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	IETESTCD

STUDYID

IE=Inclusion/Exclusion Criteria Not Met

C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC NS)

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

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

Inclusion Criteria Entry IECAT = INCLUSION

1.1	Inclusion Number: [Inclusion Number]	○ 1 ○ 2 ○ 3 ○ 4 IESPID
1.2	Cr terion Description: [Criter on Descript on]	IETEST
1.3	Cr terion met? [Criter on met?]	○ YES IEORRES ○ NO Describe details if relevant IEDESC in SUPPIE
1.4	Cr terion ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	○ IN01A00 ○ IN02A00 IETESTCD ○ IN03A00 ○ IN04A00

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.l	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 nanopart cles		EX16A01
2.o	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

Exclusion Criteria Entry IECAT = EXCLUSION

2.1	Exclusion Number: [Exclusion Number]	IESPID
2.2	Cr terion Description: [Criter on Descript on]	IETEST
2.3	Cr terion met? [Criter on met?]	○ YES IEORRES Describe details if relevant IEDESC in SUPPIE

IE=Inclusion/Exclusion Criteria Not Met

		NO
2.4	Cr terion ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	IETESTCD

STUDYID

IE=Inclusion/Exclusion Criteria Not Met

C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC NS)

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

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

Inclusion Criteria Entry IECAT = INCLUSION

1.1	Inclusion Number: [Inclusion Number]	◯ 1 ◯ 2 ◯ 3 ◯ 4 IESPID
1.2	Cr terion Description: [Criter on Descript on]	IETEST
1.3	Cr terion met? [Criter on met?]	◯ YES IEORRES ◯ NO Describe details if relevant IEDESC in SUPPIE
1.4	Cr terion ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	◯ IN01A00 ◯ IN02A00 IETESTCD ◯ IN03A00 ◯ IN04A00

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	Individuals who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids. Inhaled/nebulized, Intra-art cular, intrabursal, or topical cort costeroids are permitted		EX13A00
2.l	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.o	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

Exclusion Criteria Entry IECAT = EXCLUSION

2.1	Exclusion Number: [Exclusion Number]	IESPID
2.2	Cr terion Description: [Criter on Descript on]	IETEST
2.3	Cr terion met? [Criter on met?]	◯ YES IEORRES Describe details if relevant IEDESC in SUPPIE

IE=Inclusion/Exclusion Criteria Not Met

		○ NO
2.4	Cr terion ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	IETESTCD

STUDYID

IE=Inclusion/Exclusion Criteria Not Met

C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC S)

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

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

Inclusion Criteria Entry IECAT = INCLUSION

1.1	Inclusion Number: [Inclusion Number]	◯ 1 ◯ 2 IESPID ◯ 3 ◯ 4
1.2	Cr terion Description: [Criter on Descript on]	IETEST
1.3	Cr terion met? [Criter on met?]	◯ YES IEORRES ◯ NO Describe details if relevant IEDESC in SUPPIE
1.4	Cr terion ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	◯ IN01A00 ◯ IN02A00 IETESTCD ◯ IN03A00 ◯ IN04A00

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	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 w th a history of autoimmune disease or an active autoimmune disease requiring therapeut c intervention		EX09A04
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.l	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.o	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	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

Exclusion Criteria Entry	IECAT = EXCLUSION	
2.1	Exclusion Number: [Exclusion Number]	IESPID
2.2	Cr terion Description: [Criter on Descript on]	IETEST
2.3	Cr terion met? [Criter on met?]	YES IEORRES Describe details if relevant IEDESC in SUPPIE NO
2.4	Cr terion ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	IETESTCD

STUDYID

IE=Inclusion/Exclusion Criteria Not Met

C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC S)

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

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

Inclusion Criteria Entry IECAT = INCLUSION

1.1	Inclusion Number: [Inclusion Number]	◯ 1 ◯ 2 IESPID ◯ 3 ◯ 4
1.2	Cr terion Description: [Criter on Descript on]	IETEST
1.3	Cr terion met? [Criter on met?]	◯ YES IEORRES ◯ NO Describe details if relevant IEDESC in SUPPIE
1.4	Cr terion ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	◯ IN01A00 ◯ IN02A00 IETESTCD ◯ IN03A00 ◯ IN04A00

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	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 w th 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.l	12	Previous vaccinat on with any coronavirus vaccine		EX12A00
2.m	13	Individuals who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids. Inhaled/nebulized, Intra-art cular, intrabursal, or topical 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.o	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

Exclusion Criteria Entry	**IECAT = EXCLUSION**	
2.1	Exclusion Number: [Exclusion Number]	IESPID
2.2	Cr terion Description: [Criter on Descript on]	IETEST
2.3	Cr terion met? [Criter on met?]	YES IEORRES Describe details if relevant IEDESC in SUPPIE NO
2.4	Cr terion ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	IETESTCD

STUDYID

IE=Inclusion/Exclusion Criteria Not Met

C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC S)

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

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

Inclusion Criteria Entry IECAT = INCLUSION

1.1	Inclusion Number: [Inclusion Number]	◯ 1 ◯ 2 IESPID ◯ 3 ◯ 4
1.2	Cr terion Description: [Criter on Descript on]	IETEST
1.3	Cr terion met? [Criter on met?]	◯ YES IEORRES ◯ NO Describe details if relevant IEDESC in SUPPIE
1.4	Cr terion ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	◯ IN01A00 ◯ IN02A00 IETESTCD ◯ IN03A00 ◯ IN04A00

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	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 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.l	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.o	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	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

Exclusion Criteria Entry	**IECAT = EXCLUSION**	
2.1	Exclusion Number: [Exclusion Number]	IESPID
2.2	Cr terion Description: [Criter on Descript on]	IETEST
2.3	Cr terion met? [Criter on met?]	YES IEORRES Describe details if relevant IEDESC in SUPPIE NO
2.4	Cr terion ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	IETESTCD

C4591001: CASEBOOK SIGNATURE FORM (INVSIG) NOT SUBMITTED		
Casebook Signature Form		
1.	Casebook Signature [Casebook Signature]	◯ Click Here to Enable

STUDYID

LB=Laboratory Test Results | MB=Microbiology Specimen

C4591001: CENTRAL LAB SAMPLE COLLECTION (LAB)

Central Lab Sample Collection

1.	Collection Date: [Collect on Date:]	/ / LBDTC MBDTC
2.	Specimen Type: [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: [Category for Lab Test]	○ HEMATOLOGY ○ CLINICAL CHEMISTRY LBCAT MBCAT
3.2	Lab Sub-Panel: [Subcategory for Lab Test]	○ DIFFERENTIAL ○ BLOOD CHEMISTRY NOT SUBMITTED
3.3	Was the lab sub-panel collected?: [Lab Sub-Panel Collected]	○ YES ○ NO LBSCATYN in SUPPLB MBSCATYN in SUPPMB

STUDYID

LB=Laboratory Test Results | MB=Microbiology Specimen

C4591001: CENTRAL LAB SAMPLE COLLECTION - BASELINE (LAB BSL)

Central Lab Sample Collection

1.	Collection Date: [Collect on Date:]	/ / LBDTC MBDTC
2.	Specimen Type: [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	CLINICAL CHEMISTRY	VIROLOGY	
3.c	HEMATOLOGY	DIFFERENTIAL	

Lab Test Entry

3.1	Lab Panel: [Category for Lab Test]	HEMATOLOGY CLINICAL CHEMISTRY LBCAT MBCAT
3.2	Lab Sub-Panel: [Subcategory for Lab Test]	DIFFERENTIAL BLOOD CHEMISTRY NOT SUBMITTED VIROLOGY
3.3	Was the lab sub-panel collected?: [Lab Sub-Panel Collected]	YES NO LBSCATYN in SUPPLB MBSCATYN in SUPPMB

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

1.	Lab Panel: [Category for Lab Test]	○ CLINICAL CHEMISTRY LBCAT
2.	Laboratory Name and Address [Vendor Name]	LBNAM
3.	Collection Date: [Collect on Date:]	/ / LBDTC
4.	Specimen Type: [Specimen Type]	○ BLOOD LBSPEC

Lab Result

# ✔	Sponsor-Defined Identifier	Test:	Result:	Not Done:	Lab Normal Range
5.a		C Reactive Protein_PX329			

Lab Result Entry

5.1	Sponsor ID: [Sponsor-Defined Identifier]	LBSPID
5.2	Test: [Test:]	○ C Reactive Protein_PX329 LBTEST
5.3	Result: [Result:]	LBORRES
5.4	Not Done: *[hidden]* [Not Done:]	○ NOT DONE LBSTAT
5.5	LNMT [Lab Normal Range]	Low LBORNRLO High LBORNRHI Un t 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

1.	Lab Panel: [Category for Lab Test]	○CLINICAL CHEMISTRY LBCAT
2.	Laboratory Name and Address [Vendor Name]	LBNAM
3.	Collection Date: [Collect on Date:]	/ / LBDTC
4.	Specimen Type: [Specimen Type]	○BLOOD LBSPEC

Lab Result

# ✔	Sponsor-Defined Identifier	Test:	Result:	Not Done:	Lab Normal Range
5.a		C Reactive Protein_PX329			
5.b		Alanine Aminotransferase_PX30			
5.c		Aspartate Aminotransferase_PX28			
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: [Sponsor-Defined Identifier]	LBSPID
5.2	Test: [Test:]	LBTEST
5.3	Result: [Result:]	LBORRES
5.4	Not Done: [Not Done:]	○NOT DONE LBSTAT
5.5	LNMT [Lab Normal Range]	Low LBORNRLO High LBORNRHI Un t LBORRESU

STUDYID

LB=Laboratory Test Results

C4591001: LOCAL LABORATORY DATA - REPEATING Hematology (LAB HEM) - Repeating Form

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result
1					

Laboratory Data Hematology

1.	Lab Panel: [Category for Lab Test]	○HEMATOLOGY LBCAT
2.	Laboratory Name and Address [Vendor Name (DERIVED)]	LBNAM
3.	Collection Date: [Collect on Date:]	/ / LBDTC
4.	Specimen Type: [Specimen Type]	○BLOOD LBSPEC

Lab Result

# ✔	Sponsor-Defined Identifier	Test:	Result:	Not Done:	Lab Normal Range
5.a		Hemoglobin_PX1			
5.b		Hematocrit_PX2			
5.c		Erythrocytes_PX3			
5.d		Platelets_PX5			
5.e		Leukocytes_PX7			
5.f		Neutrophils_PX608			
5.g		Eosinophils_PX609			
5.h		Monocytes_PX612			
5.i		Basophils_PX610			
5.j		Lymphocytes_PX611			

Lab Result Entry

5.1	Sponsor ID: [Sponsor-Defined Identifier]	LBSPID
5.2	Test: [Test:]	LBTEST
5.3	Result: [Result:]	LBORRES
5.4	Not Done: [Not Done:]	○NOT DONE LBSTAT
5.5	LNMT [Lab Normal Range]	Low LBORNRLO High LBORNRHI Un t LBORRESU

STUDYID

LB=Laboratory Test Results

C4591001: LAB URINALYSIS - PREGNANCY TEST (LAB PREG)

Lab Urinalysis

1.	Lab Panel: [Category for Lab Test]	○ URINALYSIS LBCAT
2.	Lab Sub-Panel: [Subcategory for Lab Test]	○ PREGNANCY LBSCAT
3.	Collection Date: [Collect on Date:]	/ / LBDTC
4.	Laboratory Name and Address (Derived) [Vendor Name (DERIVED)]	LBNAM
5.	Specimen Type: [Specimen Type]	○ URINE LBSPEC

Lab Result

#	Sponsor-Defined Identifier	Test:	Result:	Not Done:
6.a		Chor ogonadotropin Beta_PX113		

Lab Result Entry

6.1	Sponsor ID: [Sponsor-Defined Identifier]	LBSPID
6.2	Test: [Test:]	○ Chor ogonadotropin Beta_PX113 LBTEST
6.3	Result: [Result:]	○ NEGATIVE LBORRES ○ POSITIVE
6.4	Not Done: [Not Done:]	○ NOT DONE LBSTAT

STUDYID

AE=Adverse Events

C4591001: MEDICATION ERROR (MED ERROR) - Repeating Form

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Concomitant Medication Given	Non-Drug Treatment Given	Caused Study Discontinuation	Medication Error Associated With AE	Serious Adverse Event Number
1										

Medication Error

1.	Category: [Category]	○ MEDICATION ERROR AECAT
2.	Medication Error (Type of Medication Error): [Med cat on Error]	AETERM
3.	If this is a dispensing error, record the incorrect container number that was dispensed/administered to the subject: *[hidden]* [Incorrect package ID]	AEIPKGID in SUPPAE
4.	Start Date: [Start Date]	/ / AESTDTC
5.	Is the med cation error still ongoing? [Is the med cat on error Still Ongoing]	○ YES AEENRTPT= ONGOING AEENTPT= LAST SUBJECT ENCOUNTER ○ NO End Date: / / AEENDTC
6.	Latest Action Taken with Study Treatment: [Study Medication Errors Act on]	○ NO ACTION TAKEN ○ PERMANENTLY DISCONTINUED AEACN
7.	Was a Concomitant Med cation given? [Concom tant Med cat on Given]	○ YES AECONTRT AECMGIV in SUPPAE ○ NO
8.	Was a Non-Drug Treatment given? [Non-Drug Treatment Given]	○ YES AECONTRT AENDGIV in SUPPAE ○ NO
9.	D d the Medication Error cause the subject to be discontinued from the study? [Caused Study Discontinuat on]	○ YES AESUBJDC in SUPPAE Linked to related DS record via RELREC ○ NO
10.	Was this medication error associated with any adverse events? [Med cat on Error Associated With AE]	○ YES AEMEFL in SUPPAE AE ID: AEAENO in SUPPAE AE ID: AEAENO in SUPPAE AE ID: AEAENO in SUPPAE AE ID: AEAENO in SUPPAE AE ID: AEAENO in SUPPAE ○ NO
11.	Ser ous Adverse Event Number: For Pfizer Use Only [Serious Adverse Event Number]	AEREFID
12.	Comparison Term *[hidden]* [Comparison Term]	NOT SUBMITTED
13.	Lowest Level Term *[hidden]* [Lowest Level Term]	AELLT
14.	Lowest Level Term Code *[hidden]* [Lowest Level Term Code]	AELLTCD
15.	D ctionary-Derived Term *[hidden]* [D ctionary-Derived Term]	AEDECOD

AE=Adverse Events

16.	Preferred Term Code *[hidden]* [Preferred Term Code]	AEPTCD
17.	High Level Term *[hidden]* [High Level Term]	AEHLT
18.	High Level Term Code *[hidden]* [High Level Term Code]	AEHLTCD
19.	High Level Group Term *[hidden]* [High Level Group Term]	AEHLGT
20.	High Level Group Term Code *[hidden]* [High Level Group Term Code]	AEHLGTCD
21.	Primary System Organ Class *[hidden]* [Primary System Organ Class]	AEBODSYS AESOC
22.	Primary System Organ Class Code *[hidden]* [Primary System Organ Class Code]	AEBDSYCD AESOCCD

STUDYID

MH=Medical History

C4591001: GENERAL MEDICAL HISTORY (MEDHX) MHCAT=GENERAL MEDICAL HISTORY

	Line/MH Number	Medical History Term	Start Date	Ongoing
1.				

Medical History Details Entry

1.1	Line/MH Number: [Line/MH Number]	MHSPID
1.2	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies: [Medical History Term]	MHTERM
1.3	Start Date: [Start Date]	/ / MHSTDTC
1.4	Ongoing: [Ongoing]	YES MHENRTPT= ONGOING/BEFORE MHENTPT= LAST SUBJECT ENCOUNTER NO End Date: / / MHENDTC
1.5	Comparison Term *[hidden]* [Comparison Term]	NOT SUBMITTED
1.6	Lowest Level Term *[hidden]* [Lowest Level Term]	MHLLT
1.7	Lowest Level Term Code *[hidden]* [Lowest Level Term Code]	MHLLTCD
1.8	Dict onary Derived Term *[hidden]* [Dictionary Derived Term]	MHDECOD
1.9	Preferred Term Code *[hidden]* [Preferred Term Code]	MHPTCD
1.10	High Level Term *[hidden]* [High Level Term]	MHHLT
1.11	High Level Term Code *[hidden]* [High Level Term Code]	MHHLTCD
1.12	High Level Group Term *[hidden]* [High Level Group Term]	MHHLGT
1.13	High Level Group Term Code *[hidden]* [High Level Group Term Code]	MHHLGTCD
1.14	Primary System Organ Class *[hidden]* [Primary System Organ Class]	MHBODSYS MHSOC
1.15	Primary System Organ Class Code *[hidden]* [Primary System Organ Class Code]	MHBDSYCD MHSOCCD

STUDYID

LB=Laboratory Test Results

C4591001: OXYGENATION PARAMETERS (OXYGEN) - Repeating Form LBCAT= OXYGENATION PARAMETERS

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)
1			LBSCAT= BLOOD CHEMISTRY

Oxygenation Parameters

1.	Date Time of Assessment: [Date Time of Assessment]	/ / LBDTC : 24-hour clock
2.	Arterial Blood Gases PaO2 (mmHg): [Arterial Blood Gases PaO2]	LBORRES when LBTESTCD = PO2
3.	FiO2 (Fract on of Inhaled Oxygen): [FiO2 (Fraction of Inhaled Oxygen)]	LBORRES when LBTESTCD = FIO2

STUDYID

PE=Physical Examination

C4591001: PHYSICAL EXAMINATION (PHYS EXAM) PECAT=PHYSICAL EXAMINATION

Physical Examination

1.	Exam Date: [Exam Date]	/ / PEDTC

Physical 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.l	EXTREMITIES	
2.m	NEUROLOGICAL	
2.n	LYMPH NODES	

Physical Examination Result Entry

2.1	Body System Examined: [Body System Examined]	PETEST
2.2	Result: [Result]	○ NORMAL ○ ABNORMAL PEORRES If abnormal findings, specify: (If clinically signif cant, record on the Medical History or Adverse Event CRF as appropriate). Are there clinically signif cant findings? ○ YES PECLSIG in SUPPPE ○ NO ○ NOT DONE PESTAT

STUDYID

IS=Immunogenicity Specimen Assessment | CO=Comments

C4591001: ELECTRONIC SAMPLE TRACKING - PRIOR COVID-19 INFECTION (PRIORCOV19) ISCAT=SEROLOGY

Electronic Sample Tracking

1.	Data Origin [Data Origin]	○ SITE ETRKDOR in SUPPIS
2.	Sample Type [Sample Type]	○ SERUM ISSPEC
3.	Sample Collected? [Sample Collected]	○ NO COVAL when COREF=SAMPLE COLLECTED ○ YES Date of Collect on: / / ISDTC CODTC
4.	If no sample was collected or sample was not collected according to protocol, please provide reason: [Reason sample not collected]	COVAL when RDOMAIN = IS

	Sample ID
5.	

Aliquot Entry

Please enter barcode for each aliquot.

5.1	Sample ID [Sample ID]	NOT SUBMITTED

STUDYID

CM=Concomitant Medications

C4591001: CONCOMITANT MEDICATIONS - PROHIBITED (PROHIB CM) - Repeating Form

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Dose Unit	Dose Frequency	Route	Start Date	Ongoing
1										

Concomitant Medications

1.	What is the medication dentifier? [Sponsor-Defined Identifier]	CMSPID
2.	Category: [Category for Medication]	○ CONCOMITANT IMMUNOSUPPRESSIVE THERAPY ○ CORTICOSTEROIDS CMCAT ○ IMMUNOGLOBULINS
3.	Concomitant Medications Pre-specified: [Concom tant Medications Pre-specified]	○ NO NOT SUBMITTED
4.	Med cation: Prov de the complete gener c drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Med cat on text (e.g., Ingredient(s), route, use, formulation). [Name of Medication]	CMTRT
5.	Dose: [Dose Description]	CMDOSE CMDOSTXT
6.	Dose Unit: [Dose Unit]	CMDOSU
7.	Dose Frequency: [Dose Frequency]	CMDOSFRQ
8.	Route: [Route]	CMROUTE
9.	Start Date: [Start Date]	/ / CMSTDTC
10.	Ongoing? [Ongoing]	○ YES CMENRTPT= ONGOING CMENTPT= LAST SUBJECT ENCOUNTER ○ NO End Date: / / CMENDTC
11.	Comparison Term *[hidden]* [Comparison Term]	NOT SUBMITTED
12.	Standardized Med cat on Name - Dict onary derived. *[hidden]* [Standardized Med cat on Name]	CMDECOD
13.	Standardized Med cat on Code - D ctionary derived *[hidden]* [Standardized Med cat on Code]	CMCODE in SUPPCM

STUDYID

PR=Procedures

C4591001: RADIATION TREATMENT (PROHIB ND) - Repeating Form

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Ongoing?
1						

Radiation Treatment

1.	Category: [Category]	○ RADIATION THERAPY PRCAT
2.	What is the treatment Identifier? [Treatment Identifier]	PRSPID
3.	Concomitant Non-drug Treatment Pre-specified: [Con Non-Drug Treatments Pre-specified]	○ YES PRPRESP
4.	Treatment: [Treatment]	PRTRT
5.	Start Date: [Start Date]	/ / PRSTDTC
6.	Ongoing? [Ongoing?]	○ YES PRENRTPT= ONGOING PRENTPT= LAST SUBJECT ENCOUNTER ○ NO End Date: / / PRENDTC
7.	Comparison Term *[hidden]* [Comparison Term]	NOT SUBMITTED
8.	Lowest Level Term *[hidden]* [Lowest Level Term]	PRLLT in SUPPPR
9.	Lowest Level Term Code *[hidden]* [Lowest Level Term Code]	PRLLTCD in SUPPPR
10.	D ctionary Derived Term *[hidden]* [D ctionary Derived Term]	PRDECOD
11.	Preferred Term Code *[hidden]* [Preferred Term Code]	PRPTCD in SUPPPR
12.	High Level Term *[hidden]* [High Level Term]	PRHLT in SUPPPR
13.	High Level Term Code *[hidden]* [High Level Term Code]	PRHLTCD in SUPPPR
14.	High Level Group Term *[hidden]* [High Level Group Term]	PRHLGT in SUPPPR
15.	High Level Group Term Code *[hidden]* [High Level Group Term Code]	PRHLGTCD in SUPPPR
16.	Primary System Organ Class *[hidden]* [Primary System Organ Class]	PRBODSYS in SUPPPR PRSOC in SUPPPR
17.	Primary System Organ Class Code *[hidden]* [Primary System Organ Class Code]	PRBDSYCD in SUPPPR PRSOCCD in SUPPPR

STUDYID

VS=Vital Signs

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

#	Date:	Vital Signs Details
1		

Vital Signs

1.	Date: [Date:]	/ / VSDTC

Vital Signs Details

# ✔	Record Identifier:	Oxygen Saturation
2.a	1	

Vital Signs Details Entry

2.1	Record Identifier: [Record Identifier:]	○ 1 VSSPID
2.2	SPO2 Pulse Oximetry % [Oxygen Saturation]	VSORRES when VSTESTCD = OXYSAT

STUDYID

DS=Disposition

C4591001: RANDOMIZATION (RAND) DSCAT=PROTOCOL MILESTONE

Disposition

1.	Randomizat on Date : [Randomization Date :]	/ / DSSTDTC when DSTERM/DSDECOD=RANDOMIZED
2.	Randomizat on Number: [Randomization Number]	DSREFID
3.	Randomizat on Group: [Randomization Group]	DSRANGRP in SUPPDS

STUDYID

DM=Demographics

C4591001: REACTOGENICITY DIARY (REAC DIARY)

Reactogenicity Diary

REACTOFL='Y' in SUPPDM when non-missing of vaccination start date

1.	Select appropriate response - Reactogen c ty diary collection [Trigger Response 9]	◯ YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT ◯ NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT

REACTOFL='N' in SUPPDM

STUDYID

FA=Findings About Events or Interventions

C4591001: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT (REACTION)

Unplanned Assessment Of Local Reaction FACAT=REACTOGENICITY -UNPLANNED ASSESSMENT

1.	CISR Category *[hidden]* [CISR Category]	◯ UNPLANNED ASSESSMENT OF LOCAL REACTION/SYSTEMIC EVENT NOT SUBMITTED
2.	Date of Assessment: [Date of Assessment]	/ / FADTC
3.	Injection Site Location [Injection S te Location]	◯ DELTOID MUSCLE FALOC
4.	Injection Site Body S de: [Injection S te Body Side]	◯ LEFT ◯ RIGHT FALAT

Reaction

#	Reaction:	Reaction Present:
5.a	REDNESS	
5.b	SWELLING	

Reaction Entry

5.1	Reaction: [React on:]	◯ REDNESS ◯ SWELLING FAOBJ
5.2	Reaction Present: [React on 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 FAORRES when FATESTCD=G4CRIMET ◯ NO ◯ NO

Symptom

#	Symptom:	Symptom Present:
6.a	PAIN AT INJECTION SITE	
6.b	FATIGUE/TIREDNESS	
6.c	HEADACHE	
6.d	VOMITING	
6.e	DIARRHEA	
6.f	NEW OR WORSENED MUSCLE PAIN	
6.g	NEW OR WORSENED JOINT PAIN	
6.h	CHILLS	

Symptom Entry

6.1	Symptom: [Symptom:]	FAOBJ
6.2	Symptom Present: [Symptom Present:]	◯ YES FAORRES when FATESTCD=OCCUR Symptom Grade: ◯ 1 ◯ 2 ◯ 3 ◯ 4 FAORRES when FATESTCD=SEV Event related to Study Treament? ◯ YES ◯ NO FAORRES when FATESTCD=REL ◯ NO

STUDYID

PR=Procedures

C4591001: RESPIRATORY TREATMENT (RESP TX) - Repeating Form PRCAT=GENERAL NON-DRUG TREATMENT

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Ongoing?
1						

Respiratory Treatment

1.	What is the treatment Identifier? [Treatment Identifier]	PRSPID
2.	Concomitant Non-drug Treatment Pre-specified: [Con Non-Drug Treatments Pre-specified]	○ YES PRPRESP
3.	Treatment: [Treatment]	○ NON-INVASIVE POSITIVE PRESSURE VENTILATION ○ CPAP ○ MECHANICAL VENTILATION ○ EXTRACORPOREAL MEMBRANE OXYGENATION ○ HIGH FLOW OXYGEN THERAPY PRTRT
4.	Treatment: [Treatment]	PRTRT
5.	Start Date: [Start Date]	/ / PRSTDTC
6.	Ongoing? [Ongoing?]	○ YES PRENRTPT= ONGOING PRENTPT= LAST SUBJECT ENCOUNTER ○ NO End Date: / / PRENDTC
7.	Comparison Term *[hidden]* [Comparison Term]	NOT SUBMITTED
8.	Lowest Level Term *[hidden]* [Lowest Level Term]	PRLLT in SUPPPR
9.	Lowest Level Term Code *[hidden]* [Lowest Level Term Code]	PRLLTCD in SUPPPR
10.	D ctionary Derived Term *[hidden]* [D ctionary Derived Term]	PRDECOD
11.	Preferred Term Code *[hidden]* [Preferred Term Code]	PRPTCD in SUPPPR
12.	High Level Term *[hidden]* [High Level Term]	PRHLT in SUPPPR
13.	High Level Term Code *[hidden]* [High Level Term Code]	PRHLTCD in SUPPPR
14.	High Level Group Term *[hidden]* [High Level Group Term]	PRHLGT in SUPPPR
15.	High Level Group Term Code *[hidden]* [High Level Group Term Code]	PRHLGTCD in SUPPPR
16.	Primary System Organ Class *[hidden]* [Primary System Organ Class]	PRBODSYS in SUPPPR PRSOC in SUPPPR
17.	Primary System Organ Class Code *[hidden]* [Primary System Organ Class Code]	PRBDSYCD in SUPPPR PRSOCCD in SUPPPR

STUDYID

PR=Procedures

C4591001: RESPIRATORY TREATMENT (RESP TX) - Repeating Form PRCAT=GENERAL NON-DRUG TREATMENT

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Ongoing?
1						

Respiratory Treatment

1.	What is the treatment Identifier? [Treatment Identifier]	PRSPID
2.	Concomitant Non-drug Treatment Pre-specified: [Con Non-Drug Treatments Pre-specified]	○ YES PRPRESP
3.	Treatment: [Treatment]	○ INTUBATION ○ NON-INVASIVE POSITIVE PRESSURE VENTILATION PRTRT ○ CPAP ○ OXYGEN THERAPY
4.	Treatment: [Treatment]	PRTRT
5.	Start Date: [Start Date]	/ / PRSTDTC
6.	Ongoing? [Ongoing?]	○ YES PRENRTPT= ONGOING PRENTPT= LAST SUBJECT ENCOUNTER ○ NO End Date: / / PRENDTC
7.	Comparison Term *[hidden]* [Comparison Term]	NOT SUBMITTED
8.	Lowest Level Term *[hidden]* [Lowest Level Term]	PRLLT in SUPPPR
9.	Lowest Level Term Code *[hidden]* [Lowest Level Term Code]	PRLLTCD in SUPPPR
10.	D ctionary Derived Term *[hidden]* [D ctionary Derived Term]	PRDECOD
11.	Preferred Term Code *[hidden]* [Preferred Term Code]	PRPTCD in SUPPPR
12.	High Level Term *[hidden]* [High Level Term]	PRHLT in SUPPPR
13.	High Level Term Code *[hidden]* [High Level Term Code]	PRHLTCD in SUPPPR
14.	High Level Group Term *[hidden]* [High Level Group Term]	PRHLGT in SUPPPR
15.	High Level Group Term Code *[hidden]* [High Level Group Term Code]	PRHLGTCD in SUPPPR
16.	Primary System Organ Class *[hidden]* [Primary System Organ Class]	PRBODSYS in SUPPPR PRSOC in SUPPPR
17.	Primary System Organ Class Code *[hidden]* [Primary System Organ Class Code]	PRBDSYCD in SUPPPR PRSOCCD in SUPPPR

C4591001: FURTHER VACCINATION CONFIRMATION (REVAX CONF) NOT SUBMITTED		
Further Vaccination Confirmation		
1.	Select appropriate response - Is part cipant willing to return for Vaccination 3? [Trigger Response 1]	◯ Participant is willing to return for Vaccinat on 3 Participant is: ◯ eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2 ◯ eligible per other protocol allowance(s) and confirmed to have received only placebo at Vaccination 1/2 ◯ eligible and NOT confirmed to have received only placebo at Vaccination 1/2 ◯ Participant is NOT willing 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

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

STUDYID

IE=Inclusion/Exclusion Criteria Not Met

C4591001: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION (REVAX IE)

	Criterion Description
1.	

Inclusion Criteria Not Met Entry

1.1	Description of Inclusion Cr terion Not Met [Criter on Descript on]	IETEST when IEORRES=N

	Criterion Description
2.	

Exclusion Criteria Met Entry

2.1	Description of Exclusion Cr terion Met [Criter on Descript on]	IETEST when IEORRES=Y

STUDYID

MB=Microbiology Specimen | CO=Comments

C4591001: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB (RSWAB) MBCAT=VIROLOGY

Electronic Sample Tracking

1.	Data Origin [Data Origin]	○ SITE ETRKDOR in SUPPMB
2.	Sample Type [Sample Type]	○ NASAL_SWAB ○ NASAL_SWAB_SELF MBSPEC
3.	Sample Collected? [Sample Collected]	○ NO NOT SUBMITTED ○ YES Date of Collect on: / / MBDTC
4.	If no sample was collected or sample was not collected according to protocol, please provide reason: [Reason sample not collected]	COVAL when RDOMAIN = MB

	Sample ID
5.	

Aliquot Entry

Please enter barcode for each aliquot.

5.1	Sample ID [Sample ID]	NOT SUBMITTED

STUDYID

IS=Immunogenicity Specimen Assessment | CO=Comments

C4591001: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY (SAMP TRK) ISCAT=SEROLOGY

Electronic Sample Tracking

1.	Data Origin [Data Origin]	○ SITE ETRKDOR in SUPPIS
2.	Sample Type [Sample Type]	○ SERUM ISSPEC
3.	Sample Collected? [Sample Collected]	○ NO ○ YES COVAL when COREF=SAMPLE COLLECTED Date of Collect on: / / ISDTC CODTC
4.	If no sample was collected or sample was not collected according to protocol, please provide reason: [Reason sample not collected]	COVAL when RDOMAIN = IS

	Sample ID
5.	

Aliquot Entry

Please enter barcode for each aliquot.

5.1	Sample ID [Sample ID]	NOT SUBMITTED

C4591001: INFORM SCREENING (SCREEN) NOT SUBMITTED		
InForm Screening		
1.	InForm Initials *[hidden]* [InForm Initials]	
2.	Birth Date: [Birth Year]	/ /

STUDYID

MB=Microbiology Specimen | CO=Comments

C4591001: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF (SELF SWAB) MBCAT=VIROLOGY

Electronic Sample Tracking

1.	Data Origin [Data Origin]	○ SITE ETRKDOR in SUPPMB
2.	Sample Type [Sample Type]	○ NASAL_SWAB_SELF MBSPEC
3.	Sample Collected? [Sample Collected]	○ NO NOT SUBMITTED ○ YES Date of Collect on: / / MBDTC
4.	If no sample was collected or sample was not collected according to protocol, please provide reason: [Reason sample not collected]	COVAL when RDOMAIN = MB

	Sample ID
5.	

Aliquot Entry

Please enter barcode for each aliquot.

5.1	Sample ID [Sample ID]	NOT SUBMITTED

STUDYID | Original version: VERSION 1: USED PRIOR TO JULY 6, 2020 New version: VERSION 2: USED AFTER JULY 6, 2020 | FA=Findings About Events or Interventions | CE=Clinical Events

C4591001: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 (SOD) FACAT=EFFICACY CECAT=EFFICACY

Signs and Symptoms FASCAT=RESPIRATORY ILLNESS CESCAT=SIGNS AND SYMPTOMS OF DISEASE

1.	Date of Assessment: [Date of assessment]	/ / FADTC CEDTC
2.	Date of First Symptom Started: [First Symptom Started Date]	/ / FAORRES when FATESTCD=FSYMDATE CESTDTC
3.	Symptoms Ongoing? [Symptoms Ongoing]	YES FAORRES when FATESTCD=SYMONGO CEENRTPT= ONGOING CEENTPT= ONGOING AT CURRENT VISIT NO Date of Last Symptom Resolved: / / FAORRES when FATESTCD=LSYMDATE CEENDTC

Symptoms

# ✔	Event Pre-specified	Symptoms	Symptom Present
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	

Symptoms Entry

4.1	Event Pre-specified: *[hidden]* [Event Pre-specified]	YES NOT SUBMITTED
4.2	Symptoms: [Symptoms]	FAOBJ CETERM
4.3	Was symptom present? [Symptom Present]	YES NO FAORRES when FATESTCD=OCCUR

Symptoms - Other

5. ✔	

Symptoms - Other Entry

5.1	Symptoms - Other Text: [Symptoms - Other]	NOT SUBMITTED
5.2	Comparison Term: *[hidden]* [Comparison Term]	NOT SUBMITTED
5.3	Lowest Level Term *[hidden]* [Lowest Level Term]	NOT SUBMITTED
5.4	Lowest Level Term Code *[hidden]* [Lowest Level Term Code]	NOT SUBMITTED
5.5	Dict onary Derived Term *[hidden]* [Dictionary Derived Term]	FAOBJ
5.6	Preferred Term Code *[hidden]* [Preferred Term Code]	NOT SUBMITTED
5.7	High Level Term *[hidden]* [High Level Term]	NOT SUBMITTED
5.8	High Level Term Code *[hidden]* [High Level Term Code]	NOT SUBMITTED
5.9	High Level Group Term *[hidden]* [High Level Group Term]	NOT SUBMITTED
5.10	High Level Group Term Code *[hidden]* [High Level Group Term Code]	NOT SUBMITTED
5.11	Primary System Organ Class *[hidden]* [Primary System Organ Class]	NOT SUBMITTED
5.12	Primary System Organ Class Code *[hidden]* [Primary System Organ Class	NOT SUBMITTED

	Code]	

STUDYID | Original version: VERSION 1: USED PRIOR TO JULY 6, 2020 New version: VERSION 2: USED AFTER JULY 6, 2020 | FA=Findings About Events or Interventions | CE=Clinical Events

C4591001: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 (SOD) FACAT=EFFICACY | CECAT=EFFICACY

Signs and Symptoms FASCAT=RESPIRATORY ILLNESS | CESCAT=SIGNS AND SYMPTOMS OF DISEASE

1.	Date of Assessment: [Date of assessment]	/ / FADTC | CEDTC
2.	Date of First Symptom Started: [First Symptom Started Date]	/ / FAORRES when FATESTCD=FSYMDATE | CESTDTC
3.	Symptoms Ongoing? [Symptoms Ongoing]	YES / NO FAORRES when FATESTCD=SYMONGO | CEENRTPT= ONGOING | CEENTPT= ONGOING AT CURRENT VISIT Date of Last Symptom Resolved: / / FAORRES when FATESTCD=LSYMDATE | CEENDTC

Symptoms

# ✔	Event Pre-specified	Symptoms	Symptom Present
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	

Symptoms Entry

4.1	Event Pre-specified: *[hidden]* [Event Pre-specified]	YES NOT SUBMITTED
4.2	Symptoms: [Symptoms]	FAOBJ | CETERM
4.3	Was symptom present? [Symptom Present]	YES / NO FAORRES when FATESTCD=OCCUR

Symptoms - Other

5. ✔	

Symptoms - Other Entry

5.1	Symptoms - Other Text: [Symptoms - Other]	NOT SUBMITTED
5.2	Comparison Term: *[hidden]* [Comparison Term]	NOT SUBMITTED
5.3	Lowest Level Term *[hidden]* [Lowest Level Term]	NOT SUBMITTED
5.4	Lowest Level Term Code *[hidden]* [Lowest Level Term Code]	NOT SUBMITTED
5.5	Dict onary Derived Term *[hidden]* [Dictionary Derived Term]	FAOBJ
5.6	Preferred Term Code *[hidden]* [Preferred Term Code]	NOT SUBMITTED
5.7	High Level Term *[hidden]* [High Level Term]	NOT SUBMITTED
5.8	High Level Term Code *[hidden]* [High Level Term Code]	NOT SUBMITTED
5.9	High Level Group Term *[hidden]* [High Level Group Term]	NOT SUBMITTED
5.10	High Level Group Term Code *[hidden]* [High Level Group Term Code]	NOT SUBMITTED
5.11	Primary System Organ Class *[hidden]* [Primary System Organ Class]	NOT SUBMITTED
5.12	Primary System Organ Class Code *[hidden]* [Primary System Organ Class	NOT SUBMITTED

	Code]	

C4591001: STRATIFICATION (STRAT) NOT SUBMITTED		
Stratification		
1.	Select appropriate response - Randomizat on Stage [Trigger Response 3]	◯ Non-Sentinel Stage 1
2.	Select appropriate response - Randomizat on Age Group [Trigger Response 4]	◯ Age 18 to 55 ◯ Age 65 to 85
3.	Select appropriate response - Randomizat on Dose [Trigger Response 5]	◯ 10 mcg ◯ 20 mcg ◯ 30 mcg
4.	Select appropriate response - Randomizat on Dose Group [Trigger Response 8]	◯ 21 Day ◯ 60 Day
5.	Select appropriate response - BNT Number [Trigger Response 7]	◯ (BNT162b1 or PBO) ◯ (BNT162b2 or PBO) ◯ (BNT162b3 or PBO)

C4591001: STRATIFICATION (STRAT) NOT SUBMITTED		
Stratification		
1.	Select appropriate response - Randomizat on Stage [Trigger Response 3]	◯ Stage 2
2.	Select appropriate response - Randomizat on Age Group [Trigger Response 4]	◯ Age 18 to 55 ◯ Age 56 to 85
3.	Select appropriate response - Randomizat on Dose [Trigger Response 5]	◯ 10 mcg ◯ 20 mcg ◯ 30 mcg
4.	Select appropriate response - BNT Number [Trigger Response 7]	◯ (BNT162b1 or PBO) ◯ (BNT162b2 or PBO) ◯ (BNT162b3 or PBO)

C4591001: STRATIFICATION (STRAT) NOT SUBMITTED		
Stratification		
1.	Select appropriate response - Randomizat on Stage [Trigger Response 3]	◯ Stage 1 ◯ Stage 2
2.	Select appropriate response - Randomizat on Age Group [Trigger Response 4]	◯ Age 18 to 55 ◯ Age 56 to 85 ◯ Age 65 to 85
3.	Select appropriate response - Randomizat on Dose [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 (1mcg) ◯ Mid-High dose level (50mcg) ◯ Low-Mid dose level (20mcg)
4.	Select appropriate response - Randomizat on Dose Group *[hidden]* [Trigger Response 6]	◯ 21 Day 2-dose group ◯ 60 Day 2-dose group ◯ 1-dose group
5.	Select appropriate response - Randomizat on Dose Group [Trigger Response 8]	◯ 21 Day ◯ 60 Day
6.	Select appropriate response - BNT Number [Trigger Response 7]	◯ (BNT162a1 or PBO) ◯ (BNT162b1 or PBO) ◯ (BNT162b2 or PBO) ◯ (BNT162c2 or PBO) ◯ (BNT162b3 or PBO)

C4591001: SUBJECT STATUS (SUB STATU) NOT SUBMITTED		
Subject Status		
1.	Subject Status [Subject Status]	
2.	Subject Status Date [Status Date]	/ /

STUDYID

DS=Disposition

C4591001: INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE (SURV CONS) DSCAT=PROTOCOL MILESTONE

Informed Consent - Asymptomatic Surveillance

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

STUDYID

MB=Microbiology Specimen CO=Comments

C4591001: ELECTRONIC SAMPLE TRACKING - NASAL SWAB (SWAB PFE) MBCAT=VIROLOGY

Electronic Sample Tracking

1.	Data Origin [Data Origin]	○ SITE ETRKDOR in SUPPMB
2.	Sample Type [Sample Type]	○ NASAL_SWAB MBSPEC
3.	Sample Collected? [Sample Collected]	○ NO NOT SUBMITTED ○ YES Date of Collect on: / / MBDTC
4.	If no sample was collected or sample was not collected according to protocol, please provide reason: [Reason sample not collected]	COVAL when RDOMAIN = MB

	Sample ID
5.	

Aliquot Entry

Please enter barcode for each aliquot.

5.1	Sample ID [Sample ID]	NOT SUBMITTED

STUDYID

MB=Microbiology Specimen | DI=Device Identifiers | CO=Comments

C4591001: MICROBIOLOGY SPECIMEN (SWAB SITE) - Repeating Form MBCAT=CONFIRMATION OF INFECTION

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Trade Name	Result	Comments:
1								

Microbiology Specimen

1.	Actual Date of Collection: [Date of Collection]	/ / MBDTC
2.	Specimen Type: [Specimen Type]	SWABBED MATERIAL MBSPEC
3.	Specimen Collection Location: [Specimen Collection Location]	NASAL CAVITY MBLOC
4.	Assay Code and Description: [Assay Code and Description]	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2 MBTEST
5.	Device Type: [Device Type]	SARS-COV-2 DIAGNOSTIC TEST DIVAL when DIPARMCD = DEVTYPE
6.	Trade Name: [Trade Name]	CEPHEID XPERT XPRESS SARS-COV-2 TEST DIVAL when DIPARMCD = TRADENAM
7.	Test Result: [Result]	POSITIVE NEGATIVE INDETERMINATE MBORRES when MBTESTCD = SARSCOV2
8.	Comments/Findings/Details: [Comments:]	COVAL when RDOMAIN = MB

STUDYID | CE=Clinical Events | FA=Findings About Events or Interventions | AE=Adverse Events

C4591001: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES (SYMPRDATE)

CECAT=REACTOGENICITY

Vaccination Symptoms Diary - Symptom Resolved Dates

FACAT=REACTOGENICITY | AECAT=REACTOGENICITY

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed? [Fever/Pain Medication on Last Diary Day]	○ YES Ongoing? FAORRES ○ YES FAENRTPT= ONGOING ○ NO Stop Date: / / FAORRES when FATESTCD =STPDMEDP FAENTPT= ONGOING RELATIVE TO LAST DAY OF DIARY PERIOD ○ NO

#	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 PAIN	
2.h	NEW OR WORSENED JOINT PAIN	

2.1	Symptom: [Symptom:]	CETERM FAOBJ AETERM
2.2	Were fever or system c symptoms present on the last day the Subject Diary was completed? [Were fever or systemic symptoms present on the last day the Subject Diary was completed?]	○ YES NOT SUBMITTED Ongoing? ○ YES CEENRTPT= ONGOING ○ NO CEENTPT= ONGOING RELATIVE TO LAST DAY OF DIARY PERIOD ONGNXVIS in SUPPCE AEENRTPT = ONGOING AEENTPT= ONGOING RELATIVE TO LAST DAY OF DIARY PERIOD Stop Date: / / RCENDTC in SUPPCE ○ NO
3.	Injection Site Location: [Injection S te Location:]	○ DELTOID MUSCLE CELOC AELOC
4.	Injection Site Body S de: [Injection S te Body Side:]	○ LEFT CELAT AELAT ○ RIGHT

#	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: [Injection Site Reaction:]	○ REDNESS CETERM FAOBJ AETERM ○ SWELLING ○ PAIN AT INJECTION SITE
5.2	Were injection s te reactions present on the last day the Subject Diary was completed? [Were inject on site reactions present on the last day the Subject Diary was completed?]	○ YES NOT SUBMITTED Ongoing? ○ YES CEENRTPT= ONGOING ○ NO CEENTPT= ONGOING RELATIVE TO LAST DAY OF DIARY PERIOD ONGNXVIS in SUPPCE AEENRTPT = ONGOING AEENTPT= ONGOING RELATIVE TO LAST DAY OF DIARY PERIOD Stop Date: / / RCENDTC in SUPPCE ○ NO

STUDYID

PR=Procedures

C4591001: TRANSFUSIONS (TRANSFUSE) - Repeating Form PRCAT=TRANSFUSION DETAILS

#	Transfusion Type	Date of Transfusion
1		

1.	Transfus on Type: [Transfus on Type]	◯ PACKED RBC ◯ PLATELETS ◯ WHOLE BLOOD ◯ PLASMA ◯ OTHER Specify: PRTRT
2.	Date of Transfus on: [Date of Transfusion]	/ / PRSTDTC

STUDYID

DS=Disposition

C4591001: TREATMENT UNBLINDED (TRN UNBLN) DSCAT=OTHER EVENT

Treatment Unblinded

1.	Date Treatment Unblinded : [Date Treatment Unblinded :]	/ / DSSTDTC
2.	Primary Reason for Unblinding: [Primary Reason for Unblinding]	○ SUBJECT SAFETY CONCERN DSTERM ○ OTHER If other, specify: ○ ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

C4591001: UNPLANNED VISIT (UNPL) NOT SUBMITTED		
Unplanned Assessments		
1.	Assessments [Assessments]	☐ CONTACT OUTCOME

STUDYID

EX=Exposure | EC=Exposure as Collected

C4591001: VACCINATION (VACIN TRT) EXCAT=INVESTIGATIONAL PRODUCT | ECCAT=INVESTIGATIONAL PRODUCT | ECSCAT=VACCINATION

Vaccination EXSCAT=VACCINATION

1.	Was there a temporary delay of vaccinat on? [Temporary Delay of Vaccination]	○ YES EXTDV in SUPPEX | ECTDV in SUPPEC Date of First Delay: [ ] / [ ] / [ ] FDDTC in SUPPEX | FDDTC in SUPPEC Reason(s) for Temporary Delay of Vaccination ☐ FEVER OR ACUTE ILLNESS ☐ RECENT SYSTEMIC CORTICOSTEROID TREATMENT ☐ RECENT NON-STUDY VACCINATION ☐ ANTICIPATED NON-STUDY VACCINATION ○ NO 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 ECADJ1, ECADJ2, etc. in SUPPEC
2.	Treatment Name [Treatment Name]	EXTRT | ECTRT
3.	Formulat on: [Formulat on:]	○ INJECTION EXDOSFRM | ECDOSFRM
4.	Dose Date Time: [Dose Date Time:]	[ ] / [ ] / [ ] EXSTDTC | EXENDTC | ECSTDTC | ECENDTC [ ] : [ ] *24-hour clock*
5.	Anatomical Locat on: [Anatomical Locat on:]	○ DELTOID MUSCLE EXLOC | ECLOC
6.	Body Side: [Body S de:]	○ LEFT ○ RIGHT EXLAT | ECLAT
7.	Route: [Route:]	○ INTRAMUSCULAR EXROUTE | ECROUTE
8.	Planned Dose: [Planned Dose]	[ ] ECDOSE
9.	Planned Dose Unit: [Planned Dose Unit]	○ ug ECDOSU
10.	Actual Dose: [Actual Dose:]	[ ] EXDOSE | ECDOSE
11.	Unit: [Unit:]	○ ug EXDOSU | ECDOSU
12.	Was the Actual Dose adjusted from planned? [Dose Adjusted From Planned]	○ YES EXDOSADJ in SUPPEX | ECDOSADJ in SUPPEC What was the reason the dose was adjusted? ○ ADVERSE EVENT(S) ○ INSUFFICIENT CLINICAL RESPONSE ○ OTHER SPECIFY If other, specify: EXDOSAJO in SUPPEX | ECDOSAJO in SUPPEC ○ NO 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 ECADJ1, ECADJ2, etc. in SUPPEC
13.	Timeframe Subject Was Observed [Timeframe Subject Was Observed]	○ THE PROTOCOL SPECIFIED OBSERVATION PERIOD EXOBSVT in SUPPEX | ECOBSVT in SUPPEC
14.	Was the subject observed for at least the protocol specified observation period after investigational product administration? [Observed Post Dose For Specified Time]	○ YES EXOBSV in SUPPEX | ECOBSV in SUPPEC ○ NO If No, specify reason: EXOBSVD in SUPPEX | ECOBSVD in SUPPEC
15.	Comparison Term *[hidden]* [Comparison Term]	NOT SUBMITTED
16.	Standardized Med cation Name -	EXDECOD in SUPPEX | ECDECOD in SUPPEC

EX=Exposure EC=Exposure as Collected

	D ctionary Derived. *[hidden]* [Standardized Med cation Name]	
17.	Standardized Med cation Code - D ctionary Derived *[hidden]* [Standardized Med cation Code]	EXCD in SUPPEX ECCD in SUPPEC

STUDYID

EX=Exposure | EC=Exposure as Collected

C4591001: VACCINATION (VACIN TRT) EXCAT=INVESTIGATIONAL PRODUCT | ECCAT=INVESTIGATIONAL PRODUCT | ECSCAT=VACCINATION

Vaccination EXSCAT=VACCINATION

1.	Was there a temporary delay of vaccinat on? [Temporary Delay of Vaccination]	○ YES EXTDV in SUPPEX ECTDV in SUPPEC Date of First Delay: / / FDDTC in SUPPEX FDDTC in SUPPEC Reason(s) for Temporary Delay of Vaccination ☐ FEVER OR ACUTE ILLNESS ☐ RECENT SYSTEMIC CORTICOSTEROID TREATMENT ☐ RECENT NON-STUDY VACCINATION ☐ ANTICIPATED NON-STUDY VACCINATION 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 ECADJ1, ECADJ2, etc. in SUPPEC ○ NO
2.	Treatment Name [Treatment Name]	EXTRT ECTRT
3.	Formulat on: [Formulat on:]	○ INJECTION EXDOSFRM ECDOSFRM
4.	Dose Date Time: [Dose Date Time:]	/ / EXSTDTC EXENDTC ECSTDTC ECENDTC : *24-hour clock*
5.	Anatomical Locat on: [Anatomical Locat on:]	○ DELTOID MUSCLE EXLOC ECLOC
6.	Body Side: [Body S de:]	○ LEFT ○ RIGHT EXLAT ECLAT
7.	Route: [Route:]	○ INTRAMUSCULAR EXROUTE ECROUTE
8.	Container Number: *[hidden]* [PAC / K t Number:]	NOT SUBMITTED
9.	Actual Dose: [Actual Dose:]	EXDOSE ECDOSE
10.	Unit: [Unit:]	○ mL ○ ug EXDOSU ECDOSU
11.	Timeframe Subject Was Observed [Timeframe Subject Was Observed]	○ THE PROTOCOL SPECIFIED OBSERVATION PERIOD ○ EXOBSVT in SUPPEX ECOBSVT in SUPPEC
12.	Was the subject observed for at least the protocol specified observation period after investigational product administration? [Observed Post Dose For Specified Time]	○ YES EXOBSV in SUPPEX ECOBSV in SUPPEC ○ NO If No, specify reason: EXOBSVD in SUPPEX ECOBSVD in SUPPEC
13.	Comparison Term *[hidden]* [Comparison Term]	NOT SUBMITTED
14.	Standardized Med cation Name - D ctionary Derived. *[hidden]* [Standardized Med cation Name]	EXDECOD in SUPPEX ECDECOD in SUPPEC
15.	Standardized Med cation Code - D ctionary Derived *[hidden]*	EXCD in SUPPEX ECCD in SUPPEC

	[Standardized Med cation Code]	

STUDYID

CM=Concomitant Medications

C4591001: CONCOMITANT MEDICATIONS - VASOPRESSORS (VASOPRESS) - Repeating Form

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Ongoing
1						

CMSCAT=VASOPRESSORS AGENTS

Concomitant Medications

1.	What is the medication identifier? [Sponsor-Defined Identifier]	CMSPID
2.	Category: [Category for Med cat on]	○ GENERAL CONCOMITANT MEDICATIONS CMCAT
3.	Concomitant Medications Pre-specified: [Concomitant Medications Pre-specified]	○ NO NOT SUBMITTED
4.	Medication: Provide the complete gener c drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Med cat on text (e.g., Ingredient(s), route, use, formulation). [Name of Medication]	CMTRT
5.	Start Date: [Start Date]	/ / CMSTDTC
6.	Ongoing? [Ongoing]	○ YES CMENRTPT= ONGOING CMENTPT= LAST SUBJECT ENCOUNTER ○ NO End Date: / / CMENDTC
7.	Comparison Term *[hidden]* [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 derived *[hidden]* [Standardized Med cat on Code]	CMCODE in SUPPCM

STUDYID

VS=Vital Signs

C4591001: VITAL SIGNS - TEMP (VITAL TEMP) VSCAT=REACTOGENICITY - UNPLANNED TEMPERATURE

Vital Signs VSSCAT=SYSTEMIC

1.	Date: [Date:]	/ / VSDTC

Vital Signs Details

#	Record Identifier:	Temperature	Temperature Unit	Temperature Location:
2.a	1			

Vital Signs Details Entry

2.1	Record Identifier: [Record Identifier:]	○ 1 VSSPID
2.2	Temperature: [Temperature]	VSORRES when VSTESTCD =TEMP
2.3	Unit: [Temperature Unit]	○ F ○ C VSORRESU when VSTESTCD = TEMP
2.4	Temperature Location: [Temperature Location:]	○ ORAL CAVITY ○ EAR ○ RECTUM ○ AXILLA ○ FOREHEAD VSLOC when VSTESTCD = TEMP

STUDYID

VS=Vital Signs

C4591001: VITAL SIGNS - BASELINE (VITALS BSL) VSCAT=GENERAL VITAL SIGNS

Vital Signs

1.	Date: [Date:]	/ / VSDTC
2.	Weight: [Weight]	VSORRES when VSTESTCD = WEIGHT
3.	Un t: [Weight Unit]	kg LB VSORRESU when VSTESTCD = WEIGHT
4.	Height: [Height]	VSORRES when VSTESTCD = HEIGHT
5.	Un t: [Height Un t]	cm in VSORRESU when VSTESTCD = HEIGHT
6.	Body Mass Index: [Body Mass Index]	VSORRES when VSTESTCD = BMI

Vital Signs Details

#	Record Identifier:	Temperature	Temperature Unit	Temperature Location:
7.a	1			

Vital Signs Details Entry

7.1	Record Identifier: [Record Identifier:]	1 VSSPID
7.2	Temperature: [Temperature]	VSORRES when VSTESTCD = TEMP
7.3	Unit: [Temperature Unit]	C F VSORRESU when VSTESTCD = TEMP
7.4	Temperature Location: [Temperature Location:]	ORAL CAVITY EAR RECTUM AXILLA FOREHEAD VSLOC when VSTESTCD = TEMP

STUDYID

VS=Vital Signs

C4591001: VITAL SIGNS - BASELINE (VITALS BSL) VSCAT=GENERAL VITAL SIGNS

Vital Signs

1.	Date: [Date:]	/ / VSDTC
2.	Weight: [Weight]	VSORRES when VSTESTCD = WEIGHT
3.	Un t: [Weight Unit]	kg LB VSORRESU when VSTESTCD = WEIGHT
4.	Height: [Height]	VSORRES when VSTESTCD = HEIGHT
5.	Un t: [Height Un t]	cm in VSORRESU when VSTESTCD = HEIGHT
6.	Body Mass Index: [Body Mass Index]	VSORRES when VSTESTCD = BMI

Vital Signs Details

#	Record Identifier:	Temperature	Temperature Unit	Temperature Location:	Systolic:	Diastolic:	BP Position	Pulse:
7.a	1						SITTING	

Vital Signs Details Entry

7.1	Record Identifier: [Record Identifier:]	1 VSSPID
7.2	Temperature: [Temperature]	VSORRES when VSTESTCD = TEMP
7.3	Unit: [Temperature Unit]	C F VSORRESU when VSTESTCD = TEMP
7.4	Temperature Location: [Temperature Location:]	ORAL CAVITY EAR RECTUM AXILLA FOREHEAD VSLOC when VSTESTCD = TEMP
7.5	Systol c: [Systolic:]	VSORRES when VSTESTCD = SYSBP
7.6	Diastol c: [Diastol c:]	VSORRES when VSTESTCD = DIABP
7.7	BP Posit on: [BP Position]	SITTING VSPOS when VSTESTCD = DIABP, SYSBP
7.8	Pulse: [Pulse:]	VSORRES when VSTESTCD = PULSE

STUDYID

VS=Vital Signs

C4591001: VITAL SIGNS - COVID (VITALS COV) - Repeating Form VSCAT=GENERAL VITAL SIGNS

#	Date:	Vital Signs Details
1		

Vital Signs

1.	Date: [Date:]	/ / VSDTC

Vital Signs Details

# ✔	Record Identifier:	Systolic:	Diastolic:	Respiratory Rate in respirations/minute	Heart Rate in beats/minute
2.a	1				

Vital Signs Details Entry

2.1	Record Identifier: [Record Identifier:]	1 VSSPID
2.2	Systol c: [Systolic:]	VSORRES when VSTESTCD = SYSBP
2.3	Diastol c: [Diastol c:]	VSORRES when VSTESTCD = DIABP
2.4	Respiratory Rate in respirations/minute: [Respiratory Rate in respirations/minute]	VSORRES when VSTESTCD = RESP
2.5	Heart Rate in beats/minute: [Heart Rate in beats/minute]	VSORRES when VSTESTCD = HR

STUDYID

VS=Vital Signs

C4591001: VITAL SIGNS (VITALS FUP) VSCAT=GENERAL VITAL SIGNS

Vital Signs

1.	Date: [Date:]	/ / VSDTC

Vital Signs Details

#	Record Identifier:	Temperature	Temperature Unit	Temperature Location:	Systolic:	Diastolic:	BP Position	Pulse:
2.a	1						SITTING	

Vital Signs Details Entry

2.1	Record Identifier: [Record Identifier:]	○ 1 VSSPID
2.2	Temperature: [Temperature]	VSORRES when VSTESTCD = TEMP
2.3	Unit: [Temperature Unit]	○ F ○ C VSORRESU when VSTESTCD = TEMP
2.4	Temperature Location: [Temperature Location:]	○ ORAL CAVITY ○ EAR ○ RECTUM ○ AXILLA ○ FOREHEAD VSLOC when VSTESTCD = TEMP
2.5	Systol c: [Systolic:]	VSORRES when VSTESTCD = SYSBP
2.6	Diastol c: [Diastol c:]	VSORRES when VSTESTCD = DIABP
2.7	BP Posit on: [BP Position]	○ SITTING VSPOS when VSTESTCD = DIABP, SYSBP
2.8	Pulse: [Pulse:]	VSORRES when VSTESTCD = PULSE

STUDYID

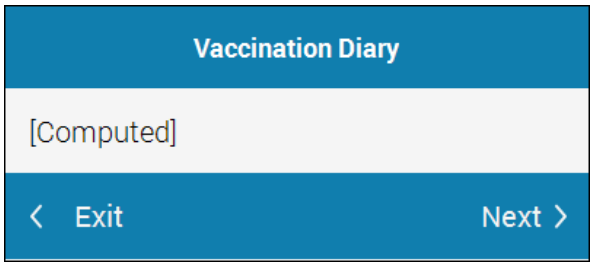
DS=Disposition

C4591001: WITHDRAWAL OF CONSENT (WOC) DSCAT=OTHER EVENT

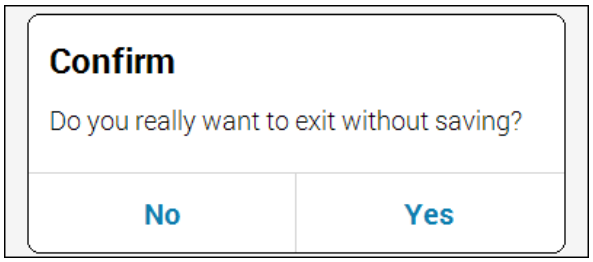
Withdrawal Of Consent

1.	Withdrawal of Consent Date : [Withdrawal of Consent Date :]	/ /	DSSTDTC when DSTERM/DSDECOD=WITHDRAWAL OF CONSENT

3 Form: Vaccination Diary



Screen 1



Message 1

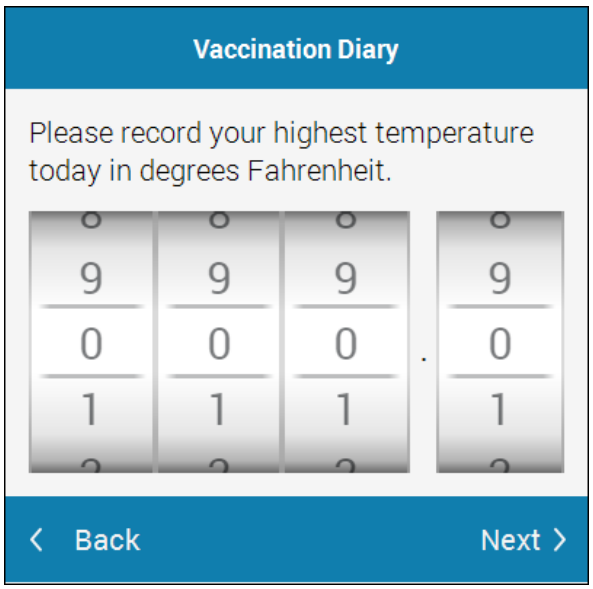
[Computed] Text will display "Hello, welcome to the vaccination diary. You will be answering the following questions about how you have been feeling since your vaccination on {1}. You will answer these questions for {2} day(s)."

{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).

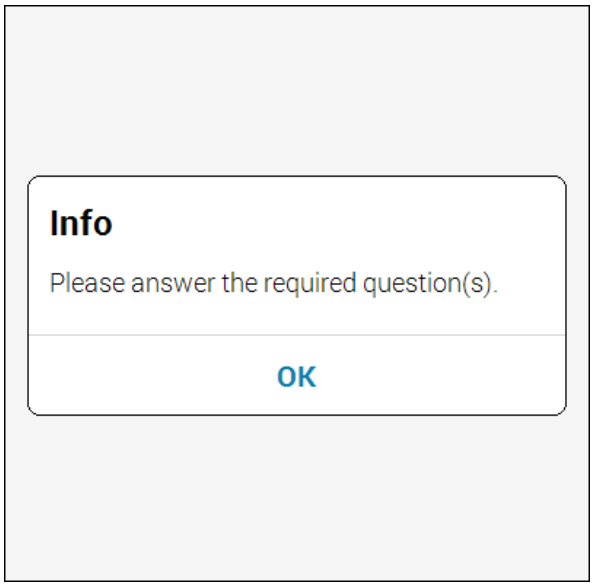
VSORRESU when VSTESTCD = TEMP



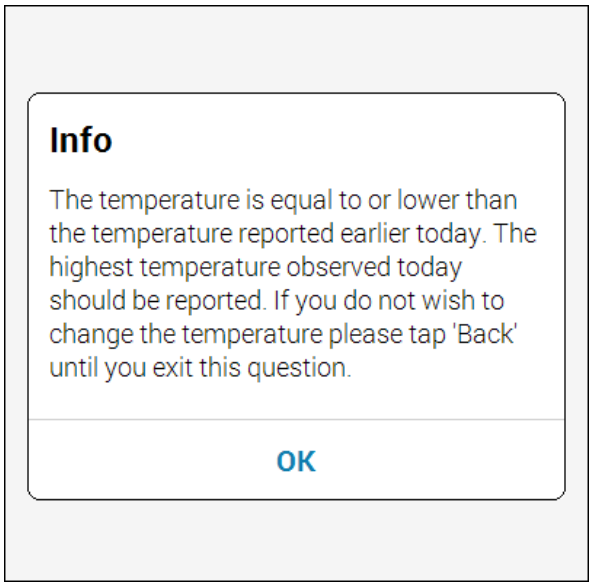
Screen 3

VSORRES when VSTESTCD = TEMP

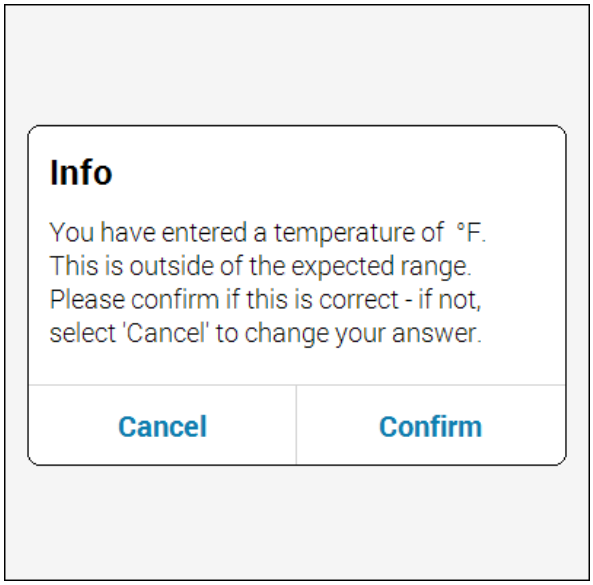
MAXIMUM in SUPPVS



Message 1

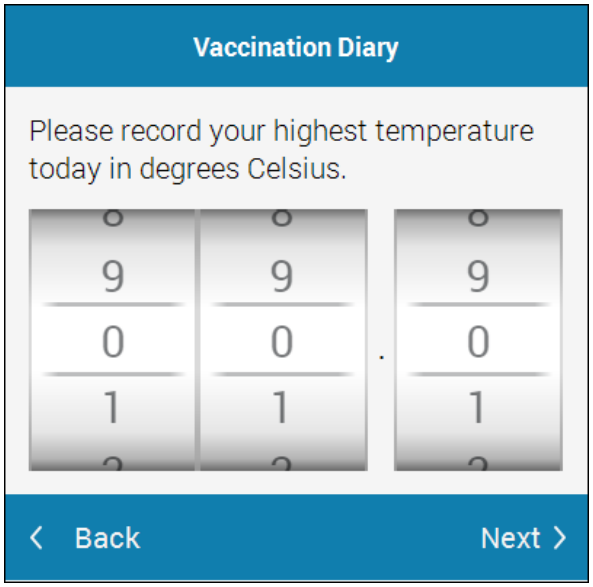


Message 2



Message 3

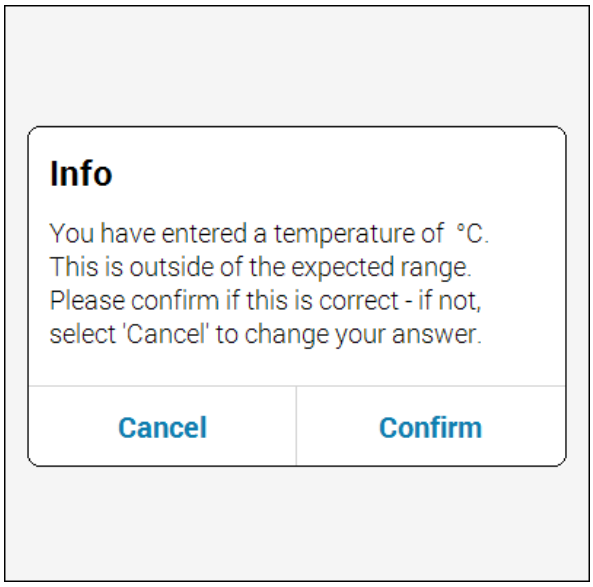
VSORRESU when VSTESTCD = TEMP



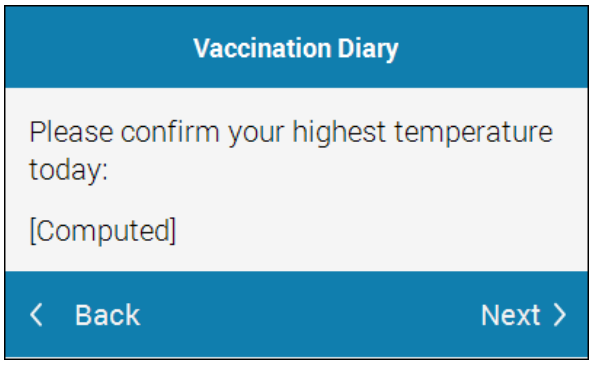
Screen 4

VSORRES when VSTESTCD = TEMP

MAXIMUM in SUPPVS

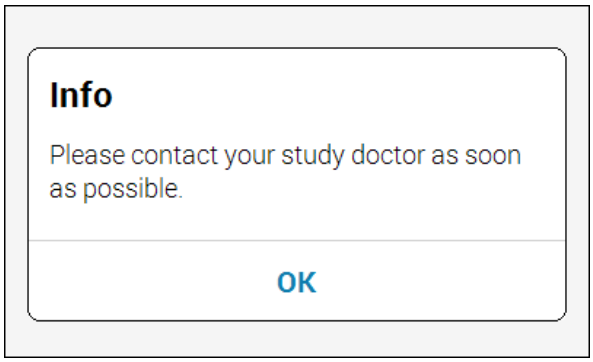


Message 3

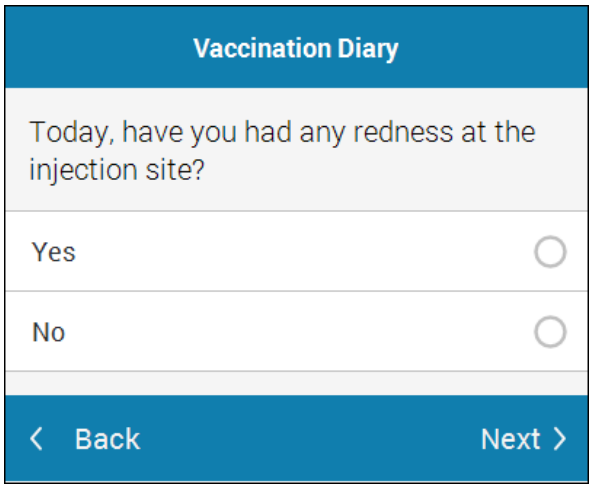


Screen 5

[Computed] will display the temperature selected on Screen 3 or Screen 4



Message 1



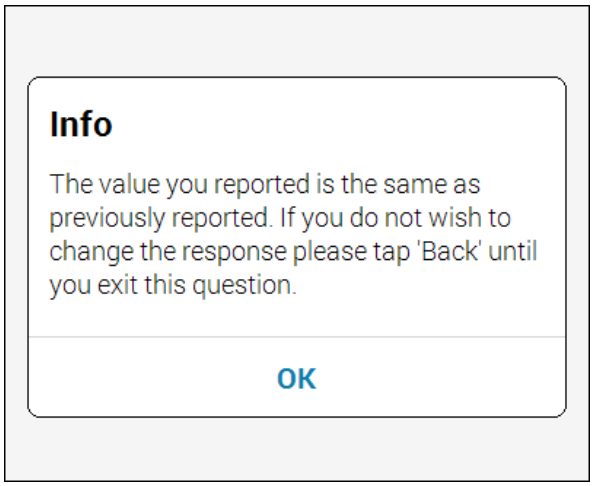
Screen 6

FAORRES when FATESTCD = OCCUR and FAOBJ = REDNESS

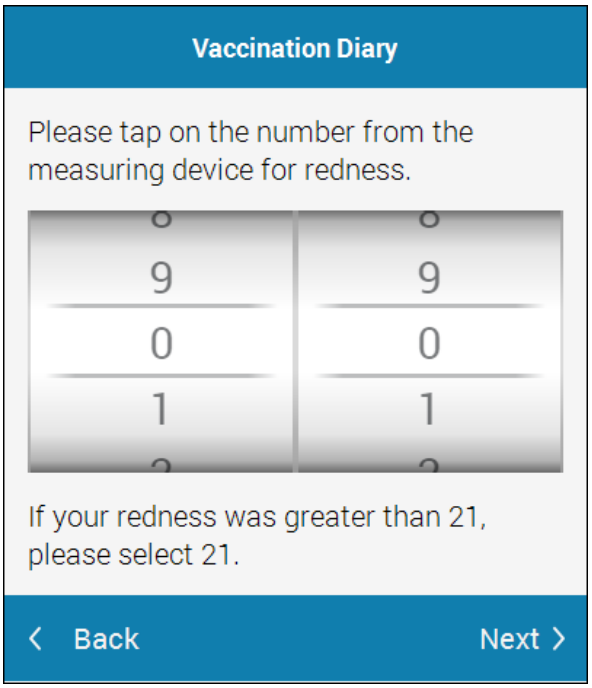
FASCAT = ADMINISTRATION SITE

FASCAT = ADMINISTRATION SITE

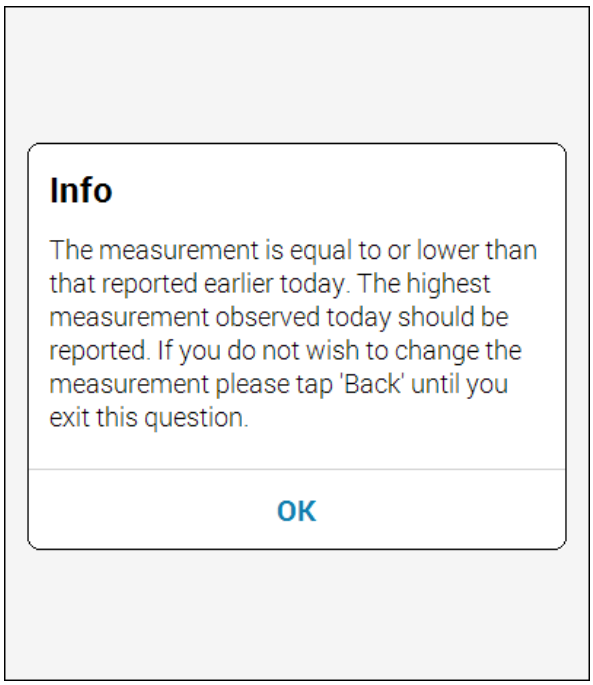
FAORRES when FATESTCD = DIAMETER and FAOBJ = REDNESS



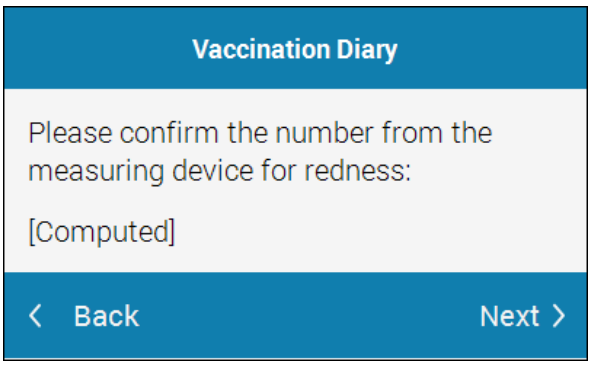
Message 2



Screen 7



Message 2

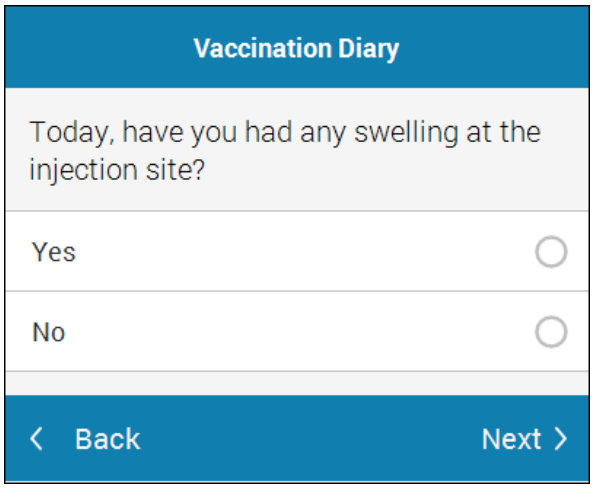


Screen 8

[Computed] will display the number selected on Screen 7.

FASCAT = ADMINISTRATION SITE

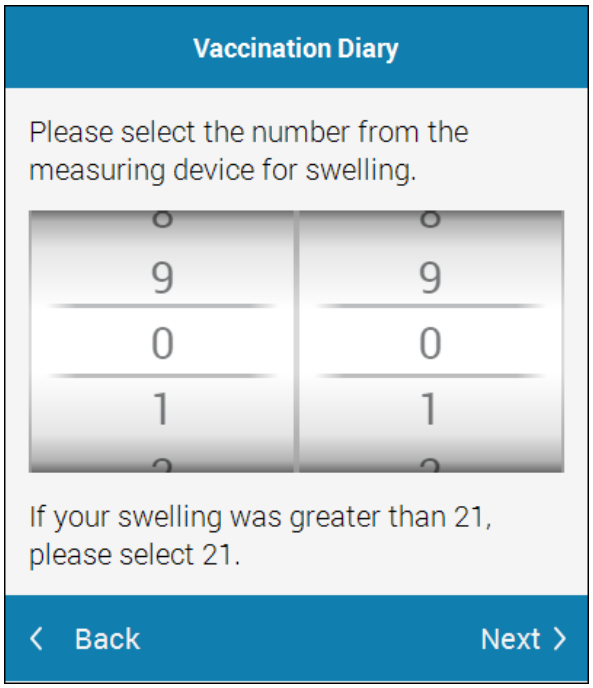
FAORRES when FATESTCD = OCCUR and FAOBJ = SWELLING



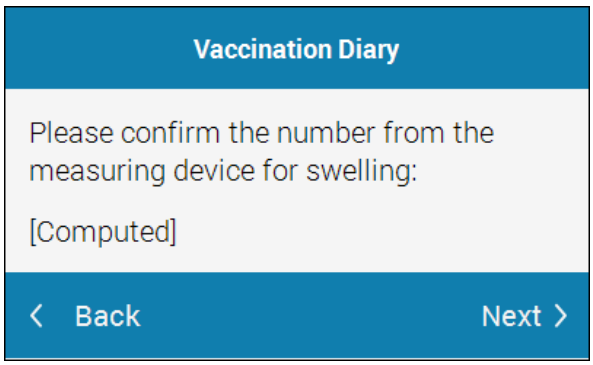
Screen 9

FASCAT = ADMINISTRATION SITE

FAORRES when FATESTCD = DIAMETER and FAOBJ = SWELLING

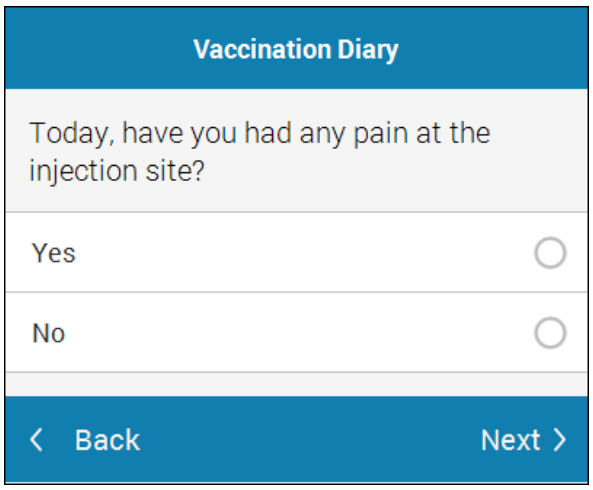


Screen 10



Screen 11

[Computed] will display the number selected on Screen 10.



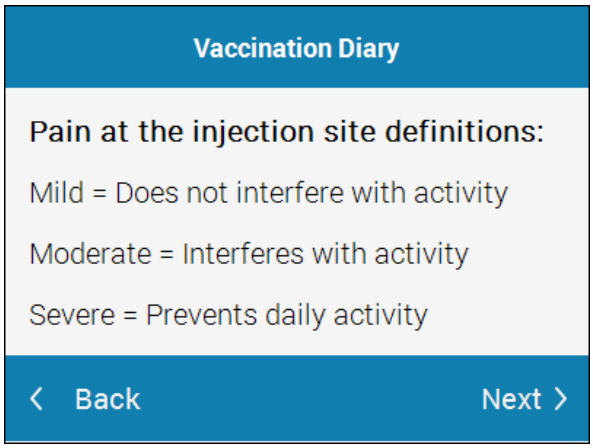
Screen 12

FAORRES when FATESTCD = OCCUR and FAOBJ = PAIN AT INJECTION SITE

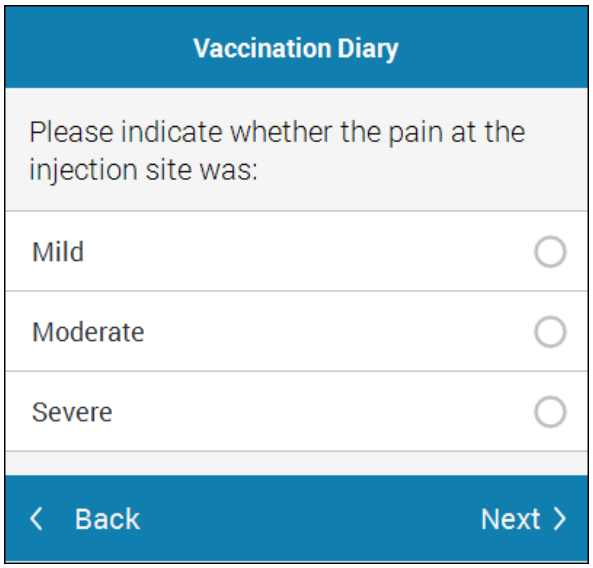
FASCAT = ADMINISTRATION SITE

FASCAT = ADMINISTRATION SITE

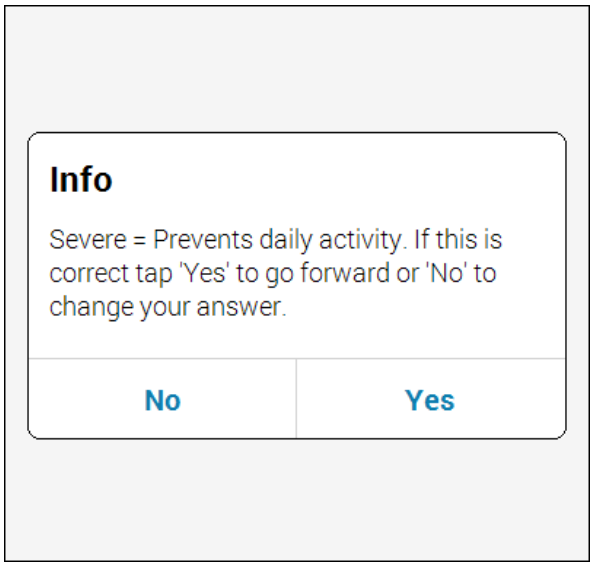
FAORRES when FATESTCD = SEV and FAOBJ = PAIN AT INJECTION SITE



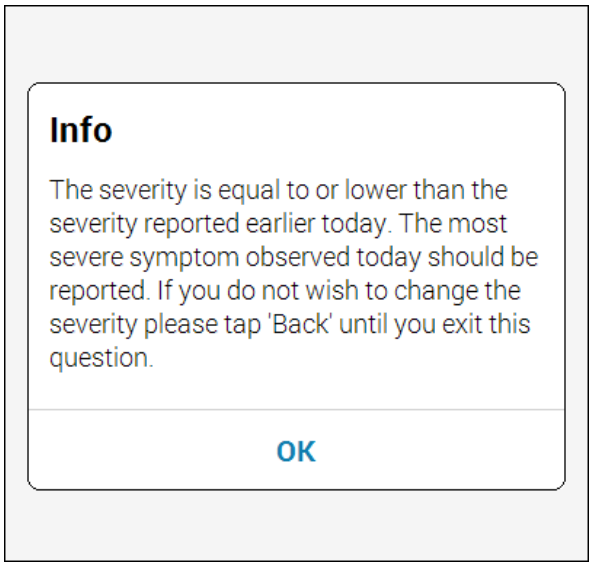
Screen 13



Screen 14



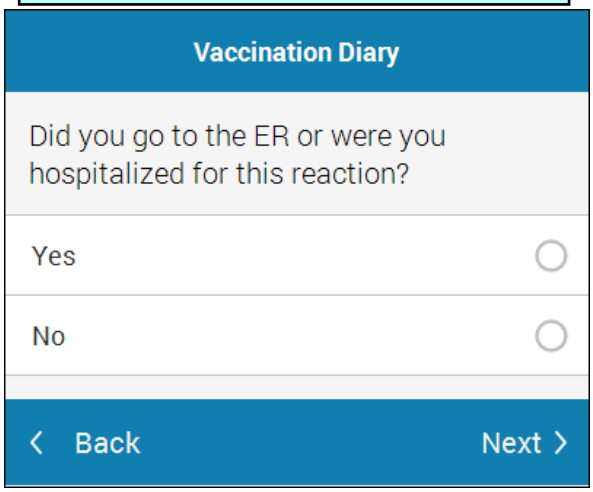
Message 2



Message 4

FASCAT = ADMINISTRATION SITE

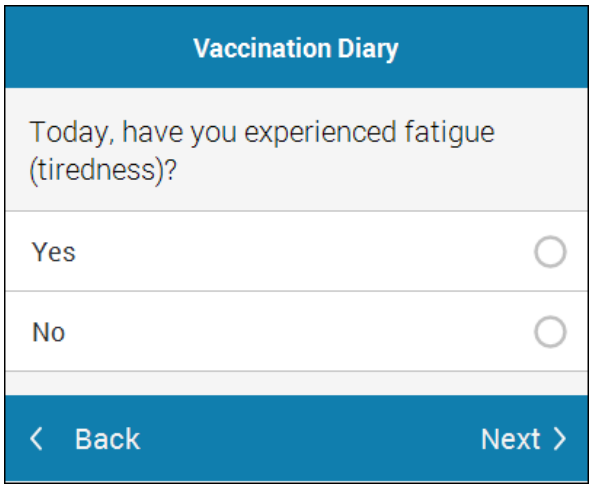
FAORRES when FATESTCD = OCCUR and FAOBJ = HOSPITALIZED FOR INJECTION SITE PAIN



Screen 15

FASCAT = SYSTEMIC

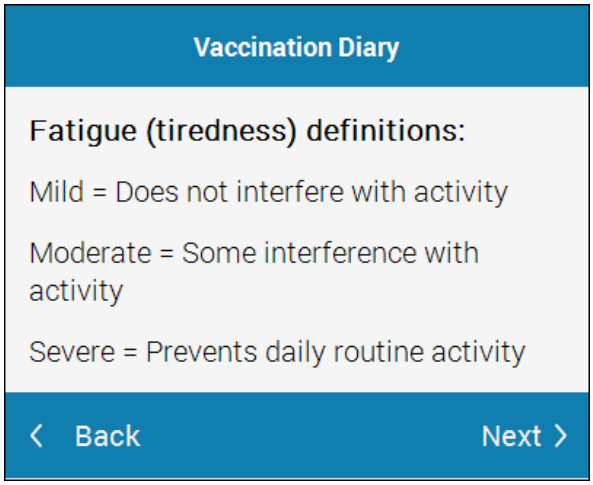
FAORRES when FATESTCD = OCCUR and FAOBJ = FATIGUE



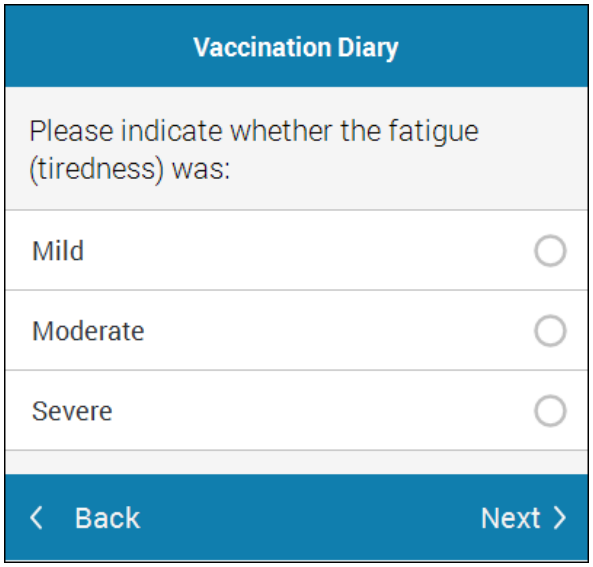
Screen 16

FASCAT = SYSTEMIC

FAORRES when FATESTCD = SEV and FAOBJ = FATIGUE

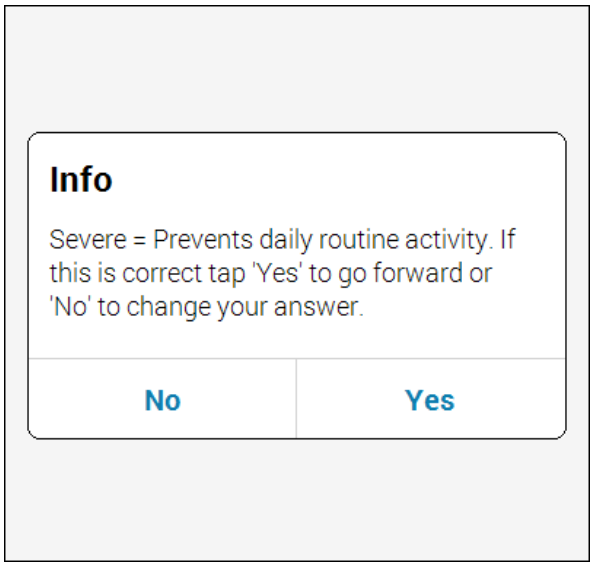


Screen 17



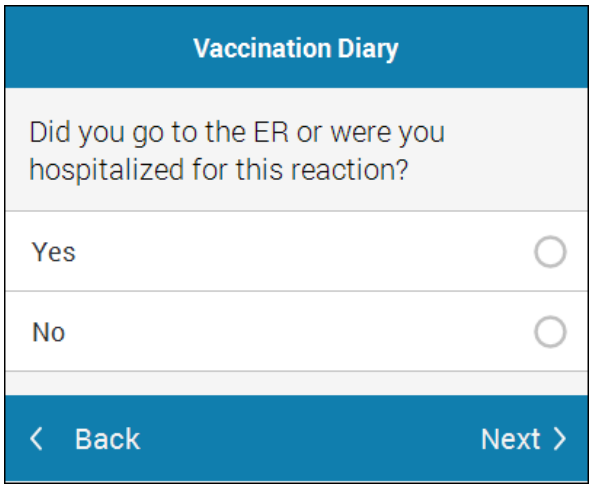
Screen 18

FASCAT = SYSTEMIC



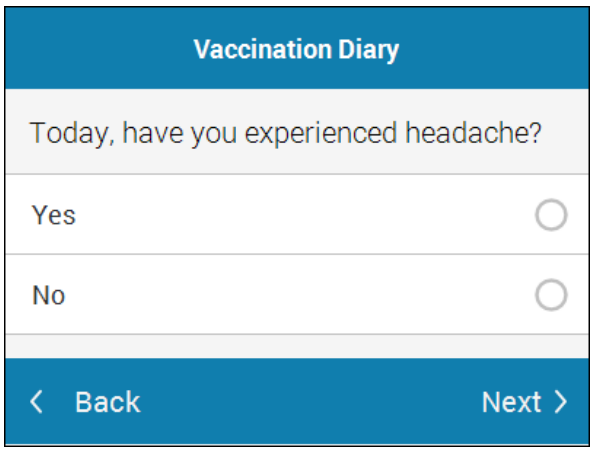
Message 2

FAORRES when FATESTCD = OCCUR and FAOBJ = HOSPITALIZED FOR TIREDNESS (FATIGUE)



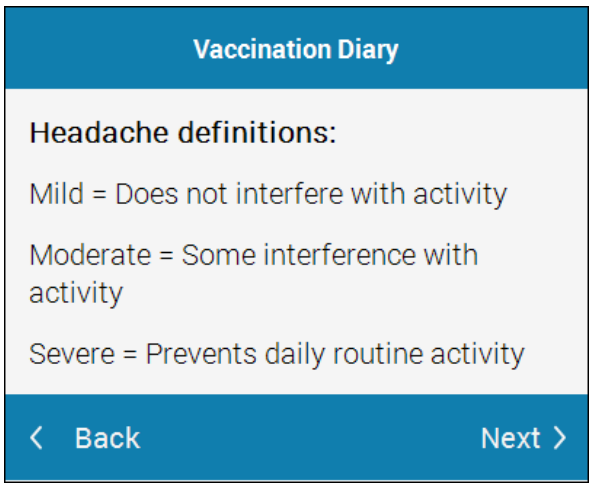
Screen 19

FAORRES when FATESTCD = OCCUR and FAOBJ = HEADACHE



Screen 20

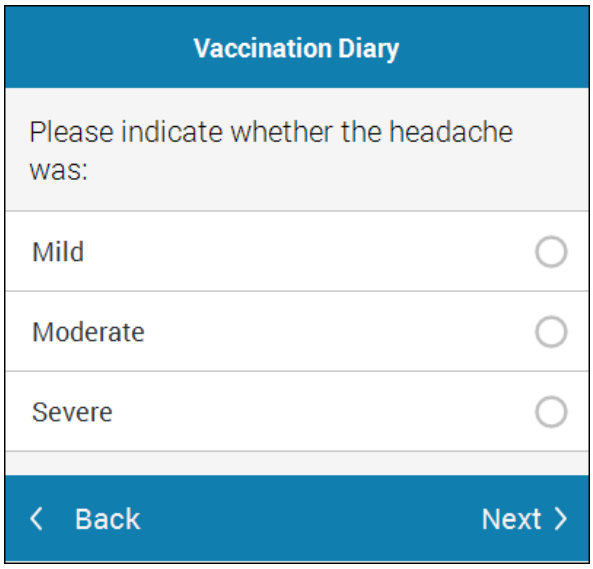
FASCAT = SYSTEMIC



Screen 21

FASCAT = SYSTEMIC

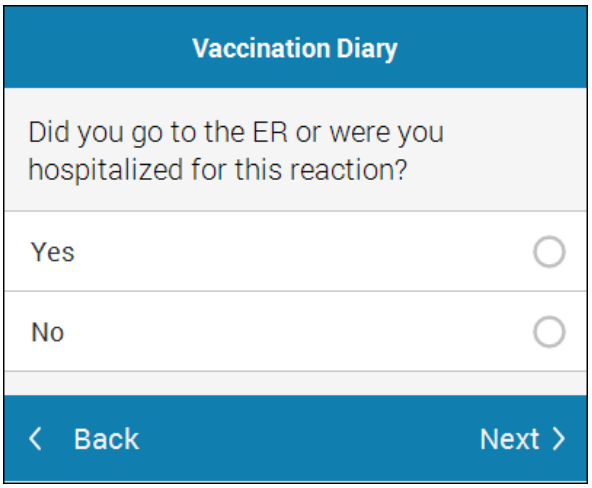
FAORRES when FATESTCD = SEV and FAOBJ = HEADACHE



Screen 22

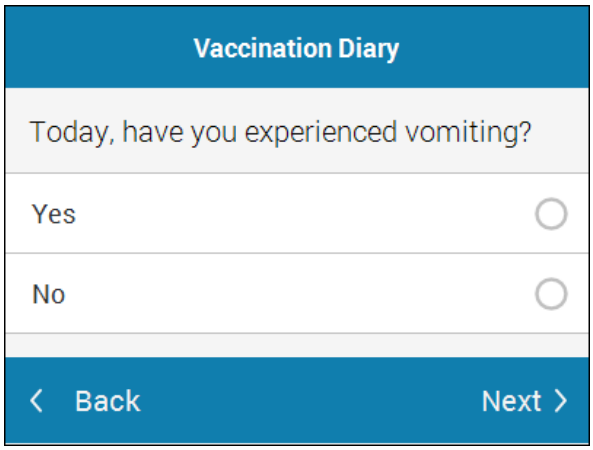
FASCAT = SYSTEMIC

FAORRES when FATESTCD = OCCUR and FAOBJ = HOSPITALIZED FOR HEADACHE



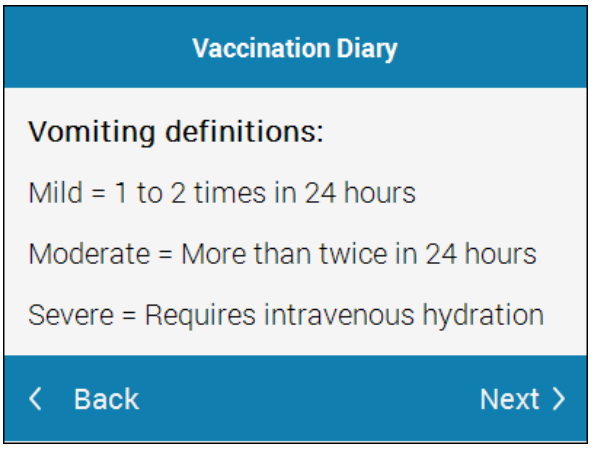
Screen 23

FAORRES when FATESTCD = OCCUR and FAOBJ = VOMITING



Screen 24

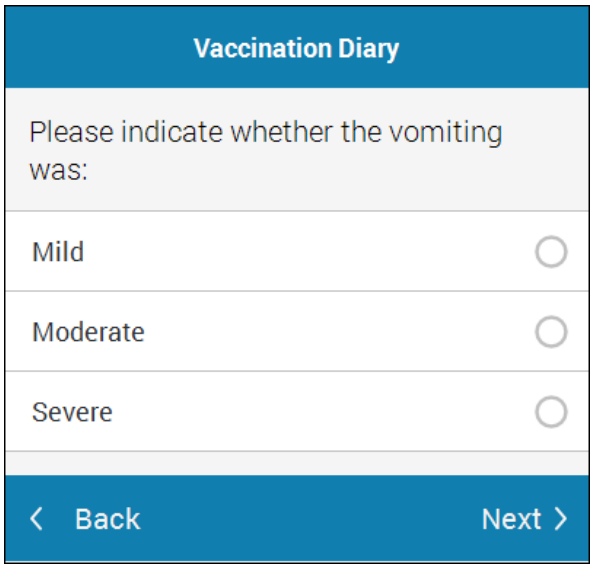
FASCAT = SYSTEMIC



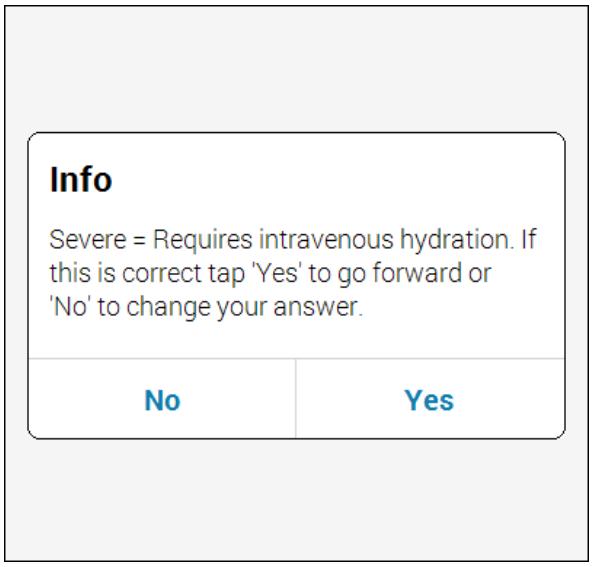
Screen 25

FAORRES when FATESTCD = SEV and FAOBJ = VOMITING

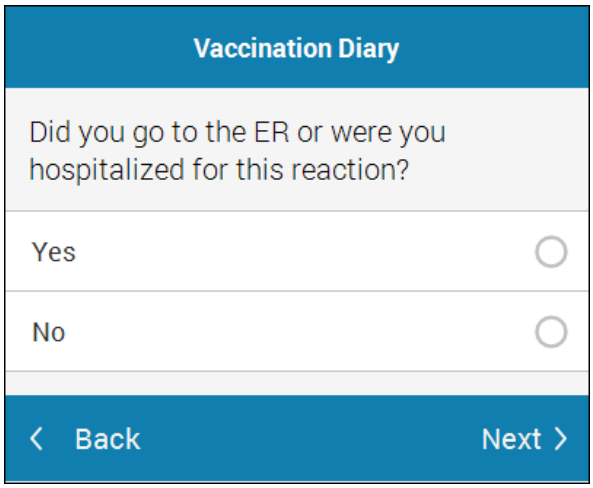
FASCAT = SYSTEMIC



Screen 26



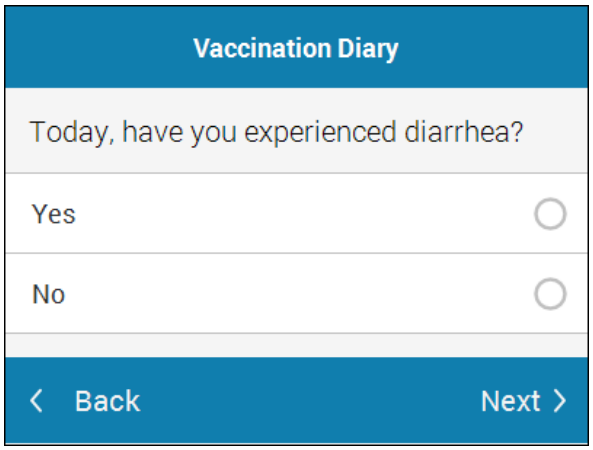
Message 2



Screen 27

FAORRES when FATESTCD = OCCUR and FAOBJ = HOSPITALIZED FOR VOMITING

FASCAT = SYSTEMIC



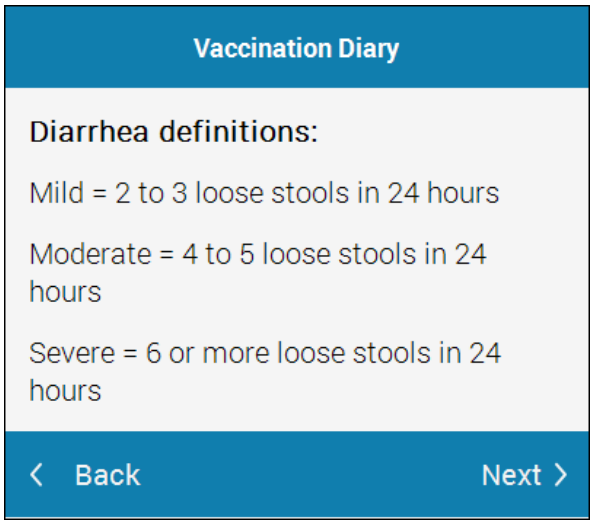
Screen 28

FAORRES when FATESTCD = OCCUR and FAOBJ = DIARRHEA

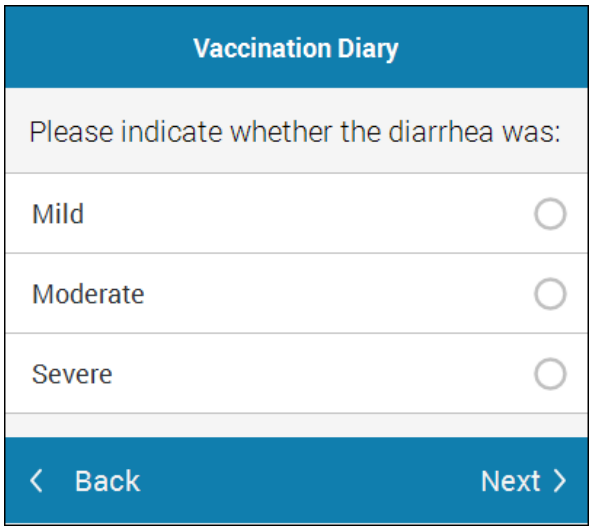
FASCAT = SYSTEMIC

FASCAT = SYSTEMIC

FAORRES when FATESTCD = SEV and FAOBJ = DIARRHEA



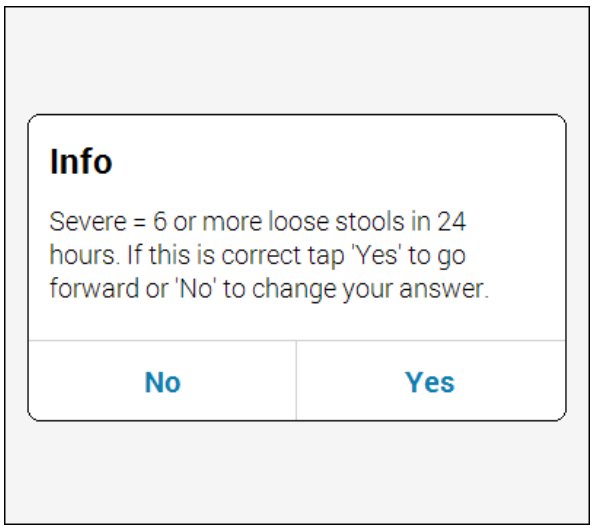
Screen 29



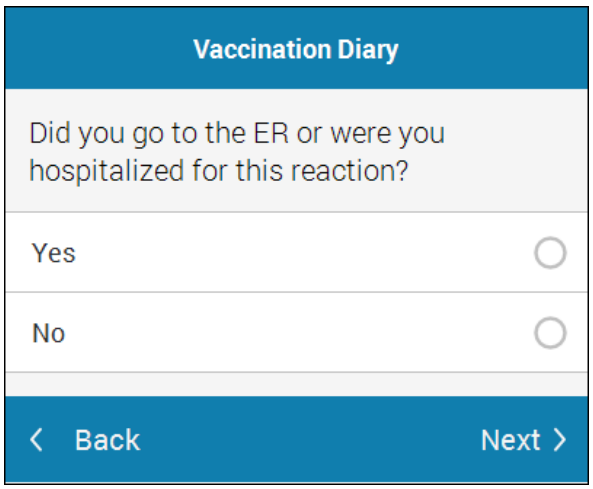
Screen 30

FASCAT = SYSTEMIC

FAORRES when FATESTCD = OCCUR and FAOBJ = HOSPITALIZED FOR DIARRHEA

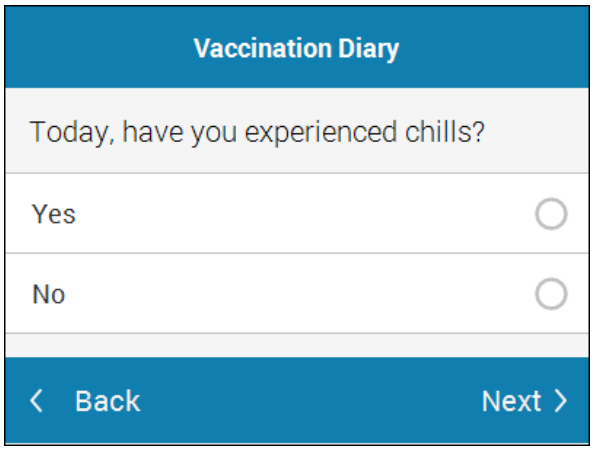


Message 2



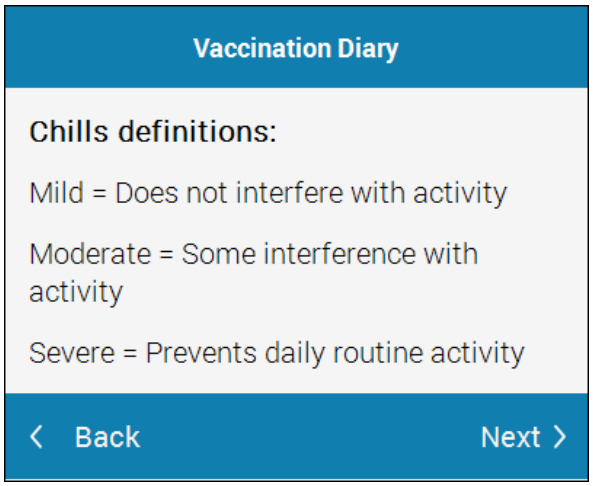
Screen 31

FAORRES when FATESTCD = OCCUR and FAOBJ = CHILLS



Screen 32

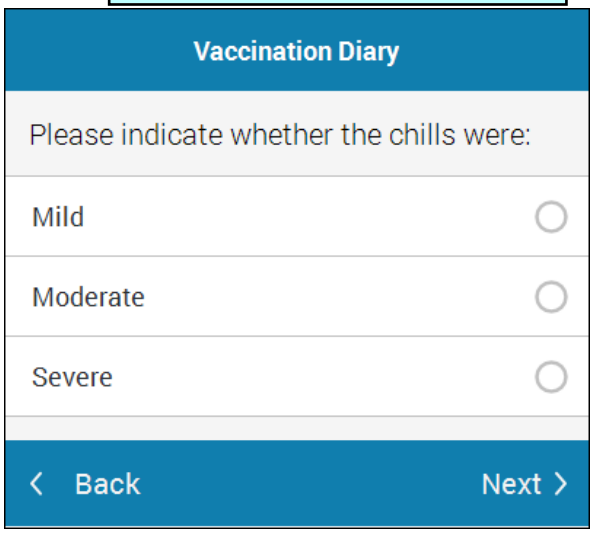
FASCAT = SYSTEMIC



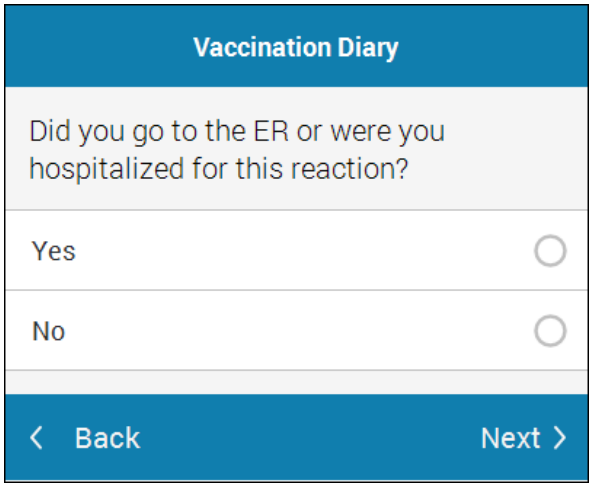
Screen 33

FASCAT = SYSTEMIC

FAORRES when FATESTCD = SEV and FAOBJ = CHILLS



Screen 34



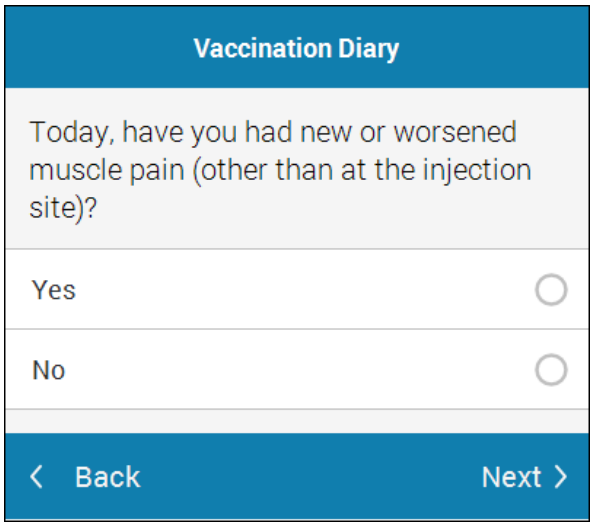
Screen 35

FAORRES when FATESTCD = OCCUR and FAOBJ = HOSPITALIZED FOR CHILLS

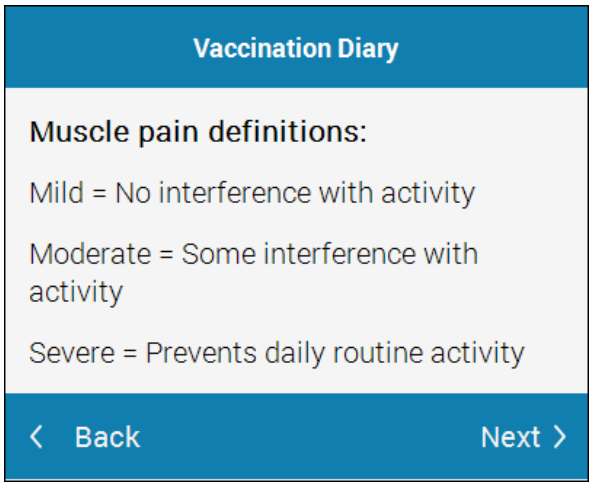
FASCAT = SYSTEMIC

FAORRES when FATESTCD = OCCUR and FAOBJ = MUSCLE PAIN

FASCAT = SYSTEMIC



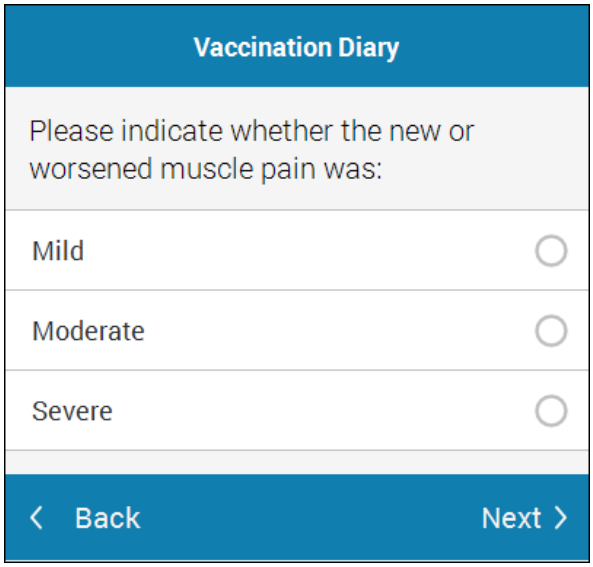
Screen 36



Screen 37

FASCAT = SYSTEMIC

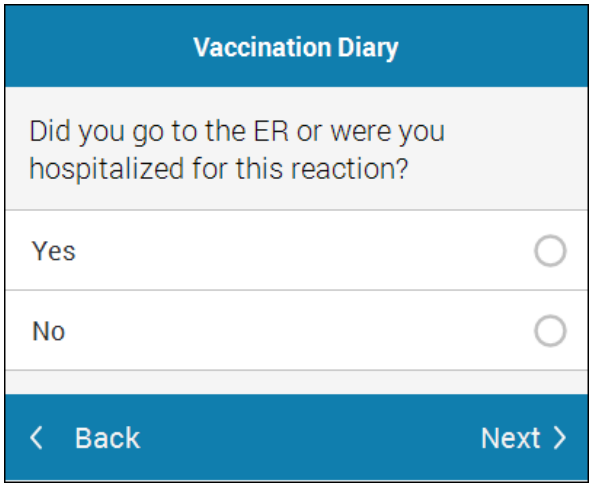
FAORRES when FATESTCD = OCCUR and FAOBJ = HOSPITALIZED FOR MUSCLE PAIN



Screen 38

FAORRES when FATESTCD = SEV and FAOBJ = MUSCLE PAIN

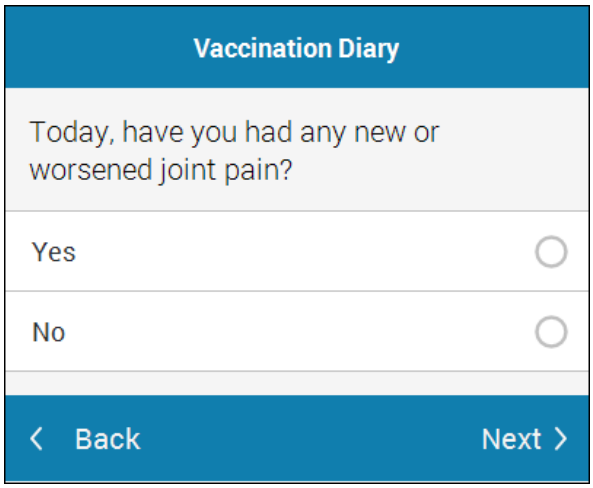
FASCAT = SYSTEMIC



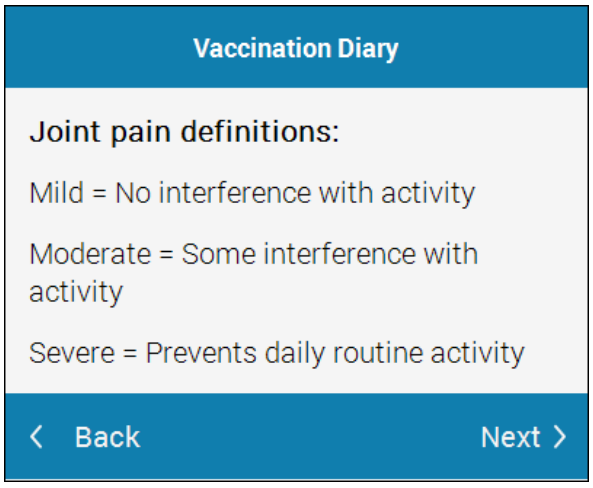
Screen 39

FAORRES when FATESTCD = OCCUR and FAOBJ = JOINT PAIN

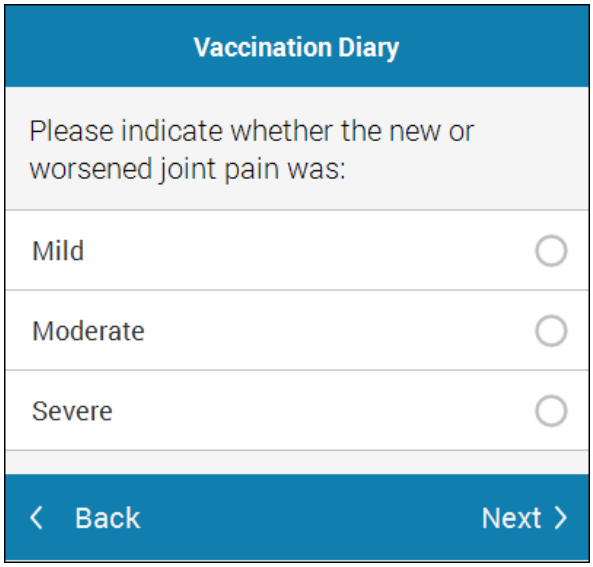
FASCAT = SYSTEMIC



Screen 40



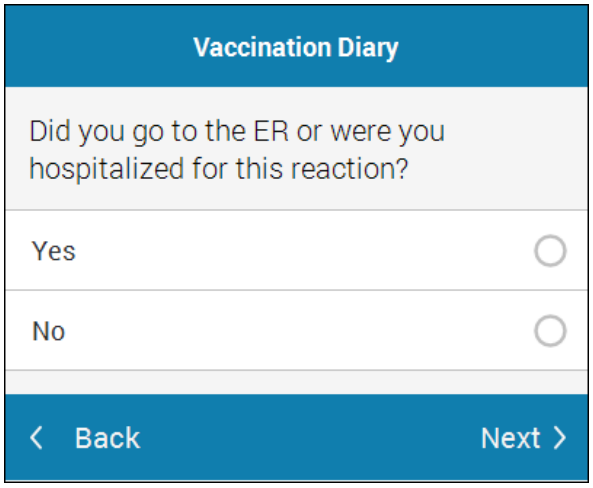
Screen 41



Screen 42

FAORRES when FATESTCD = SEV and FAOBJ = JOINT PAIN

FASCAT = SYSTEMIC



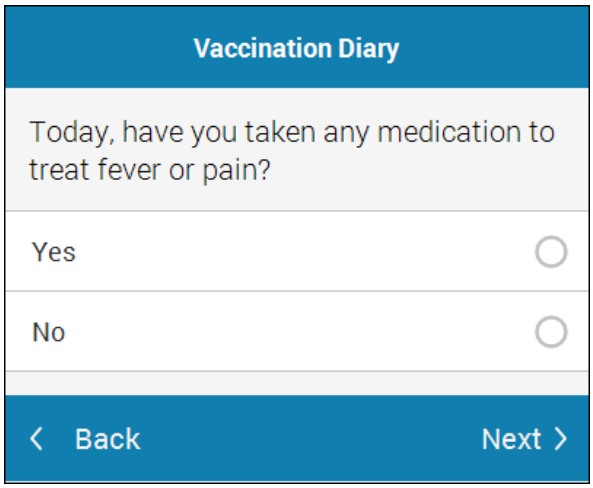
Screen 43

FAORRES when FATESTCD = OCCUR and FAOBJ = HOSPITALIZED FOR JOINT PAIN

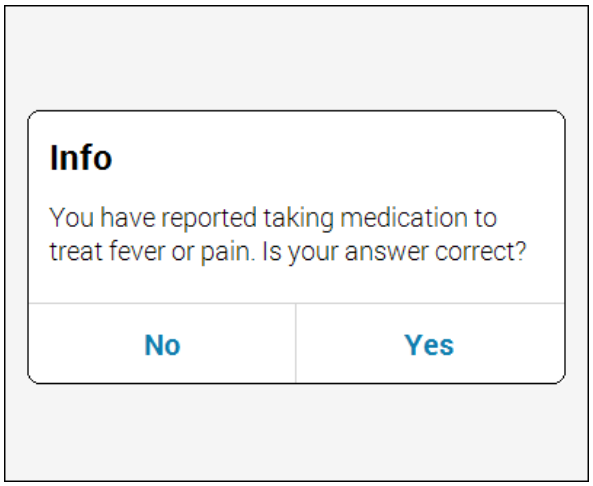
FASCAT = SYSTEMIC

FAORRES when FATESTCD = MEDTFVPN and FAOBJ = MEDICATIONS

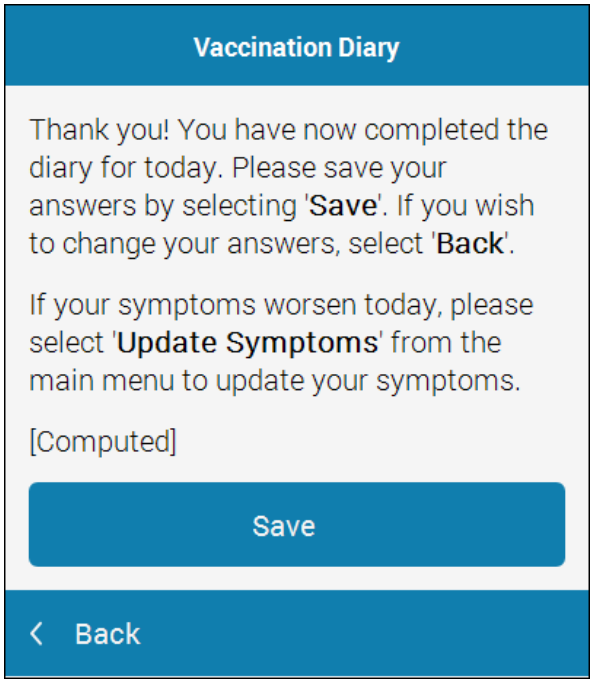
FASCAT = MEDICATIONS GIVEN



Screen 44



Message 2

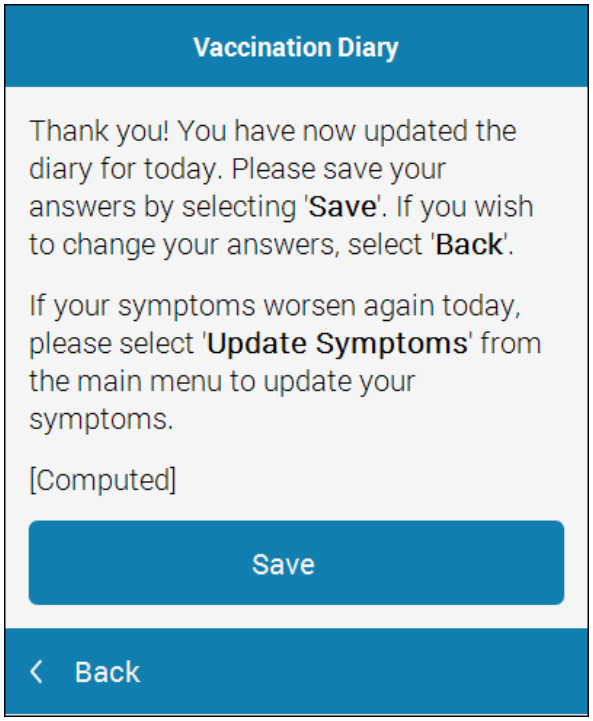


Screen 45

[Computed] will display "Please continue to fill out your diary for the next {1} day(s)."

Where {1} = a number of days

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



Screen 46

[Computed] will display "Please continue to fill out your diary for the next {1} day(s)."

Where {1} = a number of days

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