Annotated Study Book for Study Design: C4591001

Study Design Version: 16.0

Sponsor: Pfizer

Protocol: C4591001

Sponsor Drug Name: BLINDED THERAPY

C4591001 - COVID19

Generated by Central Designer TM

February 22, 2021 8:10AM

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
2.	AE ID: [AE Identifier]	
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms) [Adverse Event]	
4.	Start Date Time: [Start Date]	/ / : *24-hour clock*
5.	Is the adverse event still ongoing? [Is the Adverse Event Still Ongoing]	◯ YES ◯ NO End Date Time: / / : *24-hour clock*
6.	Toxicity Grade: [Tox c ty Grade]	◯ 1 ◯ 2 ◯ 3 ◯ 4
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongat on of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes). [Serious]	◯ YES Is this serious event associated w th congenital anomaly or birth defect? ◯ YES ◯ NO D d this ser ous event result in death? ◯ YES ◯ NO Did this ser ous event require or prolong hospitalization? ◯ YES ◯ NO Did this ser ous event result in persistent or significant disabil ty/incapacity? ◯ YES ◯ NO Is this serious event life threatening? ◯ YES ◯ NO Other med cally important ser ous event ◯ YES ◯ NO ◯ NO
8.	Is this adverse	◯ YES

	event the result of a study Medication Error? If Yes, record the type of med cation error on the Medicat on Error Log. [Is AE a Result of a Medicat on Error]	◯ NO
9.	Is this event related to study treatment: [Relationship to Study Treatment]	◯ NOT RELATED If Not Related to study treatment(s), this event is due to: ◯ CONCOMITANT DRUG TREATMENT ◯ CONCOMITANT NON-DRUG TREATMENT ◯ OTHER If Other, specify: ◯ RELATED
10.	Latest Action Taken with Study Treatment: [Action Taken w th Study Treatment]	◯ DRUG WITHDRAWN ◯ NOT APPLICABLE
11.	Was a Concomitant Medicat on given? [Concom tant Medicat on Given]	◯ YES ◯ NO
12.	Was a Non-Drug Treatment given? [Non-Drug Treatment Given]	◯ YES ◯ NO
13.	What was the outcome of this adverse event?: [Outcome]	◯ FATAL ◯ NOT RECOVERED/NOT RESOLVED ◯ RECOVERED/RESOLVED ◯ RECOVERED/RESOLVED WITH SEQUELAE ◯ RECOVERING/RESOLVING ◯ UNKNOWN
14.	Did the adverse event cause the subject to be discontinued from the study? [Caused Study Discontinuat on]	◯ YES ◯ NO
15.	Serious Adverse Event Number: For Pfizer Use Only [Serious Adverse Event Number]	
16.	Comparison Term *[hidden]* [Comparison Term]	
17.	Lowest Level Term *[hidden]*	

	[Lowest Level Term]	
18.	Lowest Level Term Code *[hidden]* [Lowest Level Term Code]	
19.	Dict onary-Derived Term *[hidden]* [Dict onary-Derived Term]	
20.	Preferred Term Code *[hidden]* [Preferred Term Code]	
21.	High Level Term *[hidden]* [High Level Term]	
22.	High Level Term Code *[hidden]* [High Level Term Code]	
23.	High Level Group Term *[hidden]* [High Level Group Term]	
24.	High Level Group Term Code *[hidden]* [High Level Group Term Code]	
25.	Primary System Organ Class *[hidden]* [Primary System Organ Class]	
26.	Primary System Organ Class Code *[hidden]* [Primary System Organ Class Code]	

C4591001: INFORMED CONSENT - BOOSTER (BOOST CONS)		
Informed Consent - Booster		
1.	Consent Was: [Consent Was:]	○ OBTAINED Date Written Consent Obtained / /

C4591001: INCLUSION/EXCLUSION CRITERIA - BOOSTER (BOOST IE)

	Criterion Description
1.	

Inclusion Criteria Not Met Entry		
1.1	Description of Inclus on Cr terion Not Met [Criter on Description]	

	Criterion Description
2.	

Exclusion Criteria Met Entry		
2.1	Description of Exclusion Cr terion Met [Criter on Description]	

C4591001: BOOSTER DOSE TRIGGER FORM (BOOST TRIG)		
Booster Dose Trigger Form		
1.	Select appropriate response - Will the participant return for consent/eligibility assessment for the booster dose vis t? [Trigger Response 13]	◯ The participant will return for consent/eligibility assessment for the booster dose vis t ◯ The participant will NOT return for consent/eligibil ty assessment for the booster dose visit

C4591001: LABORATORY DATA - HEMATOLOGY (CD4)

Laboratory Data Hematology

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

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]	
5.2	Test: [Test:]	◯ CD4_PX4722
5.3	Result: [Result:]	
5.4	Not Done: *[hidden]* [Not Done:]	◯ NOT DONE
5.5	LNMT [Lab Normal Range]	Low High Unit ◯ 10^3/mm3 ◯ /uL ◯ %

C4591001: COHORT SELECTION (COHORT SEL)		
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

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 med cation dentifier? [Sponsor-Defined Identifier]	
2.	Category: [Category for Medication]	◯ GENERAL CONCOMITANT MEDICATIONS
3.	Concomitant Med cat ons Pre-specified: [Concom tant Medicat ons Pre-specified]	◯ NO
4.	Medicat on: Provide the complete gener c drug name (including salt form, where applicable). Where gener c name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation). [Name of Medication]	
5.	Dose: [Dose Description]	
6.	Dose Unit: [Dose Unit]	
7.	Dose Frequency: [Dose Frequency]	
8.	Route: [Route]	
9.	Start Date: [Start Date]	/ /
10.	Comparison Term *[hidden]* [Comparison Term]	
11.	Standardized Medication Name - Dictionary derived. *[hidden]* [Standardized Medication Name]	
12.	Standardized Medication Code - Dict onary derived *[hidden]* [Standardized Medication Code]	

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 med cation dentifier? [Sponsor-Defined Identifier]	
2.	Category: [Category for Medication]	○ VACCINATIONS
3.	Concomitant Medications Pre-specified: [Concom tant Medicat ons Pre-specified]	○ NO
4.	Medicat on: Provide the complete gener c drug name (including salt form, where applicable). Where gener c name is unknown, enter the full trade or proprietary name. Include clarifying information in the Med cation text (e.g., Ingredient(s), route, use, formulation). [Name of Medication]	
5.	Date: [Start Date]	/ /
6.	Comparison Term *[hidden]* [Comparison Term]	
7.	Standardized Medication Name - D ctionary derived. *[hidden]* [Standardized Medication Name]	
8.	Standardized Medication Code - Dictionary derived *[hidden]* [Standardized Medication Code]	

C4591001: MAIN INFORMED CONSENT (CONSENT)		
Informed Consent		
1.	Consent Was: [Consent Was:]	○ OBTAINED Date Written Consent Obtained / /

C4591001: CONTACT OUTCOME - MONTH 1 (CONTACT 1M)		
Contact Outcome		
1.	Follow-Up Contact Category *[hidden]* [Follow Up Contact Category]	◯ CONTACT OUTCOME
2.	Contact Type: [Type of Contact/Visit]	◯ CLINIC VISIT ◯ TELEHEALTH VISIT
3.	Was contact made? [Was Contact Made]	◯ YES Date of Contact: / / ◯ NO If No, why?
4.	Comments: [Comments/Findings/Details]	

C4591001: CONTACT OUTCOME - MONTH 6 (CONTACT 6M)		
Contact Outcome		
1.	Follow-Up Contact Category *[hidden]* [Follow Up Contact Category]	◯ CONTACT OUTCOME
2.	Contact Type: [Type of Contact/Visit]	◯ CLINIC VISIT ◯ TELEHEALTH VISIT
3.	Was contact made? [Was Contact Made]	◯ YES Date of Contact: / / ◯ NO If No, why?
4.	Comments: [Comments/Findings/Details]	

C4591001: CONTACT OUTCOME (CONTACT SV)		
Contact Outcome		
1.	Follow-Up Contact Category *[hidden]* [Follow Up Contact Category]	◯ CONTACT OUTCOME
2.	Contact Type: [Type of Contact/Visit]	◯ TELEPHONE VISIT
3.	Was contact made? [Was Contact Made]	◯ YES Date of Contact: / / ◯ NO If No, why?
4.	Comments: [Comments/Findings/Details]	

C4591001: CONTACT OUTCOME - UNPLANNED (CONTACT UV)		
Contact Outcome		
1.	Follow-Up Contact Category *[hidden]* [Follow Up Contact Category]	◯ CONTACT OUTCOME
2.	Contact Type: [Type of Contact/Visit]	◯ TELEPHONE VISIT
3.	Was contact made? [Was Contact Made]	◯ YES Date of Contact: / / Contact Outcome: ◯ VISIT ARRANGED ◯ VISIT ARRANGED, BUT NOT ATTENDED ◯ 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?
4.	Comments: [Comments/Findings/Details]	

C4591001: MICROBIOLOGY SPECIMEN (COV19 SITE) - Repeating Form

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

Microbiology Specimen

1.	Actual Date of Collect on: [Date of Collect on]	/ /
2.	Specimen Type: [Specimen Type]	○ SERUM ○ BLOOD ○ PLASMA
3.	Assay Code and Description: [Assay Code and Description]	○ SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
4.	Dev ce Type: [Dev ce Type]	○ SARS-COV-2 DIAGNOSTIC TEST
5.	Test Result: [Result]	○ POSITIVE ○ NEGATIVE ○ INDETERMINATE
6.	Comments/Findings/Details: [Comments:]	

C4591001: MICROBIOLOGY SPECIMEN (COVID TEST) - Repeating Form

#	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 Collect on: [Date of Collect on]	/ /
2.	Specimen Type: [Specimen Type]	SWABBED MATERIAL RESPIRATORY SECRETIONS
3.	Specimen Collect on Location: [Specimen Collection Location]	NASOPHARYNX LOWER RESPIRATORY SYSTEM THROAT
4.	Assay Code and Description: [Assay Code and Description]	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Dev ce Type: [Dev ce Type]	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name: [Trade Name]	
7.	Test Result: [Result]	POSITIVE NEGATIVE INDETERMINATE
8.	Comments/Findings/Details: [Comments:]	
9.	Trade Name Other, Specify: [Trade Name Other, Specify]	

C4591001: DEATH DETAILS CODED (DEATH DTL)

Death Details

1.	Date of Collection / Notif cation of Death: [Date of Collect on / Notif cation of Death]	/ /

	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
2.2	Cause of Death: [Cause of Death]	
2.3	Comparison Term *[hidden]* [Comparison Term]	
2.4	Lowest Level Term *[hidden]* [Lowest Level Term]	
2.5	Lowest Level Term Code *[hidden]* [Lowest Level Term Code]	
2.6	D ctionary-Derived Term *[hidden]* [D ctionary-Derived Term]	
2.7	Preferred Term Code *[hidden]* [Preferred Term Code]	
2.8	High Level Term *[hidden]* [High Level Term]	
2.9	High Level Term Code *[hidden]* [High Level Term Code]	
2.10	High Level Group Term *[hidden]* [High Level Group Term]	
2.11	High Level Group Term Code *[hidden]* [High Level Group Term Code]	
2.12	Primary System Organ Class *[hidden]* [Primary System Organ Class]	
2.13	Primary System Organ Class Code *[hidden]* [Primary System Organ Class Code]	

C4591001: DEMOGRAPHY (DEMOG)		
Demography		
1.	Subject ID [Subject ID]	
2.	Birth Date: [Birth Date]	/ /
3.	Sex: [Sex]	FEMALE MALE
4.	Ethnicity: [Ethn c ty]	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN NOT REPORTED
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
6.	Racial Designation: [Racial Designation]	JAPANESE OTHER

C4591001: DISPOSITION - SCREENING FOR BOOSTER DOSE (DISP BOOST)		
Disposition - Screening for Booster Dose		
1.	Date of Completion/Discontinuation/Death : [Date of Completion/Discontinuat on/Death :]	/ /
2.	Phase of Disposit on: [Disposition Phase]	REPEAT SCREENING 2
3.	Status: [Status]	
4.	Specify Status: [Specify Status]	

C4591001: DISPOSITION - FOLLOW-UP (DISP FUP)		
Disposition - Follow-Up		
1.	Date of Completion/Discontinuation/Death : [Date of Completion/Discontinuat on/Death :]	/ /
2.	Phase of Disposit on: [Disposition Phase]	FOLLOW-UP
3.	Status: [Status]	
4.	Specify Status: [Specify Status]	

C4591001: DISPOSITION - SCREENING FOR FURTHER VACCINATION (DISP RESCR)		
Disposition - Screening for Further Vaccination		
1.	Date of Completion/Discontinuation/Death : [Date of Completion/Discontinuat on/Death :]	/ /
2.	Phase of Disposit on: [Disposition Phase]	REPEAT SCREENING 1
3.	Status: [Status]	
4.	Specify Status: [Specify Status]	

C4591001: DISPOSITION - SCREENING (DISP SCR)		
Disposition - Screening		
1.	Date of Completion/Discontinuation/Death [Date of Completion/Discontinuat on/Death]	/ /
2.	Phase of Disposit on: [Disposition Phase]	SCREENING
3.	Status: [Status]	
4.	Specify Status: [Specify Status]	

C4591001: DISPOSITION - TREATMENT (DISP TRT)		
Disposition - Treatment		
1.	Date of Completion/Discontinuation/Death : [Date of Completion/Discontinuat on/Death :]	/ /
2.	Phase of Disposit on: [Disposition Phase]	VACCINATION OPEN LABEL TREATMENT SUBSTUDY
3.	Status: [Status]	
4.	Specify Status: [Specify Status]	

C4591001: DATE OF VISIT (DOV)		
Date of Visit		
1.	Date of Visit [Date of Visit]	/ /
2.	Erroneous Visit [Vis t Error]	ERRONEOUS VISIT

C4591001: DATE OF VISIT - ILLNESS CONVALESCENT (DOV CONV)		
Date of Visit		
1.	Date of Visit [Date of Visit]	/ /
2.	Erroneous Visit [Vis t Error]	ERRONEOUS VISIT
COVID-19 Illness Visit		
3.	COVID-19 Illness Vis t: [COVID-19 Illness Visit]	

C4591001: DATE OF VISIT - ILLNESS ONSET (DOV ILL)		
Date of Visit		
1.	Date of Visit [Date of Visit]	/ /
2.	Erroneous Visit [Vis t Error]	ERRONEOUS VISIT
COVID-19 Illness Visit		
3.	COVID-19 Illness Vis t: [COVID-19 Illness Visit]	

C4591001: DATE OF VISIT - ASYMPTOMATIC SURVEILLANCE (DOV SURV)		
Date of Visit		
1.	Date of Visit [Date of Visit]	/ /
2.	Erroneous Visit [Vis t Error]	ERRONEOUS VISIT
COVID-19 Surveillance Visit		
3.	COVID-19 Surveillance Vis t: [COVID-19 Surveillance Vis t]	

C4591001: DATE OF VISIT - REPEAT SWAB (DOV SWAB)		
Date of Visit		
1.	Date of Visit [Date of Visit]	/ /
2.	Erroneous Visit [Vis t Error]	ERRONEOUS VISIT
COVID-19 Repeat Swab		
3.	COVID-19 Repeat Swab: [COVID-19 Repeat Swab]	

C4591001: INFORM ENROLLMENT (ENROLL)		
InForm Enrollment		
1.	Subject ID [Subject ID]	

C4591001: HIV STATUS (HIV)		
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

C4591001: LAB CHEMISTRY (HIV RNA)

Lab Chemistry Details

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

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]	
5.2	Test: [Test:]	◯ HIV RNA (Ultrasens tive)
5.3	Result: [Result:]	
5.4	Not Done: *[hidden]* [Not Done:]	◯ NOT DONE
5.5	LNMT [Lab Normal Range]	Low High Unit ◯ /mL

C4591001: HEALTH CARE UTILIZATION (HLTHCARE)

Health Care Utilization

1.	Evaluation Interval: *[hidden]* [Evaluat on Interval]	◯ SINCE THE START OF THE RESPIRATORY ILLNESS EPISODE
2.	Disease Name: *[hidden]* [Disease Name]	◯ RESPIRATORY ILLNESS

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
3.2	Phys cian or Healthcare Professional: [Type of Pract t oner]	◯ SPECIALIST ◯ EMERGENCY ROOM ◯ PRIMARY CARE PHYSICIAN ◯ URGENT CARE ◯ TELEPHONE CONSULTATION ◯ OTHER
3.3	Occurrence of Visits or Contacts: [Occurrence of Visits or Contacts]	◯ YES Number of Visits or Contacts: ◯ NO

Health Care Utilization Other

4.	Other Type of Practit oner Specify: [Other Type of Practitioner Specify]	

Health Care Utilization

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

C4591001: HOSPITALIZATION DETAILS (HOSP) - Repeating Form

#	Hospitalization Category	Hospitalization Term	Admission Date	Ongoing
1				

Hospitalization Details

1.	Hospitalization Category: [Hospitalization Category]	◯ HOSPITALIZATION STATUS
2.	Hospitalization Term: [Hospitalization Term]	◯ ICU ◯ HOSPITAL
3.	Admission Date: [Admission Date]	/ /
4.	Ongoing? [Ongoing]	◯ YES ◯ NO Discharge Date: / /

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C4591001: ILLNESS DETAILS (ILL POTEN)

Illness Details

1.	Category of Clinical Event: [Category of Clinical Event:]	○ POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness? [Diagnosis Obtained]	○ YES Respiratory Illness Diagnosis: Date of Diagnosis: / / ○ NO
3.	Toxicity Grade: [Tox c ty Grade]	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5
4.	Comparison Term: *[hidden]* [Comparison Term]	
5.	Lowest Level Term *[hidden]* [Lowest Level Term]	
6.	Lowest Level Term Code *[hidden]* [Lowest Level Term Code]	
7.	Dict onary Derived Term *[hidden]* [Dict onary Derived Term]	
8.	Preferred Term Code *[hidden]* [Preferred Term Code]	
9.	High Level Term *[hidden]* [High Level Term]	
10.	High Level Term Code *[hidden]* [High Level Term Code]	
11.	High Level Group Term *[hidden]* [High Level Group Term]	
12.	High Level Group Term Code *[hidden]* [High Level Group Term Code]	
13.	Primary System Organ Class *[hidden]* [Primary System Organ Class]	
14.	Primary System Organ Class Code *[hidden]* [Primary System Organ Class Code]	

C4591001: ILLNESS DETAILS - SEVERE (ILL SEVERE)

Illness Details

1.	Category of Clinical Event: [Category of Clinical Event:]	○ SEVERE COVID-19 ILLNESS
2.	Subcategory of Clinical Event: [Subcategory of Clinical Event]	○ SIGNIFICANT ACUTE RENAL DYSFUNCTION ○ SIGNIFICANT ACUTE HEPATIC DYSFUNCTION ○ SIGNIFICANT ACUTE NEUROLOGIC DYSFUNCTION
3.	Was a diagnosis obtained? [Diagnosis Obtained]	○ YES Diagnosis: Start Date: / / Ongoing?: ○ YES ○ NO End Date: / / ○ NO
4.	Toxicity Grade: [Tox c ty Grade]	○ 1 ○ 2 ○ 3 ○ 4 ○ 5
5.	Comparison Term: *[hidden]* [Comparison Term]	
6.	Lowest Level Term *[hidden]* [Lowest Level Term]	
7.	Lowest Level Term Code *[hidden]* [Lowest Level Term Code]	
8.	Dict onary Derived Term *[hidden]* [Dict onary Derived Term]	
9.	Preferred Term Code *[hidden]* [Preferred Term Code]	
10.	High Level Term *[hidden]* [High Level Term]	
11.	High Level Term Code *[hidden]* [High Level Term Code]	
12.	High Level Group Term *[hidden]* [High Level Group Term]	
13.	High Level Group Term Code *[hidden]* [High Level Group Term Code]	
14.	Primary System Organ Class *[hidden]* [Primary System Organ Class]	

15.	Primary System Organ Class Code *[hidden]* [Primary System Organ Class Code]	

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 Clinical Event:]	○ SEVERE COVID-19 ILLNESS
2.	Subcategory of Clinical Event: [Subcategory of Clinical Event]	○ SIGNIFICANT ACUTE RENAL DYSFUNCTION ○ SIGNIFICANT ACUTE HEPATIC DYSFUNCTION ○ SIGNIFICANT ACUTE NEUROLOGIC DYSFUNCTION
3.	Was a diagnosis obtained? [Diagnosis Obtained]	○ YES Diagnosis: Start Date: / / Ongoing?: ○ YES ○ NO End Date: / / ○ NO
4.	Toxicity Grade: [Tox c ty Grade]	○ 1 ○ 2 ○ 3 ○ 4 ○ 5
5.	Comparison Term: *[hidden]* [Comparison Term]	
6.	Lowest Level Term *[hidden]* [Lowest Level Term]	
7.	Lowest Level Term Code *[hidden]* [Lowest Level Term Code]	
8.	Dict onary Derived Term *[hidden]* [Dict onary Derived Term]	
9.	Preferred Term Code *[hidden]* [Preferred Term Code]	
10.	High Level Term *[hidden]* [High Level Term]	
11.	High Level Term Code *[hidden]* [High Level Term Code]	
12.	High Level Group Term *[hidden]* [High Level Group Term]	
13.	High Level Group Term Code *[hidden]* [High Level Group Term Code]	
14.	Primary System Organ Class *[hidden]*	

	[Primary System Organ Class]	
15.	Primary System Organ Class Code *[hidden]* [Primary System Organ Class Code]	

C4591001: IMAGING (IMAGING) - Repeating Form

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

Imaging

1.	Date of Assessment: [Date of Assessment]	/ /
2.	Location of Assessment: [Location of Assessment]	○ CHEST ○ HEAD ○ OTHER If other, specify:
3.	Type of Imaging Exam: [Imaging Method]	○ CT SCAN ○ X-RAY ○ ULTRASOUND ○ MRI ○ OTHER If other, specify:
4.	Assessment: [Overall Assessment]	○ ABNORMAL If abnormal, specify findings: ○ INDETERMINATE ○ NORMAL ○ UNKNOWN ○ NOT EVALUABLE

C4591001: INCLUSION/EXCLUSION CRITERIA (IN EX STG3)

Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclus on 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 visits, vaccination plan, laboratory tests, lifestyle considerat ons, and other study procedures		IN02A00
1.c	3	Healthy participants who are determined by medical history, physical examination, and clin cal judgment of the investigator to be eligible for inclus on in the study		IN03A00
1.d	4	Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol		IN04A00

Inclusion Criteria Entry

1.1	Inclusion Number: [Inclus on Number]	○ 1 ○ 2 ○ 3 ○ 4
1.2	Criter on Description: [Criter on Description]	
1.3	Criter on met? [Criter on met?]	○ YES ○ NO Describe details if relevant
1.4	Criter on ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	○ IN01A00 ○ IN02A00 ○ 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 abnormality that may increase the risk of study participation		EX01A00
2.b	2	Known infect on with human immunodef ciency 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 medications intended to prevent COVID-19		EX04A00
2.e	8	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination		EX08A00
2.f	9	Indiv duals with a history of autoimmune disease or an active autoimmune disease requiring therapeut c intervention		EX09A00
2.g	10	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection		EX10A00
2.h	11	Women who are pregnant or breastfeeding		EX11A00
2.i	12	Prev ous vaccinat on with any coronavirus vaccine		EX12A00
2.j	13	Indiv duals who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids. Inhaled/nebulized, Intra-articular, intrabursal, or topical corticosteroids are permitted		EX13A00
2.k	14	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervent on administration or planned receipt throughout the study		EX14A00

2.l	15	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participat on		EX15A00
2.m	16	Prev ous participation in other studies involving study intervention containing lipid nanoparticles		EX16A00
2.n	21	Investigator site staff or Pfizer employees directly involved in the conduct of the study, s te staff otherwise supervised by the investigator, and their respective family members		EX21A00

Exclusion Criteria Entry		
2.1	Exclusion Number: [Exclusion Number]	
2.2	Criter on Description: [Criter on Description]	
2.3	Criter on met? [Criter on met?]	○ YES Describe details if relevant ○ NO
2.4	Criter on ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	

C4591001: INCLUSION/EXCLUSION CRITERIA (IN EX STG3)

Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclus on 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 visits, vaccination plan, laboratory tests, lifestyle considerat ons, and other study procedures		IN02A00
1.c	3	Healthy participants who are determined by medical history, physical examination, and clin cal judgment of the investigator to be eligible for inclus on in the study		IN03A00
1.d	4	Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol		IN04A00

Inclusion Criteria Entry

1.1	Inclusion Number: [Inclus on Number]	○ 1 ○ 2 ○ 3 ○ 4
1.2	Criter on Description: [Criter on Description]	
1.3	Criter on met? [Criter on met?]	○ YES ○ NO Describe details if relevant
1.4	Criter on ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	○ IN01A00 ○ IN02A00 ○ 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 abnormality that may increase the risk of study participation		EX01A00
2.b	2	Known infect on with human immunodef ciency 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 medications intended to prevent COVID-19		EX04A00
2.e	8	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination		EX08A00
2.f	10	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection		EX10A00
2.g	11	Women who are pregnant or breastfeeding		EX11A00
2.h	12	Prev ous vaccinat on with any coronavirus vaccine		EX12A00
2.i	13	Subjects who receive immunosuppressive therapy, such as cytotox c agents or system c corticosteroids		EX13A01
2.j	15	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervent on administration or planned receipt throughout the study		EX14A01
2.k	16	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participat on		EX15A01
2.l	17	Previous participation in other studies involving study intervention containing lipid nanoparticles		EX16A01

2.m	22	Investigator site staff or Pfizer employees directly involved in the conduct of the study, s te staff otherwise supervised by the investigator, and their respective family members		EX21A01

Exclusion Criteria Entry

2.1	Exclusion Number: [Exclusion Number]	
2.2	Criter on Description: [Criter on Description]	
2.3	Criter on met? [Criter on met?]	○ YES Describe details if relevant ○ NO
2.4	Criter on ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	

C4591001: INCLUSION/EXCLUSION CRITERIA (IN EX STG3)

Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclus on 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 visits, vaccination plan, laboratory tests, lifestyle considerat ons, and other study procedures		IN02A00
1.c	3	Healthy participants who are determined by medical history, physical examination, and clin cal judgment of the investigator to be eligible for inclus on in the study		IN03A00
1.d	4	Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol		IN04A00

Inclusion Criteria Entry

1.1	Inclusion Number: [Inclus on Number]	○ 1 ○ 2 ○ 3 ○ 4
1.2	Criter on Description: [Criter on Description]	
1.3	Criter on met? [Criter on met?]	○ YES ○ NO Describe details if relevant
1.4	Criter on ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	○ IN01A00 ○ IN02A00 ○ 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 abnormality that may increase the risk of study participation		EX01A00
2.b	2	Known infect on with human immunodef ciency 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 medications intended to prevent COVID-19		EX04A00
2.e	8	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination		EX08A00
2.f	9	Indiv duals with a history of autoimmune disease or an active autoimmune disease requiring therapeut c intervention		EX09A00
2.g	10	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection		EX10A00
2.h	11	Women who are pregnant or breastfeeding		EX11A00
2.i	12	Prev ous vaccinat on with any coronavirus vaccine		EX12A00
2.j	13	Subjects who receive immunosuppressive therapy, such as cytotox c agents or system c corticosteroids		EX13A01
2.k	15	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervent on administration or planned receipt throughout the study		EX14A01
2.l	16	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participat on		EX15A01

2.m	17	Prev ous participation in other studies involving study intervention containing lipid nanoparticles		EX16A01
2.n	22	Investigator site staff or Pfizer employees directly involved in the conduct of the study, s te staff otherwise supervised by the investigator, and their respective family members		EX21A01

Exclusion Criteria Entry

2.1	Exclusion Number: [Exclusion Number]	
2.2	Criter on Description: [Criter on Description]	
2.3	Criter on met? [Criter on met?]	○ YES Describe details if relevant ○ NO
2.4	Criter on ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	

C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC)		
	Criterion Description	
1.		
Inclusion Criteria Not Met Entry		
1.1	Description of Inclus on Cr terion Not Met [Criter on Description]	
	Criterion Description	
2.		
Exclusion Criteria Met Entry		
2.1	Description of Exclusion Cr terion Met [Criter on Description]	

C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC NS)

Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclus on 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 visits, vaccination plan, laboratory tests, lifestyle considerat ons, and other study procedures		IN02A00
1.c	3	Healthy participants who are determined by medical history, physical examination, and clin cal judgment of the investigator to be eligible for inclus on in the study		IN03A00
1.d	4	Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol		IN04A00

Inclusion Criteria Entry

1.1	Inclusion Number: [Inclus on Number]	○ 1 ○ 2 ○ 3 ○ 4
1.2	Criter on Description: [Criter on Description]	
1.3	Criter on met? [Criter on met?]	○ YES ○ NO Describe details if relevant
1.4	Criter on ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	○ IN01A00 ○ IN02A00 ○ 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 abnormality that may increase the risk of study participation		EX01A00
2.b	2	Known infect on with human immunodef ciency 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 medications intended to prevent COVID-19		EX04A00
2.e	5	Stages 1 and 2 only: Previous clin cal or microb olog cal diagnosis of COVID-19		EX05A00
2.f	8	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination		EX08A00
2.g	10	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection		EX10A00
2.h	11	Women who are pregnant or breastfeeding		EX11A00
2.i	12	Prev ous vaccinat on with any coronavirus vaccine		EX12A00
2.j	13	Subjects who receive immunosuppressive therapy, such as cytotox c agents or system c corticosteroids		EX13A01
2.k	15	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervent on administration or planned receipt throughout the study		EX14A01
2.l	16	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participat on		EX15A01

2.m	17	Prev ous participation in other studies involving study intervention containing lipid nanoparticles		EX16A01
2.n	22	Investigator site staff or Pfizer employees directly involved in the conduct of the study, s te staff otherwise supervised by the investigator, and their respective family members		EX21A01

Exclusion Criteria Entry

2.1	Exclusion Number: [Exclusion Number]	
2.2	Criter on Description: [Criter on Description]	
2.3	Criter on met? [Criter on met?]	○ YES Describe details if relevant ○ NO
2.4	Criter on ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	

C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC NS)

Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclus on 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 visits, vaccination plan, laboratory tests, lifestyle considerat ons, and other study procedures		IN02A00
1.c	3	Healthy participants who are determined by medical history, physical examination, and clin cal judgment of the investigator to be eligible for inclus on in the study		IN03A00
1.d	4	Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol		IN04A00

Inclusion Criteria Entry

1.1	Inclusion Number: [Inclus on Number]	○ 1 ○ 2 ○ 3 ○ 4
1.2	Criter on Description: [Criter on Description]	
1.3	Criter on met? [Criter on met?]	○ YES ○ NO Describe details if relevant
1.4	Criter on ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	○ IN01A00 ○ IN02A00 ○ 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 abnormality that may increase the risk of study participation		EX01A00
2.b	2	Known infect on with human immunodef ciency 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 medications intended to prevent COVID-19		EX04A00
2.e	5	Stages 1 and 2 only: Previous clin cal or microb olog cal diagnosis of COVID-19		EX05A00
2.f	8	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination		EX08A00
2.g	9	Indiv duals with a history of autoimmune disease or an active autoimmune disease requiring therapeut c intervention		EX09A00
2.h	10	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection		EX10A00
2.i	11	Women who are pregnant or breastfeeding		EX11A00
2.j	12	Prev ous vaccinat on with any coronavirus vaccine		EX12A00
2.k	13	Subjects who receive immunosuppressive therapy, such as cytotox c agents or system c corticosteroids		EX13A01
2.l	15	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervent on administration or planned receipt throughout the study		EX14A01

2.m	16	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participat on		EX15A01
2.n	17	Prev ous participation in other studies involving study intervention containing lipid nanoparticles		EX16A01
2.o	22	Investigator site staff or Pfizer employees directly involved in the conduct of the study, s te staff otherwise supervised by the investigator, and their respective family members		EX21A01

Exclusion Criteria Entry

2.1	Exclusion Number: [Exclusion Number]	
2.2	Criter on Description: [Criter on Description]	
2.3	Criter on met? [Criter on met?]	○ YES Describe details if relevant ○ NO
2.4	Criter on ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	

C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC NS)

Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclus on 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 visits, vaccination plan, laboratory tests, lifestyle considerat ons, and other study procedures		IN02A00
1.c	3	Healthy participants who are determined by medical history, physical examination, and clin cal judgment of the investigator to be eligible for inclus on in the study		IN03A00
1.d	4	Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol		IN04A00

Inclusion Criteria Entry

1.1	Inclusion Number: [Inclus on Number]	○ 1 ○ 2 ○ 3 ○ 4
1.2	Criter on Description: [Criter on Description]	
1.3	Criter on met? [Criter on met?]	○ YES ○ NO Describe details if relevant
1.4	Criter on ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	○ IN01A00 ○ IN02A00 ○ 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 abnormality that may increase the risk of study participation		EX01A00
2.b	2	Known infect on with human immunodef ciency 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 medications intended to prevent COVID-19		EX04A00
2.e	5	Stages 1 and 2 only: Previous clin cal or microb olog cal diagnosis of COVID-19		EX05A00
2.f	8	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination		EX08A00
2.g	9	Indiv duals with a history of autoimmune disease or an active autoimmune disease requiring therapeut c intervention		EX09A00
2.h	10	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection		EX10A00
2.i	11	Women who are pregnant or breastfeeding		EX11A00
2.j	12	Prev ous vaccinat on with any coronavirus vaccine		EX12A00
2.k	13	Indiv duals who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids. Inhaled/nebulized, Intra-articular, intrabursal, or topical corticosteroids are permitted		EX13A00
2.l	14	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervent on administration or planned receipt throughout the		EX14A00

		study		
2.m	15	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participat on		EX15A00
2.n	16	Prev ous participation in other studies involving study intervention containing lipid nanoparticles		EX16A00
2.o	21	Investigator site staff or Pfizer employees directly involved in the conduct of the study, s te staff otherwise supervised by the investigator, and their respective family members		EX21A00

Exclusion Criteria Entry

2.1	Exclusion Number: [Exclusion Number]	
2.2	Criter on Description: [Criter on Description]	
2.3	Criter on met? [Criter on met?]	YES Describe details if relevant NO
2.4	Criter on ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	

C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC S)

Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclus on 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 visits, vaccination plan, laboratory tests, lifestyle considerat ons, and other study procedures		IN02A00
1.c	3	Healthy participants who are determined by medical history, physical examination, and clin cal judgment of the investigator to be eligible for inclus on in the study		IN03A00
1.d	4	Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol		IN04A00

Inclusion Criteria Entry

1.1	Inclusion Number: [Inclus on Number]	○ 1 ○ 2 ○ 3 ○ 4
1.2	Criter on Description: [Criter on Description]	
1.3	Criter on met? [Criter on met?]	○ YES ○ NO Describe details if relevant
1.4	Criter on ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	○ IN01A00 ○ IN02A00 ○ 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 abnormality that may increase the risk of study participation		EX01A00
2.b	2	Known infect on with human immunodef ciency 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 medications intended to prevent COVID-19		EX04A00
2.e	5	Stages 1 and 2 only: Previous clin cal or microb olog cal diagnosis of COVID-19		EX05A00
2.f	6	Sentinel participants in Stage 1 only: Indiv duals at high risk for severe COVID-19 (full details in protocol)		EX06A01
2.g	7	Sentinel participants in Stage 1 only: Indiv duals currently working in occupat ons with high risk of exposure to SARS-CoV-2 (eg, healthcare worker, emergency response personnel)		EX07A00
2.h	8	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination		EX08A00
2.i	9	Sentinel participants in Stage 1 only: Indiv duals w th a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention		EX09A04
2.j	10	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection		EX10A00
2.k	11	Women who are pregnant or breastfeeding		EX11A00

2.l	12	Prev ous vaccinat on with any coronavirus vaccine		EX12A00
2.m	13	Subjects who receive immunosuppressive therapy, such as cytotox c agents or system c corticosteroids		EX13A01
2.n	14	Sentinel participants in Stage 1 only: Regular receipt of inhaled/nebulized cort costeroids		EX22A01
2.o	15	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervent on administration or planned receipt throughout the study		EX14A01
2.p	16	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participat on		EX15A01
2.q	17	Prev ous participation in other studies involving study intervention containing lipid nanoparticles		EX16A01
2.r	18	Sentinel participants in Stage 1 only: Pos tive serological test for SARS-CoV-2 IgM and/or IgG antibodies at the screening visit		EX17A01
2.s	19	Sentinel participants in Stage 1 only: Screening hematology/blood chemistry lab >=Grade 1 abnormal ty. Except Bilirubin, other stable Grade1 abnormal ties may be considered eligible by Investigator		EX18A01
2.t	20	Sentinel participants in Stage 1 only: Pos tive 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		EX19A01
2.u	21	Sentinel participants in Stage 1 only: SARS-CoV-2 NAAT-pos tive nasal swab w thin 24 hours before receipt of study intervent on		EX20A01
2.v	22	Investigator site staff or Pfizer employees directly involved in the conduct of the study, s te staff otherwise supervised by the investigator, and their respective family members		EX21A01

Exclusion Criteria Entry

2.1	Exclusion Number: [Exclusion Number]	
2.2	Criter on Description: [Criter on Description]	
2.3	Criter on met? [Criter on met?]	○ YES Describe details if relevant ○ NO
2.4	Criter on ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	

C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC S)

Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclus on 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 visits, vaccination plan, laboratory tests, lifestyle considerat ons, and other study procedures		IN02A00
1.c	3	Healthy participants who are determined by medical history, physical examination, and clin cal judgment of the investigator to be eligible for inclus on in the study		IN03A00
1.d	4	Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol		IN04A00

Inclusion Criteria Entry

1.1	Inclusion Number: [Inclus on Number]	○ 1 ○ 2 ○ 3 ○ 4
1.2	Criter on Description: [Criter on Description]	
1.3	Criter on met? [Criter on met?]	○ YES ○ NO Describe details if relevant
1.4	Criter on ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	○ IN01A00 ○ IN02A00 ○ 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 abnormality that may increase the risk of study participation		EX01A00
2.b	2	Known infect on with human immunodef ciency 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 medications intended to prevent COVID-19		EX04A00
2.e	5	Stages 1 and 2 only: Previous clin cal or microb olog cal diagnosis of COVID-19		EX05A00
2.f	6	Sentinel participants in Stage 1 only: Indiv duals at high risk for severe COVID-19		EX06A00
2.g	7	Sentinel participants in Stage 1 only: Indiv duals currently working in occupat ons with high risk of exposure to SARS-CoV-2 (eg, healthcare worker, emergency response personnel)		EX07A00
2.h	8	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination		EX08A00
2.i	9	Indiv duals with a history of autoimmune disease or an active autoimmune disease requiring therapeut c intervention		EX09A00
2.j	10	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection		EX10A00
2.k	11	Women who are pregnant or breastfeeding		EX11A00
2.l	12	Prev ous vaccinat on with any coronavirus vaccine		EX12A00

2.m	13	Indiv duals who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids. Inhaled/nebulized, Intra-articular, intrabursal, or topical corticosteroids are permitted		EX13A00
2.n	14	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervent on administration or planned receipt throughout the study		EX14A00
2.o	15	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participat on		EX15A00
2.p	16	Prev ous participation in other studies involving study intervention containing lipid nanoparticles		EX16A00
2.q	17	Sentinel participants in Stage 1 only: Pos tive serological test for SARS-CoV-2 IgM and/or IgG antibodies at the screening visit		EX17A00
2.r	18	Sentinel participants in Stage 1 only: Screening hematology/blood chemistry lab >=Grade 1 abnormal ty. Except Bilirubin, other stable Grade1 abnormal ties may be considered eligible by Investigator		EX18A00
2.s	19	Sentinel participants in Stage 1 only: Pos tive 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
2.t	20	Sentinel participants in Stage 1 only: SARS-CoV-2 NAAT-pos tive nasal swab w thin 24 hours before receipt of study intervent on		EX20A00
2.u	21	Investigator site staff or Pfizer employees directly involved in the conduct of the study, s te staff otherwise supervised by the investigator, and their respective family members		EX21A00

Exclusion Criteria Entry

2.1	Exclusion Number: [Exclusion Number]	
2.2	Criter on Description: [Criter on Description]	
2.3	Criter on met? [Criter on met?]	YES Describe details if relevant NO
2.4	Criter on ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	

C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC S)

Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclus on 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 visits, vaccination plan, laboratory tests, lifestyle considerat ons, and other study procedures		IN02A00
1.c	3	Healthy participants who are determined by medical history, physical examination, and clin cal judgment of the investigator to be eligible for inclus on in the study		IN03A00
1.d	4	Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol		IN04A00

Inclusion Criteria Entry

1.1	Inclusion Number: [Inclus on Number]	○ 1 ○ 2 ○ 3 ○ 4
1.2	Criter on Description: [Criter on Description]	
1.3	Criter on met? [Criter on met?]	○ YES ○ NO Describe details if relevant
1.4	Criter on ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	○ IN01A00 ○ IN02A00 ○ 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 abnormality that may increase the risk of study participation		EX01A00
2.b	2	Known infect on with human immunodef ciency 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 medications intended to prevent COVID-19		EX04A00
2.e	5	Stages 1 and 2 only: Previous clin cal or microb olog cal diagnosis of COVID-19		EX05A00
2.f	6	Sentinel participants in Stage 1 only: Indiv duals at high risk for severe COVID-19 (full details in protocol)		EX06A01
2.g	7	Sentinel participants in Stage 1 only: Indiv duals currently working in occupat ons with high risk of exposure to SARS-CoV-2 (eg, healthcare worker, emergency response personnel)		EX07A00
2.h	8	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination		EX08A00
2.i	9	Indiv duals with a history of autoimmune disease or an active autoimmune disease requiring therapeut c intervention		EX09A00
2.j	10	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection		EX10A00
2.k	11	Women who are pregnant or breastfeeding		EX11A00
2.l	12	Prev ous vaccinat on with any coronavirus vaccine		EX12A00

2.m	13	Subjects who receive immunosuppressive therapy, such as cytotox c agents or system c corticosteroids		EX13A01
2.n	14	Sentinel participants in Stage 1 only: Regular receipt of inhaled/nebulized cort costeroids		EX22A01
2.o	15	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervent on administration or planned receipt throughout the study		EX14A01
2.p	16	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participat on		EX15A01
2.q	17	Prev ous participation in other studies involving study intervention containing lipid nanoparticles		EX16A01
2.r	18	Sentinel participants in Stage 1 only: Pos tive serological test for SARS-CoV-2 IgM and/or IgG antibodies at the screening visit		EX17A01
2.s	19	Sentinel participants in Stage 1 only: Screening hematology/blood chemistry lab >=Grade 1 abnormal ty. Except Bilirubin, other stable Grade1 abnormal ties may be considered eligible by Investigator		EX18A01
2.t	20	Sentinel participants in Stage 1 only: Pos tive 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		EX19A01
2.u	21	Sentinel participants in Stage 1 only: SARS-CoV-2 NAAT-pos tive nasal swab w thin 24 hours before receipt of study intervent on		EX20A01
2.v	22	Investigator site staff or Pfizer employees directly involved in the conduct of the study, s te staff otherwise supervised by the investigator, and their respective family members		EX21A01

Exclusion Criteria Entry

2.1	Exclusion Number: [Exclusion Number]	
2.2	Criter on Description: [Criter on Description]	
2.3	Criter on met? [Criter on met?]	YES Describe details if relevant NO
2.4	Criter on ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	

C4591001: CASEBOOK SIGNATURE FORM (INVSIG)		
Casebook Signature Form		
1.	Casebook Signature [Casebook Signature]	Click Here to Enable

C4591001: CENTRAL LAB SAMPLE COLLECTION (LAB)

Central Lab Sample Collection

1.	Collect on Date: [Collection Date:]	/ /
2.	Specimen Type: [Specimen Type]	◯ BLOOD

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
3.2	Lab Sub-Panel: [Subcategory for Lab Test]	◯ DIFFERENTIAL ◯ BLOOD CHEMISTRY
3.3	Was the lab sub-panel collected?: [Lab Sub-Panel Collected]	◯ YES ◯ NO

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

Central Lab Sample Collection

1.	Collect on Date: [Collection Date:]	/ /
2.	Specimen Type: [Specimen Type]	◯ BLOOD

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
3.2	Lab Sub-Panel: [Subcategory for Lab Test]	◯ DIFFERENTIAL ◯ BLOOD CHEMISTRY ◯ VIROLOGY
3.3	Was the lab sub-panel collected?: [Lab Sub-Panel Collected]	◯ YES ◯ NO

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
2.	Laboratory Name and Address [Vendor Name]	
3.	Collect on Date: [Collection Date:]	/ /
4.	Specimen Type: [Specimen Type]	◯ BLOOD

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]	
5.2	Test: [Test:]	
5.3	Result: [Result:]	
5.4	Not Done: [Not Done:]	◯ NOT DONE
5.5	LNMT [Lab Normal Range]	Low High Unit

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
2.	Laboratory Name and Address [Vendor Name]	
3.	Collect on Date: [Collection Date:]	/ /
4.	Specimen Type: [Specimen Type]	◯ BLOOD

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]	
5.2	Test: [Test:]	◯ C Reactive Protein_PX329
5.3	Result: [Result:]	
5.4	Not Done: *[hidden]* [Not Done:]	◯ NOT DONE
5.5	LNMT [Lab Normal Range]	Low High Unit

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
2.	Laboratory Name and Address [Vendor Name (DERIVED)]	
3.	Collect on Date: [Collection Date:]	/ /
4.	Specimen Type: [Specimen Type]	○ BLOOD

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]	
5.2	Test: [Test:]	
5.3	Result: [Result:]	
5.4	Not Done: [Not Done:]	○ NOT DONE
5.5	LNMT [Lab Normal Range]	Low High Unit

C4591001: LAB URINALYSIS - PREGNANCY TEST (LAB PREG)

Lab Urinalysis

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

Lab Result

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

Lab Result Entry

6.1	Sponsor ID: [Sponsor-Defined Identifier]	
6.2	Test: [Test:]	◯ Chor ogonadotropin Beta_PX113
6.3	Result: [Result:]	◯ NEGATIVE ◯ POSITIVE
6.4	Not Done: [Not Done:]	◯ NOT DONE

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
2.	Medicat on Error (Type of Med cation Error): [Medicat on Error]	
3.	If this is a dispensing error, record the incorrect container number that was dispensed/administered to the subject: *[hidden]* [Incorrect package ID]	
4.	Start Date: [Start Date]	/ /
5.	Is the medication error still ongoing? [Is the med cation error Still Ongoing]	◯ YES ◯ NO End Date: / /
6.	Latest Action Taken with Study Treatment: [Study Medication Errors Action]	◯ NO ACTION TAKEN ◯ PERMANENTLY DISCONTINUED
7.	Was a Concomitant Medicat on given? [Concom tant Medicat on Given]	◯ YES ◯ NO
8.	Was a Non-Drug Treatment given? [Non-Drug Treatment Given]	◯ YES ◯ NO
9.	Did the Med cation Error cause the subject to be discontinued from the study? [Caused Study Discontinuat on]	◯ YES ◯ NO
10.	Was this medicat on error associated w th any adverse events? [Medicat on Error Associated With AE]	◯ YES AE ID: AE ID: AE ID: AE ID: AE ID: ◯ NO
11.	Serious Adverse Event	

	Number: For Pfizer Use Only [Serious Adverse Event Number]	
12.	Comparison Term *[hidden]* [Comparison Term]	
13.	Lowest Level Term *[hidden]* [Lowest Level Term]	
14.	Lowest Level Term Code *[hidden]* [Lowest Level Term Code]	
15.	Dict onary-Derived Term *[hidden]* [Dict onary-Derived Term]	
16.	Preferred Term Code *[hidden]* [Preferred Term Code]	
17.	High Level Term *[hidden]* [High Level Term]	
18.	High Level Term Code *[hidden]* [High Level Term Code]	
19.	High Level Group Term *[hidden]* [High Level Group Term]	
20.	High Level Group Term Code *[hidden]* [High Level Group Term Code]	
21.	Primary System Organ Class *[hidden]* [Primary System Organ Class]	
22.	Primary System Organ Class Code *[hidden]* [Primary System Organ Class Code]	

C4591001: GENERAL MEDICAL HISTORY (MEDHX)

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

Medical History Details Entry

1.1	Line/MH Number: [Line/MH Number]	
1.2	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies: [Medical History Term]	
1.3	Start Date: [Start Date]	/ /
1.4	Ongoing: [Ongoing]	YES NO End Date: / /
1.5	Comparison Term *[hidden]* [Comparison Term]	
1.6	Lowest Level Term *[hidden]* [Lowest Level Term]	
1.7	Lowest Level Term Code *[hidden]* [Lowest Level Term Code]	
1.8	D ctionary Derived Term *[hidden]* [D ctionary Derived Term]	
1.9	Preferred Term Code *[hidden]* [Preferred Term Code]	
1.10	High Level Term *[hidden]* [High Level Term]	
1.11	High Level Term Code *[hidden]* [High Level Term Code]	
1.12	High Level Group Term *[hidden]* [High Level Group Term]	
1.13	High Level Group Term Code *[hidden]* [High Level Group Term Code]	
1.14	Primary System Organ Class *[hidden]* [Primary System Organ Class]	
1.15	Primary System Organ Class Code *[hidden]* [Primary System Organ Class Code]	

C4591001: OXYGENATION PARAMETERS (OXYGEN) - Repeating Form			
#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)
1			

Oxygenation Parameters		
1.	Date Time of Assessment: [Date Time of Assessment]	/ / : *24-hour clock*
2.	Arterial Blood Gases PaO2 (mmHg): [Arterial Blood Gases PaO2]	
3.	FiO2 (Fract on of Inhaled Oxygen): [FiO2 (Fract on of Inhaled Oxygen)]	

C4591001: PHYSICAL EXAMINATION (PHYS EXAM)

Physical Examination

1.	Exam Date: [Exam Date]	/ /

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]	
2.2	Result: [Result]	○ NORMAL ○ ABNORMAL If abnormal findings, specify: (If clin cally signif cant, record on the Medical History or Adverse Event CRF as appropriate). Are there clinically significant findings? ○ YES ○ NO ○ NOT DONE

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

Electronic Sample Tracking

1.	Data Origin [Data Origin]	○ SITE
2.	Sample Type [Sample Type]	○ SERUM
3.	Sample Collected? [Sample Collected]	○ NO ○ YES Date of Collect on: / /
4.	If no sample was collected or sample was not collected according to protocol, please prov de reason: [Reason sample not collected]	

	Sample ID
5.	

Aliquot Entry

Please enter barcode for each aliquot.

5.1	Sample ID [Sample ID]	

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 med cation dentifier? [Sponsor-Defined Identifier]	
2.	Category: [Category for Medication]	◯ CONCOMITANT IMMUNOSUPPRESSIVE THERAPY ◯ CORTICOSTEROIDS ◯ IMMUNOGLOBULINS
3.	Concomitant Med cat ons Pre-specified: [Concom tant Medicat ons Pre-specified]	◯ NO
4.	Medicat on: Provide the complete gener c drug name (including salt form, where applicable). Where gener c name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation). [Name of Medication]	
5.	Dose: [Dose Description]	
6.	Dose Unit: [Dose Unit]	
7.	Dose Frequency: [Dose Frequency]	
8.	Route: [Route]	
9.	Start Date: [Start Date]	/ /
10.	Ongoing? [Ongoing]	◯ YES ◯ NO End Date: / /
11.	Comparison Term *[hidden]* [Comparison Term]	
12.	Standardized Medication Name - Dictionary derived. *[hidden]* [Standardized Medication Name]	
13.	Standardized Medication Code - Dict onary derived *[hidden]* [Standardized Medication Code]	

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
2.	What is the treatment Identifier? [Treatment Identifier]	
3.	Concomitant Non-drug Treatment Pre-specified: [Con Non-Drug Treatments Pre-specified]	◯ YES
4.	Treatment: [Treatment]	
5.	Start Date: [Start Date]	/ /
6.	Ongoing? [Ongoing?]	◯ YES ◯ NO End Date: / /
7.	Comparison Term *[hidden]* [Comparison Term]	
8.	Lowest Level Term *[hidden]* [Lowest Level Term]	
9.	Lowest Level Term Code *[hidden]* [Lowest Level Term Code]	
10.	Dict onary Derived Term *[hidden]* [Dict onary Derived Term]	
11.	Preferred Term Code *[hidden]* [Preferred Term Code]	
12.	High Level Term *[hidden]* [High Level Term]	
13.	High Level Term Code *[hidden]* [High Level Term Code]	
14.	High Level Group Term *[hidden]* [High Level Group Term]	
15.	High Level Group Term Code *[hidden]* [High Level Group Term Code]	
16.	Primary System Organ Class *[hidden]* [Primary System Organ Class]	
17.	Primary System Organ Class Code *[hidden]* [Primary System Organ Class Code]	

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

#	Date:	Vital Signs Details
1		

Vital Signs

1.	Date: [Date:]	/ /

Vital Signs Details

# ✔	Record Identifier:	Oxygen Saturation
2.a	1	

Vital Signs Details Entry

2.1	Record Identifier: [Record Identifier:]	1
2.2	SPO2 Pulse Oximetry % [Oxygen Saturat on]	

C4591001: RANDOMIZATION (RAND)		
Disposition		
1.	Randomizat on Date : [Randomizat on Date :]	/ /
2.	Randomizat on Number: [Randomizat on Number]	
3.	Randomizat on Group: [Randomizat on Group]	

C4591001: REACTOGENICITY DIARY (REAC DIARY)		
Reactogenicity Diary		
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

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

Unplanned Assessment Of Local Reaction

1.	CISR Category *[hidden]* [CISR Category]	◯ UNPLANNED ASSESSMENT OF LOCAL REACTION/SYSTEMIC EVENT
2.	Date of Assessment: [Date of Assessment]	/ /
3.	Inject on S te Location [Inject on S te Locat on]	◯ DELTOID MUSCLE
4.	Inject on Site Body Side: [Inject on S te Body Side]	◯ LEFT ◯ RIGHT

Reaction

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

Reaction Entry

5.1	React on: [Reaction:]	◯ REDNESS ◯ SWELLING
5.2	React on Present: [Reaction Present:]	◯ YES Maximum Diameter (cm): Minimum Diameter (cm): Meets Grade 4 Reaction Criteria: ◯ YES ◯ 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:]	
6.2	Symptom Present: [Symptom Present:]	◯ YES Symptom Grade: ◯ 1 ◯ 2 ◯ 3 ◯ 4 Event related to Study Treament? ◯ YES

NO
NO

C4591001: RESPIRATORY TREATMENT (RESP TX) - Repeating Form

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

Respiratory Treatment

1.	What is the treatment Identifier? [Treatment Identifier]	
2.	Concomitant Non-drug Treatment Pre-specified: [Con Non-Drug Treatments Pre-specified]	◯ YES
3.	Treatment: [Treatment]	◯ INTUBATION ◯ NON-INVASIVE POSITIVE PRESSURE VENTILATION ◯ CPAP ◯ OXYGEN THERAPY
4.	Treatment: [Treatment]	
5.	Start Date: [Start Date]	/ /
6.	Ongoing? [Ongoing?]	◯ YES ◯ NO End Date: / /
7.	Comparison Term *[hidden]* [Comparison Term]	
8.	Lowest Level Term *[hidden]* [Lowest Level Term]	
9.	Lowest Level Term Code *[hidden]* [Lowest Level Term Code]	
10.	Dict onary Derived Term *[hidden]* [Dict onary Derived Term]	
11.	Preferred Term Code *[hidden]* [Preferred Term Code]	
12.	High Level Term *[hidden]* [High Level Term]	
13.	High Level Term Code *[hidden]* [High Level Term Code]	
14.	High Level Group Term *[hidden]* [High Level Group Term]	
15.	High Level Group Term Code *[hidden]* [High Level Group Term Code]	
16.	Primary System Organ Class *[hidden]* [Primary System Organ Class]	
17.	Primary System Organ Class Code *[hidden]* [Primary System Organ Class Code]	

C4591001: RESPIRATORY TREATMENT (RESP TX) - Repeating Form

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

Respiratory Treatment

1.	What is the treatment Identifier? [Treatment Identifier]	
2.	Concomitant Non-drug Treatment Pre-specified: [Con Non-Drug Treatments Pre-specified]	◯ YES
3.	Treatment: [Treatment]	◯ NON-INVASIVE POSITIVE PRESSURE VENTILATION ◯ CPAP ◯ MECHANICAL VENTILATION ◯ EXTRACORPOREAL MEMBRANE OXYGENATION ◯ HIGH FLOW OXYGEN THERAPY
4.	Treatment: [Treatment]	
5.	Start Date: [Start Date]	/ /
6.	Ongoing? [Ongoing?]	◯ YES ◯ NO End Date: / /
7.	Comparison Term *[hidden]* [Comparison Term]	
8.	Lowest Level Term *[hidden]* [Lowest Level Term]	
9.	Lowest Level Term Code *[hidden]* [Lowest Level Term Code]	
10.	Dict onary Derived Term *[hidden]* [Dict onary Derived Term]	
11.	Preferred Term Code *[hidden]* [Preferred Term Code]	
12.	High Level Term *[hidden]* [High Level Term]	
13.	High Level Term Code *[hidden]* [High Level Term Code]	
14.	High Level Group Term *[hidden]* [High Level Group Term]	
15.	High Level Group Term Code *[hidden]* [High Level Group Term Code]	
16.	Primary System Organ Class *[hidden]* [Primary System Organ Class]	
17.	Primary System Organ Class Code *[hidden]* [Primary System Organ Class Code]	

C4591001: FURTHER VACCINATION CONFIRMATION (REVAX CONF)		
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 Vaccination 3 Participant is: ◯ eligible per local/nat onal recommendat ons 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 Vaccinat on 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

C4591001: INFORMED CONSENT - FURTHER VACCINATION (REVAX CONS)		
Informed Consent - Further Vaccination		
1.	Consent Was: [Consent Was:]	OBTAINED Date Written Consent Obtained / /

C4591001: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION (REVAX IE)		
	Criterion Description	
1.		
Inclusion Criteria Not Met Entry		
1.1	Description of Inclus on Cr terion Not Met [Criter on Description]	
	Criterion Description	
2.		
Exclusion Criteria Met Entry		
2.1	Description of Exclusion Cr terion Met [Criter on Description]	

C4591001: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB (RSWAB)

Electronic Sample Tracking

1.	Data Origin [Data Origin]	○ SITE
2.	Sample Type [Sample Type]	○ NASAL_SWAB ○ NASAL_SWAB_SELF
3.	Sample Collected? [Sample Collected]	○ NO ○ YES Date of Collect on: / /
4.	If no sample was collected or sample was not collected according to protocol, please prov de reason: [Reason sample not collected]	

	Sample ID
5.	

Aliquot Entry

Please enter barcode for each aliquot.

5.1	Sample ID [Sample ID]	

C4591001: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY (SAMP TRK)

Electronic Sample Tracking

1.	Data Origin [Data Origin]	○ SITE
2.	Sample Type [Sample Type]	○ SERUM
3.	Sample Collected? [Sample Collected]	○ NO ○ YES Date of Collect on: / /
4.	If no sample was collected or sample was not collected according to protocol, please prov de reason: [Reason sample not collected]	

	Sample ID
5.	

Aliquot Entry

Please enter barcode for each aliquot.

5.1	Sample ID [Sample ID]	

C4591001: INFORM SCREENING (SCREEN)		
InForm Screening		
1.	InForm Initials *[hidden]* [InForm Initials]	
2.	Birth Date: [Birth Year]	/ /

C4591001: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF (SELF SWAB)

Electronic Sample Tracking

1.	Data Origin [Data Origin]	○ SITE
2.	Sample Type [Sample Type]	○ NASAL_SWAB_SELF
3.	Sample Collected? [Sample Collected]	○ NO ○ YES Date of Collect on: / /
4.	If no sample was collected or sample was not collected according to protocol, please prov de reason: [Reason sample not collected]	

	Sample ID
5.	

Aliquot Entry

Please enter barcode for each aliquot.

5.1	Sample ID [Sample ID]	

C4591001: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 (SOD)

Signs and Symptoms

1.	Date of Assessment: [Date of assessment]	/ /
2.	Date of First Symptom Started: [First Symptom Started Date]	/ /
3.	Symptoms Ongoing? [Symptoms Ongoing]	YES NO Date of Last Symptom Resolved: / /

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
4.2	Symptoms: [Symptoms]	
4.3	Was symptom present? [Symptom Present]	YES NO

	Symptoms - Other
5. ✔	

Symptoms - Other Entry

5.1	Symptoms - Other Text: [Symptoms - Other]	
5.2	Comparison Term: *[hidden]* [Comparison Term]	
5.3	Lowest Level Term *[hidden]* [Lowest Level Term]	
5.4	Lowest Level Term Code *[hidden]* [Lowest Level Term Code]	
5.5	D ctionary Derived Term *[hidden]* [D ctionary Derived Term]	

5.6	Preferred Term Code *[hidden]* [Preferred Term Code]	
5.7	High Level Term *[hidden]* [High Level Term]	
5.8	High Level Term Code *[hidden]* [High Level Term Code]	
5.9	High Level Group Term *[hidden]* [High Level Group Term]	
5.10	High Level Group Term Code *[hidden]* [High Level Group Term Code]	
5.11	Primary System Organ Class *[hidden]* [Primary System Organ Class]	
5.12	Primary System Organ Class Code *[hidden]* [Primary System Organ Class Code]	

C4591001: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 (SOD)

Signs and Symptoms

1.	Date of Assessment: [Date of assessment]	/ /
2.	Date of First Symptom Started: [First Symptom Started Date]	/ /
3.	Symptoms Ongoing? [Symptoms Ongoing]	YES NO Date of Last Symptom Resolved: / /

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
4.2	Symptoms: [Symptoms]	
4.3	Was symptom present? [Symptom Present]	YES NO

	Symptoms - Other
5. ✔	

Symptoms - Other Entry

5.1	Symptoms - Other Text: [Symptoms - Other]	
5.2	Comparison Term: *[hidden]* [Comparison Term]	
5.3	Lowest Level Term *[hidden]* [Lowest Level Term]	
5.4	Lowest Level Term Code *[hidden]* [Lowest Level Term Code]	
5.5	D ctionary Derived Term *[hidden]* [D ctionary Derived Term]	

5.6	Preferred Term Code *[hidden]* [Preferred Term Code]	
5.7	High Level Term *[hidden]* [High Level Term]	
5.8	High Level Term Code *[hidden]* [High Level Term Code]	
5.9	High Level Group Term *[hidden]* [High Level Group Term]	
5.10	High Level Group Term Code *[hidden]* [High Level Group Term Code]	
5.11	Primary System Organ Class *[hidden]* [Primary System Organ Class]	
5.12	Primary System Organ Class Code *[hidden]* [Primary System Organ Class Code]	

C4591001: STRATIFICATION (STRAT)		
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)		
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)		
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-M d 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)		
Subject Status		
1.	Subject Status [Subject Status]	
2.	Subject Status Date [Status Date]	/ /

C4591001: INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE (SURV CONS)		
Informed Consent - Asymptomatic Surveillance		
1.	Consent Was: [Consent Was:]	○ OBTAINED Date Written Consent Obtained / /

C4591001: ELECTRONIC SAMPLE TRACKING - NASAL SWAB (SWAB PFE)

Electronic Sample Tracking

1.	Data Origin [Data Origin]	○ SITE
2.	Sample Type [Sample Type]	○ NASAL_SWAB
3.	Sample Collected? [Sample Collected]	○ NO ○ YES Date of Collect on: / /
4.	If no sample was collected or sample was not collected according to protocol, please prov de reason: [Reason sample not collected]	

	Sample ID
5.	

Aliquot Entry

Please enter barcode for each aliquot.

5.1	Sample ID [Sample ID]	

C4591001: MICROBIOLOGY SPECIMEN (SWAB SITE) - Repeating Form

#	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 Collect on: [Date of Collect on]	/ /
2.	Specimen Type: [Specimen Type]	○ SWABBED MATERIAL
3.	Specimen Collect on Location: [Specimen Collection Location]	○ NASAL CAVITY
4.	Assay Code and Description: [Assay Code and Description]	○ SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Dev ce Type: [Dev ce Type]	○ SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name: [Trade Name]	○ CEPHEID XPERT XPRESS SARS-COV-2 TEST
7.	Test Result: [Result]	○ POSITIVE ○ NEGATIVE ○ INDETERMINATE
8.	Comments/Findings/Details: [Comments:]	

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

Vaccination Symptoms Diary - Symptom Resolved Dates

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? ○ YES ○ NO Stop Date: / / ○ NO

#	Symptom:	Were fever or systemic symptoms present on the last day the Subject Diary was completed?
2.a	FEVER	
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:]	
2.2	Were fever or systemic 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 Ongoing? ○ YES ○ NO Stop Date: / / ○ NO
3.	Inject on S te Location: [Inject on S te Locat on:]	○ DELTOID MUSCLE
4.	Inject on Site Body Side: [Inject on S te Body Side:]	○ LEFT ○ RIGHT

#	Injection Site Reaction:	Were injection site reactions present on the last day the Subject Diary was completed?
5.a	REDNESS	
5.b	SWELLING	
5.c	PAIN AT INJECTION SITE	

5.1	Injection Site Reaction: [Injection Site Reaction:]	○ REDNESS ○ SWELLING ○ PAIN AT INJECTION SITE
5.2	Were injection site 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 Ongoing? ○ YES ○ NO Stop Date: / / ○ NO

C4591001: TRANSFUSIONS (TRANSFUSE) - Repeating Form

#	Transfusion Type	Date of Transfusion
1		

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

C4591001: TREATMENT UNBLINDED (TRN UNBLN)		
Treatment Unblinded		
1.	Date Treatment Unblinded : [Date Treatment Unblinded :]	/ /
2.	Primary Reason for Unblinding: [Primary Reason for Unblinding]	○ SUBJECT SAFETY CONCERN ○ OTHER If other, specify: ○ ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

C4591001: UNPLANNED VISIT (UNPL)		
Unplanned Assessments		
1.	Assessments [Assessments]	☐ CONTACT OUTCOME

C4591001: VACCINATION (VACIN TRT)

Vaccination

1.	Was there a temporary delay of vaccination? [Temporary Delay of Vaccination]	◯ YES Date of First Delay: __ / __ / __ Reason(s) for Temporary Delay of Vaccination ☐ FEVER OR ACUTE ILLNESS ☐ RECENT SYSTEMIC CORTICOSTEROID TREATMENT ☐ RECENT NON-STUDY VACCINATION ☐ ANTICIPATED NON-STUDY VACCINATION ◯ NO
2.	Treatment Name [Treatment Name]	
3.	Formulat on: [Formulat on:]	◯ INJECTION
4.	Dose Date Time: [Dose Date Time:]	__ / __ / __ __ : __ *24-hour clock*
5.	Anatomical Locat on: [Anatom cal Location:]	◯ DELTOID MUSCLE
6.	Body S de: [Body S de:]	◯ LEFT ◯ RIGHT
7.	Route: [Route:]	◯ INTRAMUSCULAR
8.	Planned Dose: [Planned Dose]	
9.	Planned Dose Unit: [Planned Dose Unit]	◯ ug
10.	Actual Dose: [Actual Dose:]	
11.	Unit: [Unit:]	◯ ug
12.	Was the Actual Dose adjusted from planned? [Dose Adjusted From Planned]	◯ YES What was the reason the dose was adjusted? ◯ ADVERSE EVENT(S) ◯ INSUFFICIENT CLINICAL RESPONSE ◯ OTHER SPECIFY If other, specify: ◯ NO
13.	Timeframe Subject Was Observed [Timeframe Subject Was Observed]	◯ THE PROTOCOL SPECIFIED OBSERVATION PERIOD
14.	Was the subject observed for at least the protocol specified observation period after investigational product	◯ YES ◯ NO If No, specify reason:

	administration? [Observed Post Dose For Specified Time]	
15.	Comparison Term *[hidden]* [Comparison Term]	
16.	Standardized Medicat on Name - Dict onary Derived. *[hidden]* [Standardized Medicat on Name]	
17.	Standardized Medicat on Code - Dict onary Derived *[hidden]* [Standardized Medicat on Code]	

C4591001: VACCINATION (VACIN TRT)

Vaccination

1.	Was there a temporary delay of vaccination? [Temporary Delay of Vaccination]	◯ YES Date of First Delay: __ / __ / __ Reason(s) for Temporary Delay of Vaccination ☐ FEVER OR ACUTE ILLNESS ☐ RECENT SYSTEMIC CORTICOSTEROID TREATMENT ☐ RECENT NON-STUDY VACCINATION ☐ ANTICIPATED NON-STUDY VACCINATION ◯ NO
2.	Treatment Name [Treatment Name]	
3.	Formulat on: [Formulat on:]	◯ INJECTION
4.	Dose Date Time: [Dose Date Time:]	__ / __ / __ __ : __ *24-hour clock*
5.	Anatomical Locat on: [Anatom cal Location:]	◯ DELTOID MUSCLE
6.	Body S de: [Body S de:]	◯ LEFT ◯ RIGHT
7.	Route: [Route:]	◯ INTRAMUSCULAR
8.	Container Number: *[hidden]* [PAC / Kit Number:]	
9.	Actual Dose: [Actual Dose:]	
10.	Unit: [Unit:]	◯ mL ◯ ug
11.	Timeframe Subject Was Observed [Timeframe Subject Was Observed]	◯ THE PROTOCOL SPECIFIED OBSERVATION PERIOD ◯ 30 MINUTES
12.	Was the subject observed for at least the protocol specified observation period after investigational product administration? [Observed Post Dose For Specified Time]	◯ YES ◯ NO If No, specify reason:
13.	Comparison Term *[hidden]* [Comparison Term]	
14.	Standardized	

	Medicat on Name - Dict onary Derived. *[hidden]* [Standardized Medicat on Name]	
15.	Standardized Medicat on Code - Dict onary Derived *[hidden]* [Standardized Medicat on Code]	

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

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

Concomitant Medications

1.	What is the med cation dentifier? [Sponsor-Defined Identifier]	
2.	Category: [Category for Medication]	○ GENERAL CONCOMITANT MEDICATIONS
3.	Concomitant Medications Pre-specified: [Concom tant Medicat ons Pre-specified]	○ NO
4.	Medicat on: Provide the complete gener c drug name (including salt form, where applicable). Where gener c name is unknown, enter the full trade or proprietary name. Include clarifying information in the Med cation text (e.g., Ingredient(s), route, use, formulation). [Name of Medication]	
5.	Start Date: [Start Date]	/ /
6.	Ongoing? [Ongoing]	○ YES ○ NO End Date: / /
7.	Comparison Term *[hidden]* [Comparison Term]	
8.	Standardized Medication Name - D ctionary derived. *[hidden]* [Standardized Medication Name]	
9.	Standardized Medication Code - Dictionary derived *[hidden]* [Standardized Medication Code]	

C4591001: VITAL SIGNS - TEMP (VITAL TEMP)

Vital Signs

1.	Date: [Date:]	/ /

Vital Signs Details

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

Vital Signs Details Entry

2.1	Record Identifier: [Record Identifier:]	○ 1
2.2	Temperature: [Temperature]	
2.3	Un t: [Temperature Unit]	○ F ○ C
2.4	Temperature Location: [Temperature Locat on:]	○ ORAL CAVITY ○ EAR ○ RECTUM ○ AXILLA ○ FOREHEAD

C4591001: VITAL SIGNS - BASELINE (VITALS BSL)

Vital Signs

1.	Date: [Date:]	/ /
2.	Weight: [Weight]	
3.	Unit: [Weight Unit]	○ kg ○ LB
4.	Height: [Height]	
5.	Unit: [Height Un t]	○ cm ○ in
6.	Body Mass Index: [Body Mass Index]	

Vital Signs Details

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

Vital Signs Details Entry

7.1	Record Identifier: [Record Identifier:]	○ 1
7.2	Temperature: [Temperature]	
7.3	Un t: [Temperature Unit]	○ C ○ F
7.4	Temperature Location: [Temperature Locat on:]	○ ORAL CAVITY ○ EAR ○ RECTUM ○ AXILLA ○ FOREHEAD

C4591001: VITAL SIGNS - BASELINE (VITALS BSL)

Vital Signs

1.	Date: [Date:]	/ /
2.	Weight: [Weight]	
3.	Unit: [Weight Unit]	kg LB
4.	Height: [Height]	
5.	Unit: [Height Un t]	cm in
6.	Body Mass Index: [Body Mass Index]	

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
7.2	Temperature: [Temperature]	
7.3	Un t: [Temperature Unit]	C F
7.4	Temperature Location: [Temperature Locat on:]	ORAL CAVITY EAR RECTUM AXILLA FOREHEAD
7.5	Systolic: [Systolic:]	
7.6	Diastol c: [Diastolic:]	
7.7	BP Position: [BP Position]	SITTING
7.8	Pulse: [Pulse:]	

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

#	Date:	Vital Signs Details
1		

Vital Signs

1.	Date: [Date:]	/ /

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
2.2	Systolic: [Systolic:]	
2.3	Diastol c: [Diastolic:]	
2.4	Respiratory Rate in respirations/minute: [Respiratory Rate in respirations/minute]	
2.5	Heart Rate in beats/minute: [Heart Rate in beats/minute]	

C4591001: VITAL SIGNS (VITALS FUP)

Vital Signs

1.	Date: [Date:]	/ /

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
2.2	Temperature: [Temperature]	
2.3	Un t: [Temperature Unit]	○ F ○ C
2.4	Temperature Location: [Temperature Locat on:]	○ ORAL CAVITY ○ EAR ○ RECTUM ○ AXILLA ○ FOREHEAD
2.5	Systolic: [Systolic:]	
2.6	Diastol c: [Diastolic:]	
2.7	BP Position: [BP Position]	○ SITTING
2.8	Pulse: [Pulse:]	

C4591001: WITHDRAWAL OF CONSENT (WOC)		
Withdrawal Of Consent		
1.	W thdrawal of Consent Date : [Withdrawal of Consent Date :]	/ /

A-1426-0086 / C4591001-Post-12-July-2020
App Subject Facing Screen Report

Localized texts are displayed in English (US).

Contents

Localized months and days of the week will display throughtout the app.

Month	January	February	March	April	May	June	July	August	September	October	November	December
Abbr.	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec

Days	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Abbr.	Mon	Tue	Wed	Thu	Fri	Sat	Sun

Note: Text below the screens/messages is for information purposes only and gives instruction on when particular wording on a screen/message may display or what a computed value may display

1 Notifications / Subject card

Email notification/Subject card to provisioned device subjects:

Welcome to the C4591001-Post-12-July-2020 study!

Email notification only: [Hello, **]**

The information below will guide you on how to start using the TrialMax App.

On the phone provided to you by the study clinic, open the TrialMax App and type in the following code to activate it:
[Activation Code]

Then log in with your temporary PIN provided by your study clinic personnel. You will be asked to change the PIN to a new personal one.

During your study clinic visit, the study personnel will help you with any questions related to the TrialMax App activation.

You must activate the App with the provided activation code during your study clinic visit. If you need any help with the activation, contact your study clinic or the Helpdesk.

If you contact your study clinic or the Helpdesk, you may need to give the following information:

Subject card only: [Participant number: XXXXXXXX **]**

Subject card only: [Site number: XXXX **]**

Trial ID: C4591001-Post-12-July-2020

Email notification only: [----------
This is an automatic e-mail message sent by Signant Health, an electronic patient diary provider for clinical trials. This email message and its contents are for the sole use of the intended recipient(s) and may contain confidential and privileged information. Any unauthorized review, use, disclosure or distribution is strictly prohibited. Please do not reply to this email; the email address cannot receive messages. If you need any assistance, please contact the Helpdesk. **]**

SMS Body for Provisioned Devices:
Welcome to the C4591001-Post-12-July-2020 Study! Activate the TrialMax App with code:

[Activation Code]

Email notification/Subject card to BYOD subjects:

Welcome to the C4591001-Post-12-July-2020 study!

Email notification only: [Hello, **]**

The information below will guide you on how to install the TrialMax App onto your cell phone and how to start using the TrialMax App after the installation.

Email notification only: [To install the TrialMax App, tap the link below and follow the on-screen instructions. **]**

Subject card only: [To install the TrialMax App, tap the link in the installation text message (SMS) or email you will receive in a few minutes, and follow the on-screen instructions.

If you have not received the text message or email, enter the following internet address into the web browser of your device: **]**
[Link]

After the installation has completed, open the TrialMax App and type in the following code to activate it:
[Activation Code]

Then log in with your temporary PIN provided by your study clinic personnel. You will be asked to change the PIN to a new personal one.

During your study clinic visit, the study clinic personnel will help you with any questions related to the TrialMax App installation.

You must activate the App with the provided activation code during your study clinic visit. If you need any help with the installation, contact your study clinic or the Helpdesk.

If you contact your study clinic or the Helpdesk, you may need to give the following information:

Subject card only: [Participant number: XXXXXXXX **]**

Subject card only: [Site number: XXXX **]**

Trial ID: C4591001-Post-12-July-2020

Email notification only: [----------
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SMS Body for BYOD subjects:

Welcome to the C4591001-Post-12-July-2020 Study! To install the TrialMax App, select the link:
[Link]
Activate the TrialMax App with code:
[Activation Code]

App notification:

Please fill in your diary!

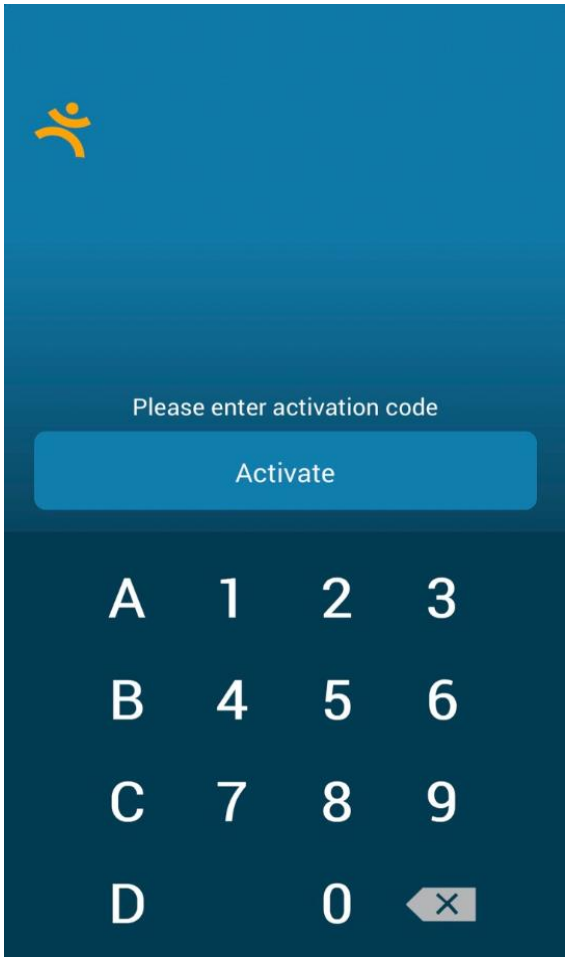
Email notification subject :
COVID-19 Illness Diary Reminder

Email and SMS Body for COVID-19 Illness Diary Reminder:

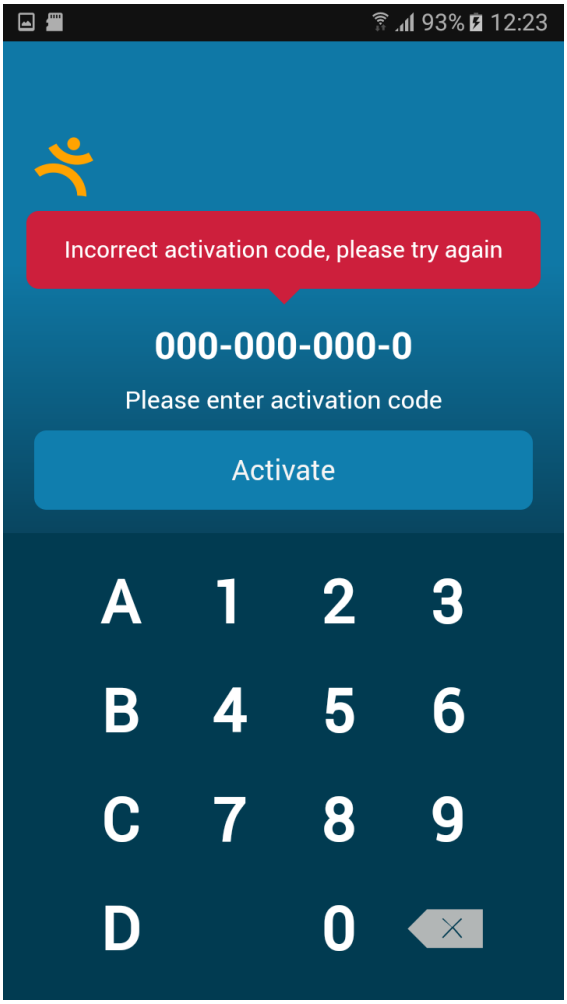
Please continue to complete the illness diary weekly or if you experience COVID-19 symptoms or have a COVID-19 diagnosis. Contact your study doctor with any suspected COVID-19 symptoms.

Email notification only: [----------
This is an automatic e-mail message sent by Signant Health, an electronic patient diary provider for clinical trials. This email message and its contents are for the sole use of the intended recipient(s) and may contain confidential and privileged information. Any unauthorized review, use, disclosure or distribution is strictly prohibited. Please do not reply to this email; the email address cannot receive messages. If you need any assistance, please contact the Helpdesk. **]**

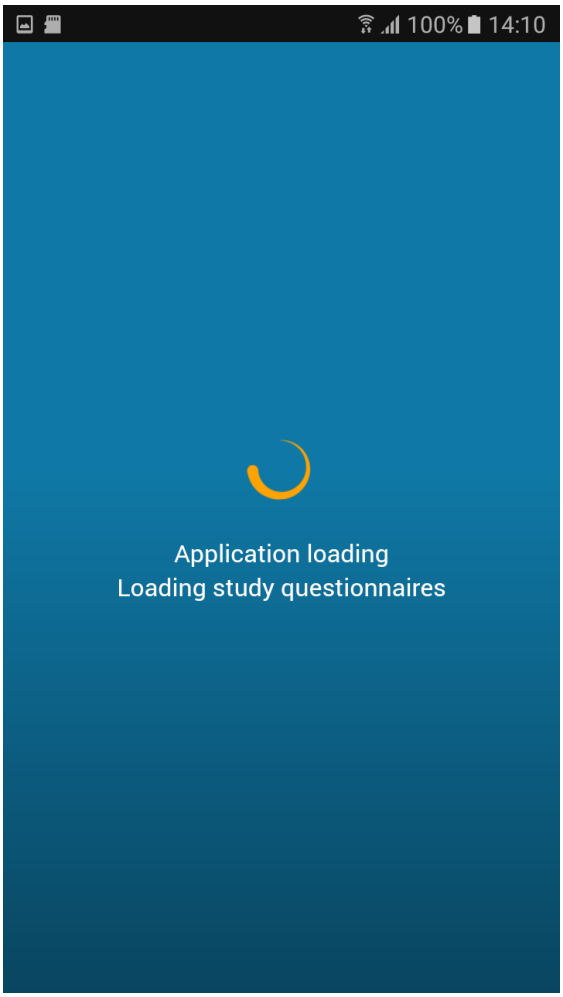
2 Common



Screen 1



Screen 2



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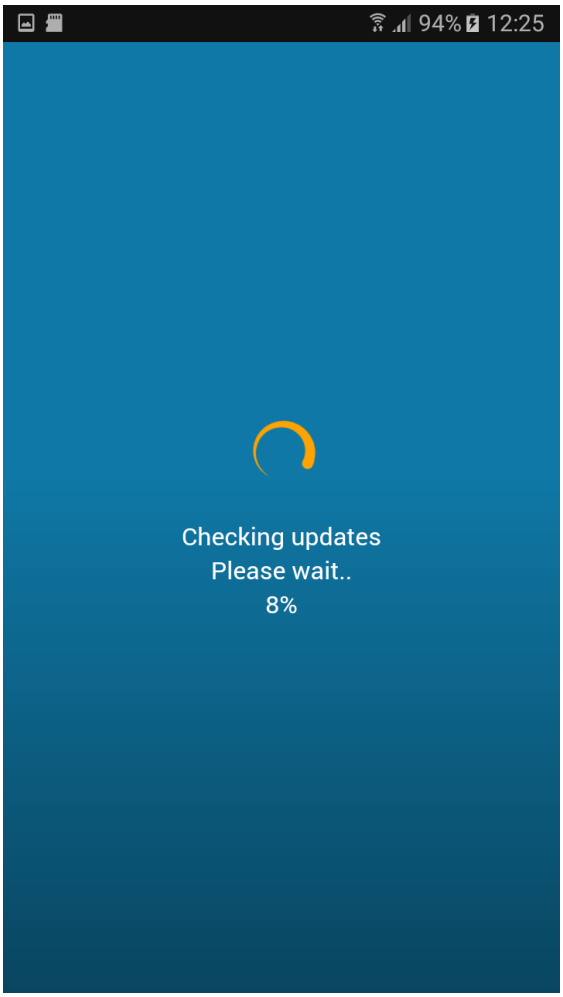

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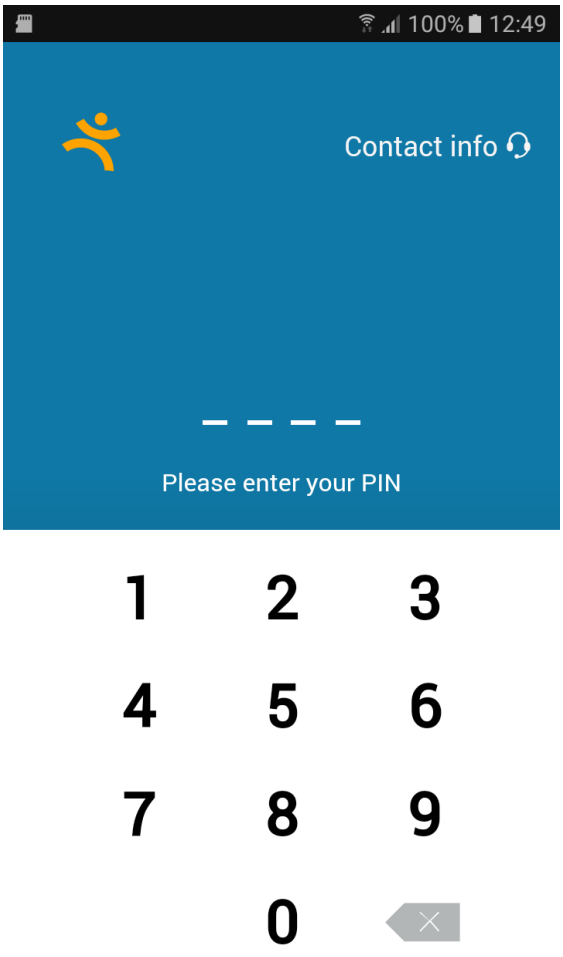

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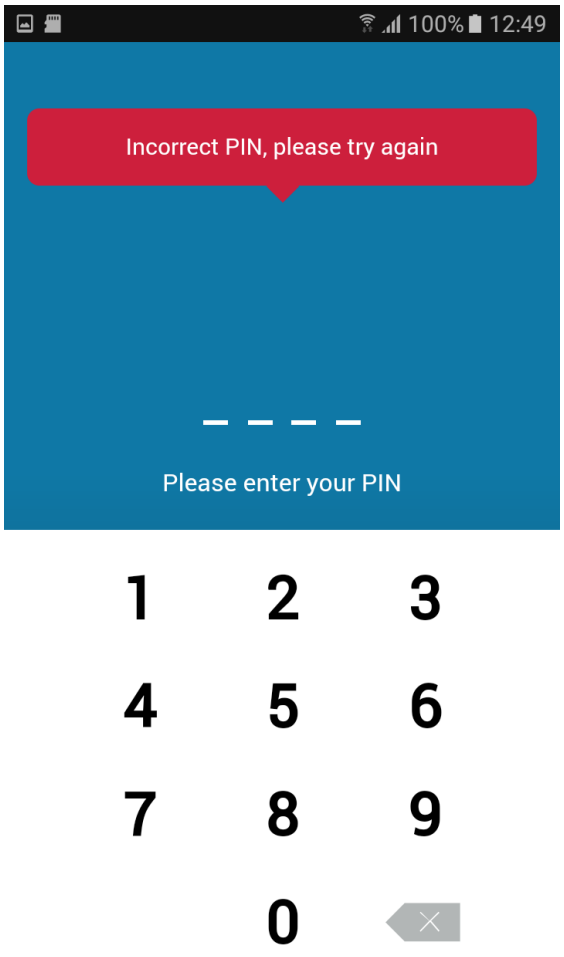

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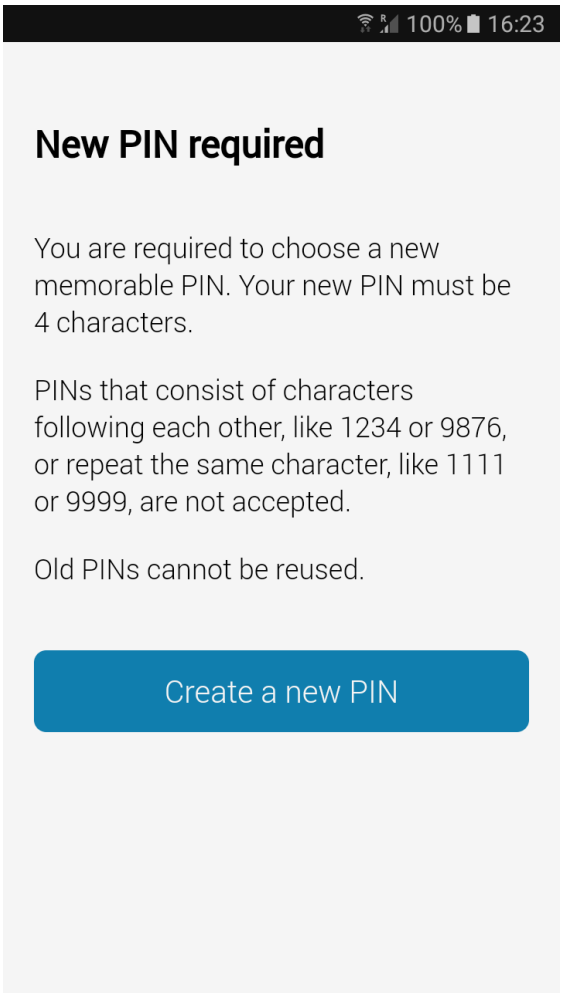
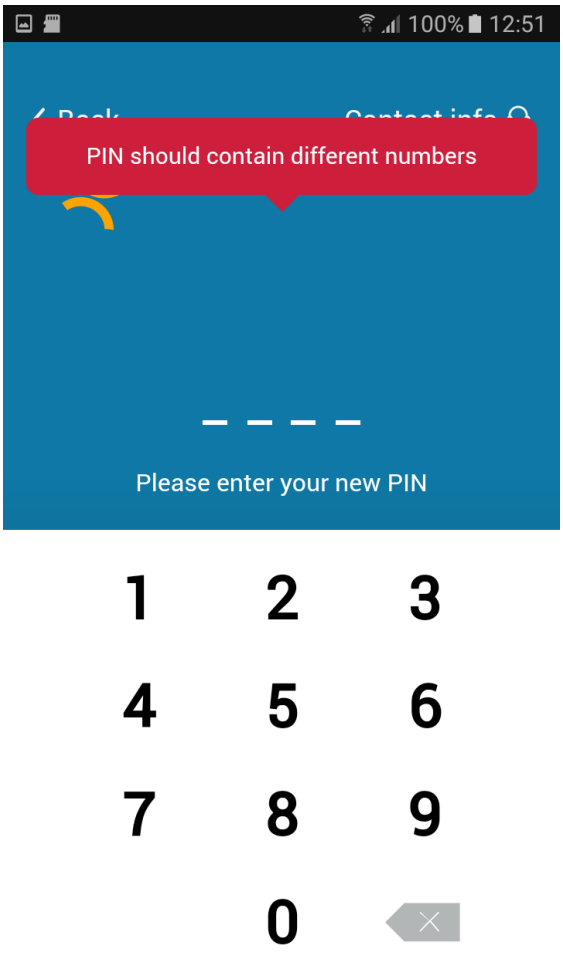


Screen 7

Screen 8



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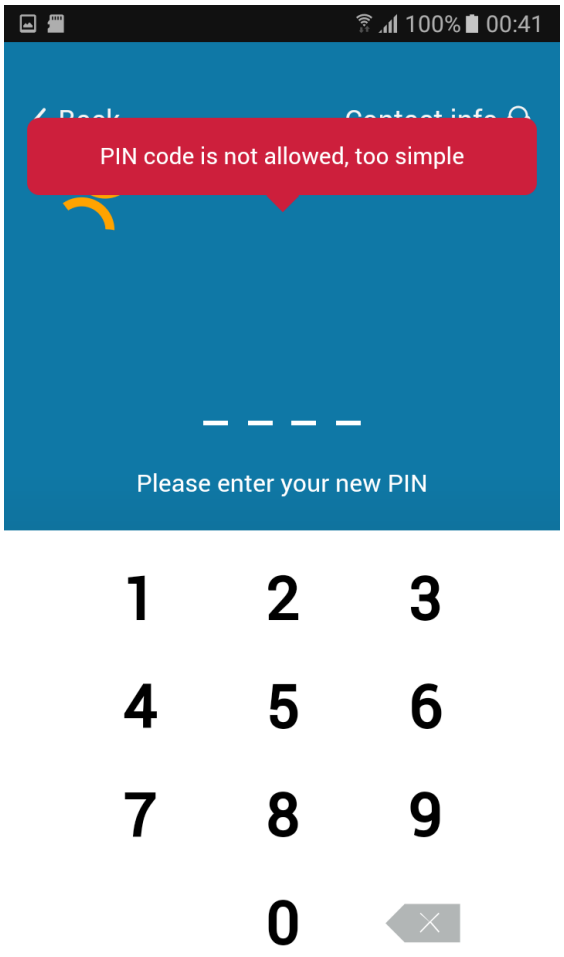

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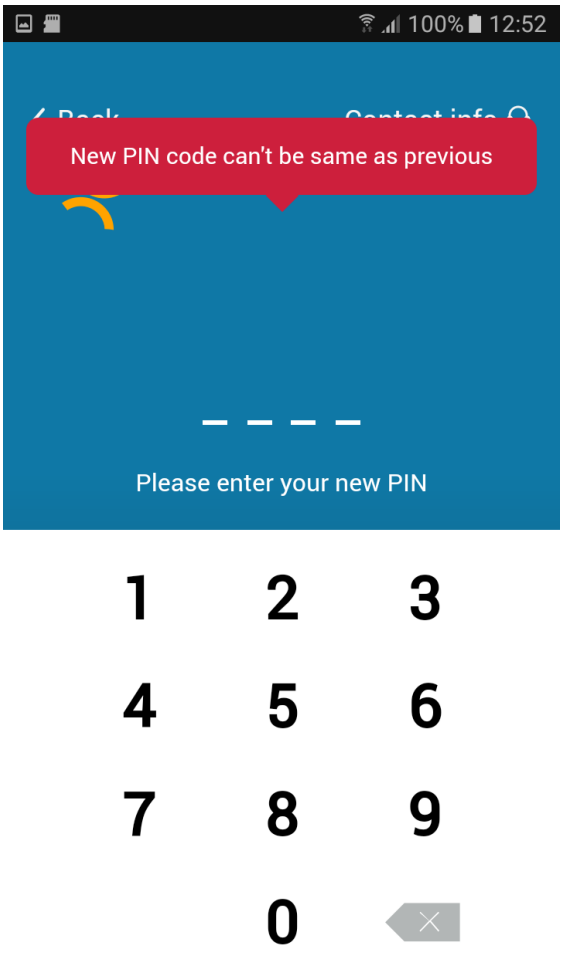

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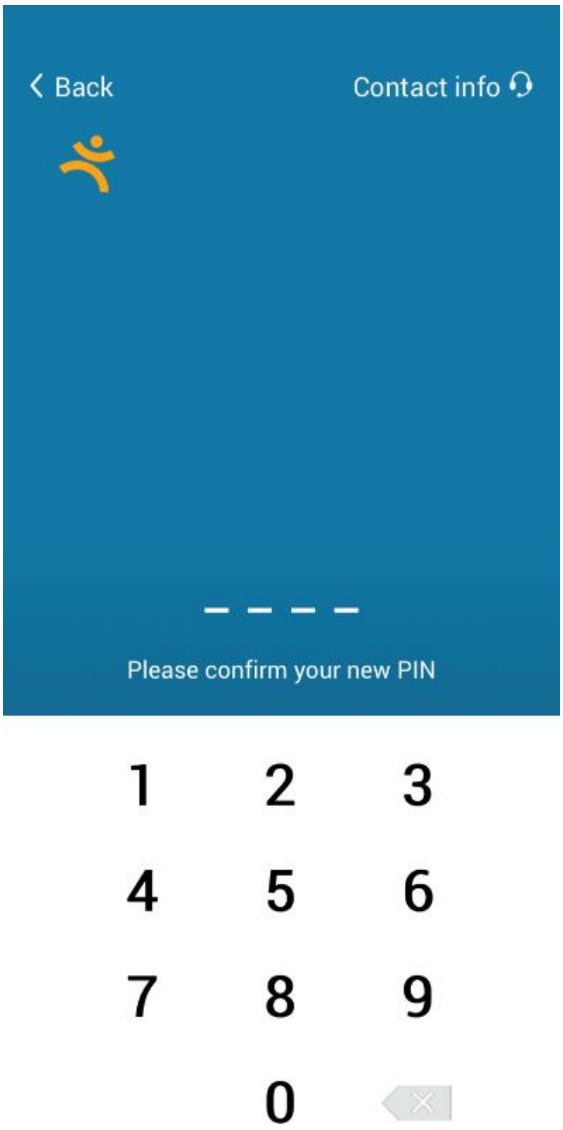

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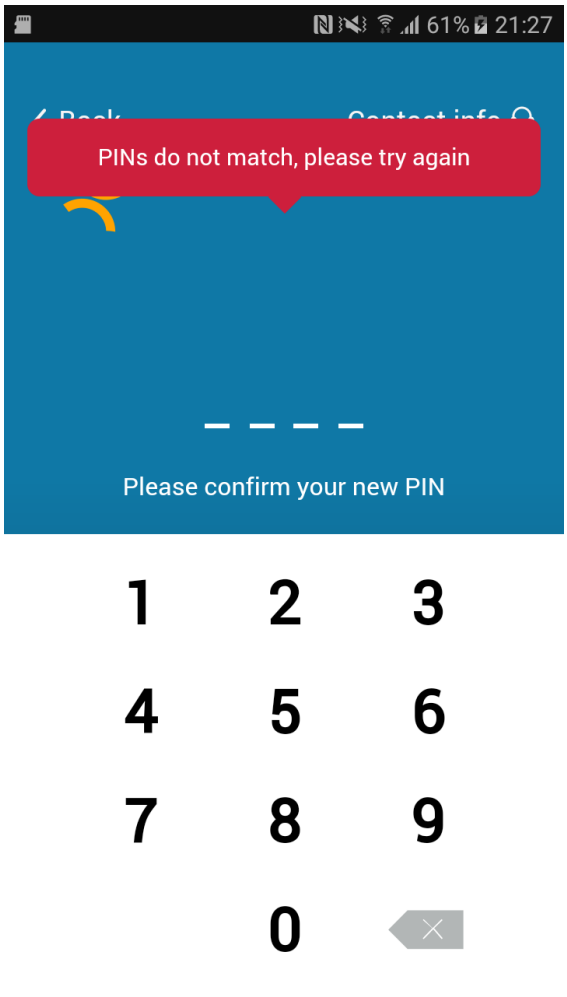

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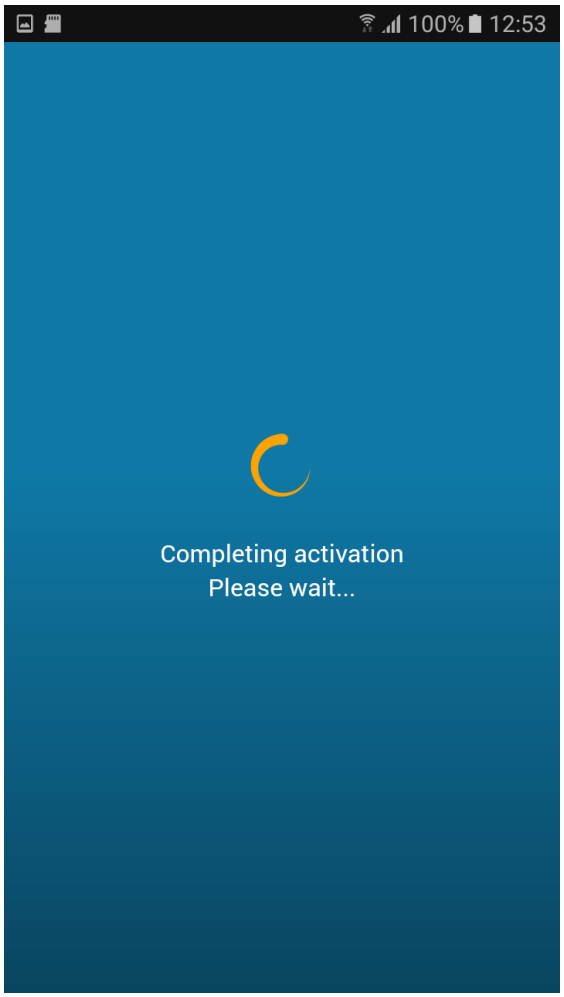

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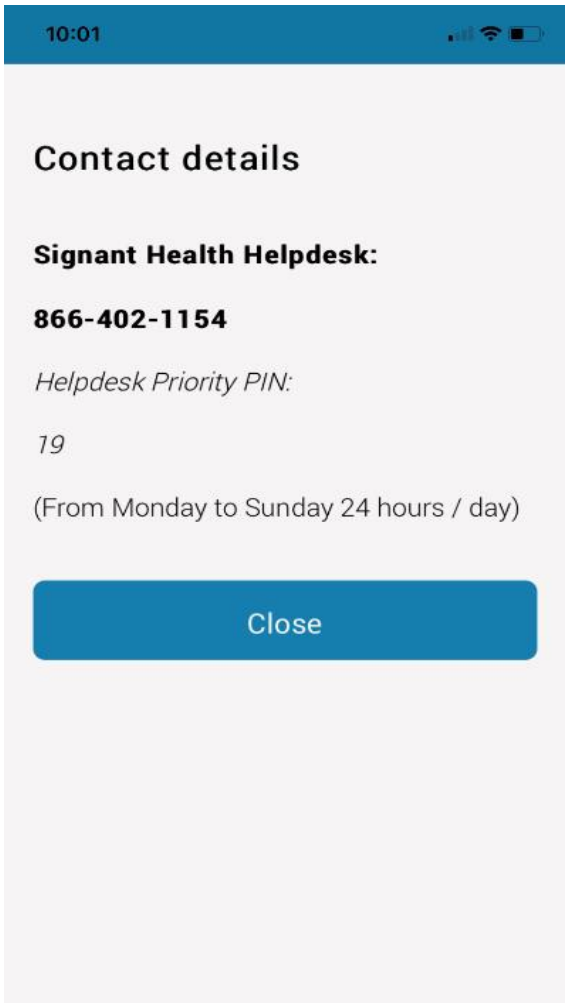

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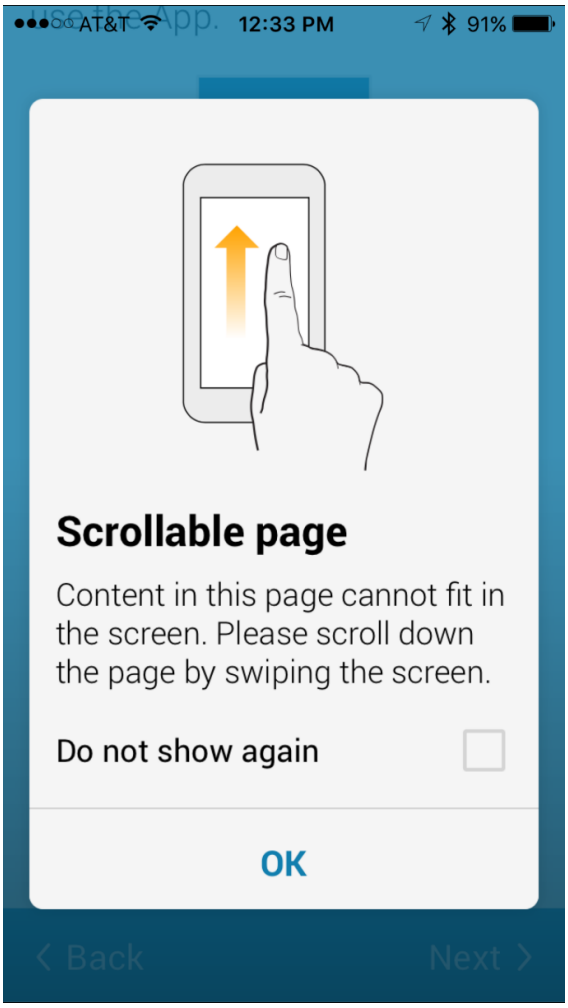

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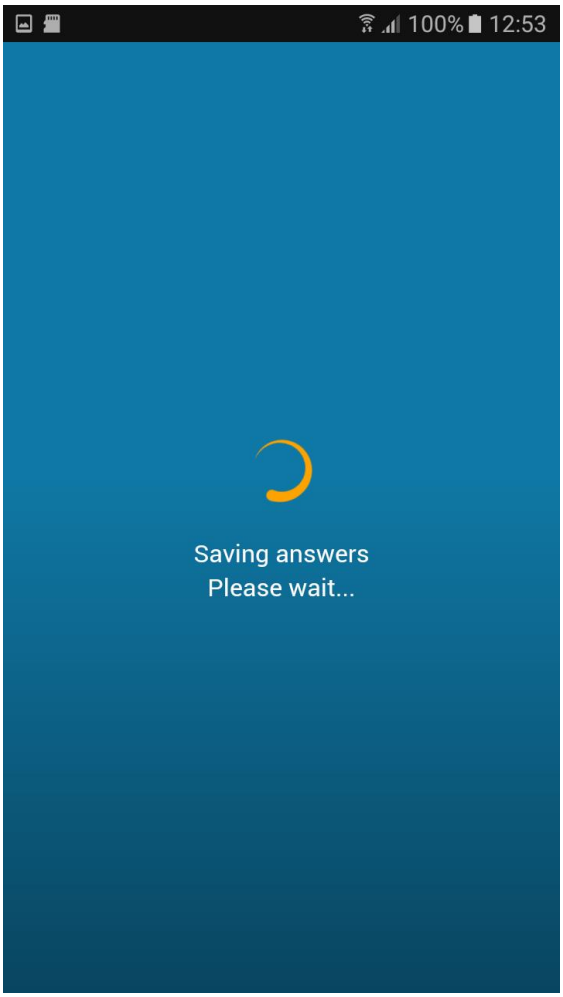

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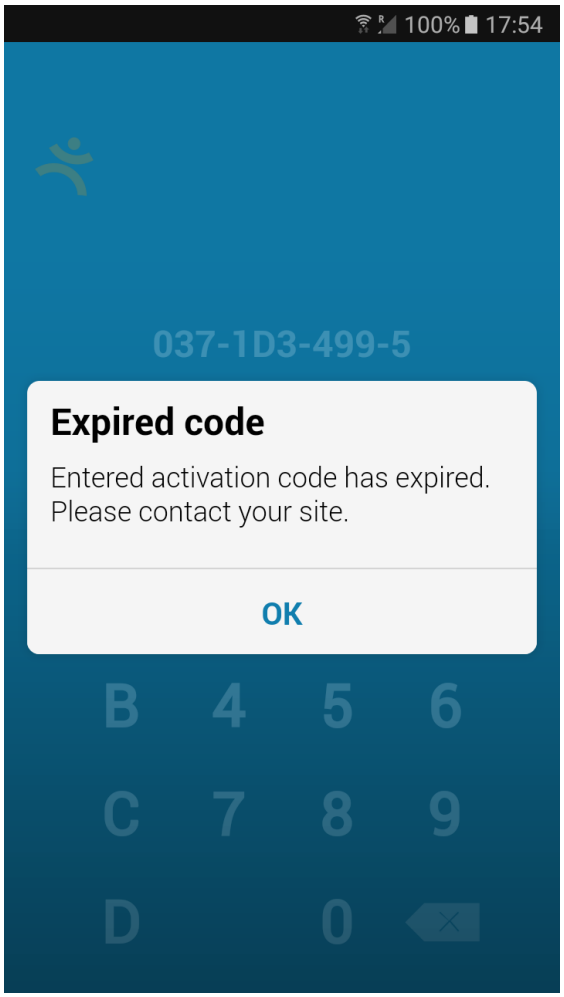

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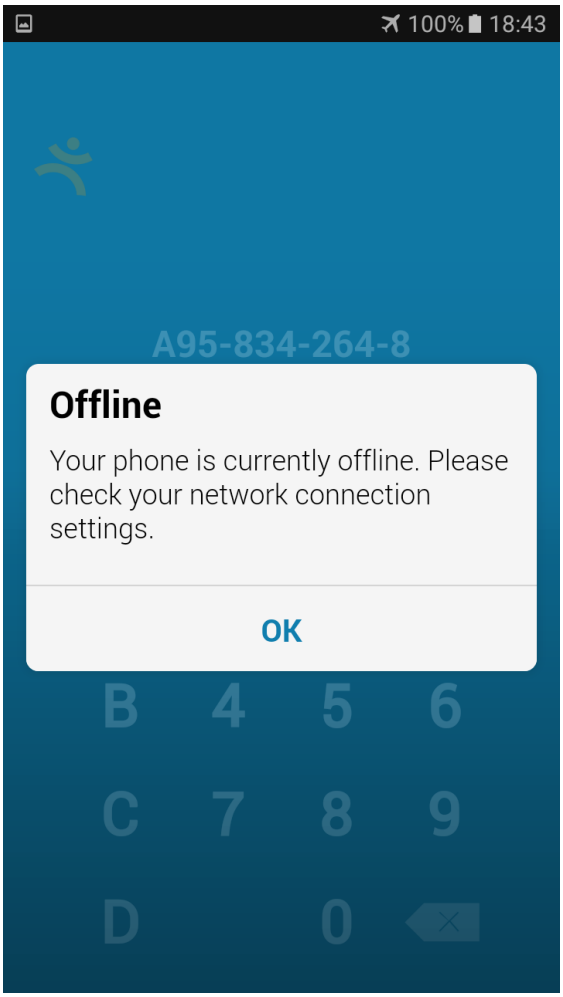

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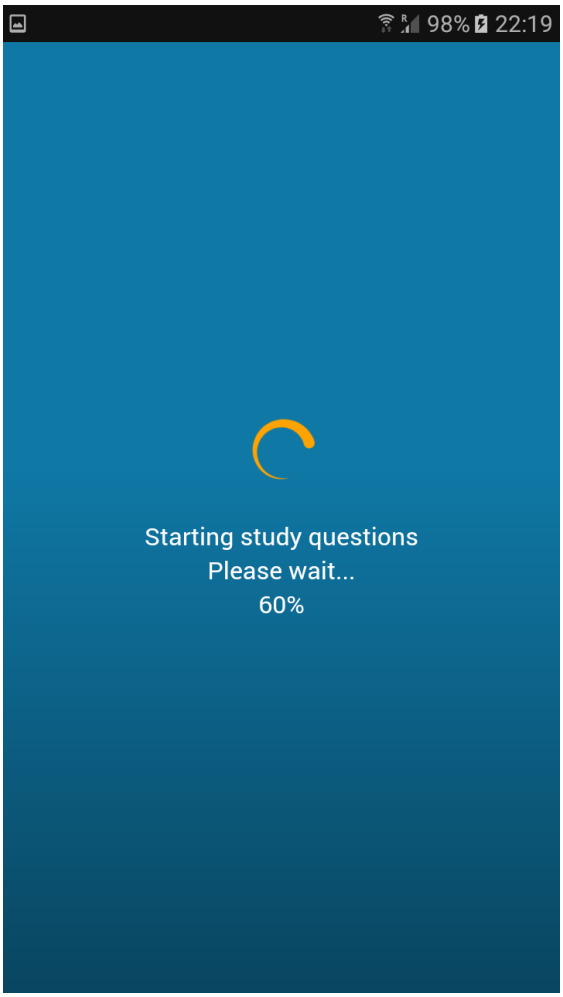

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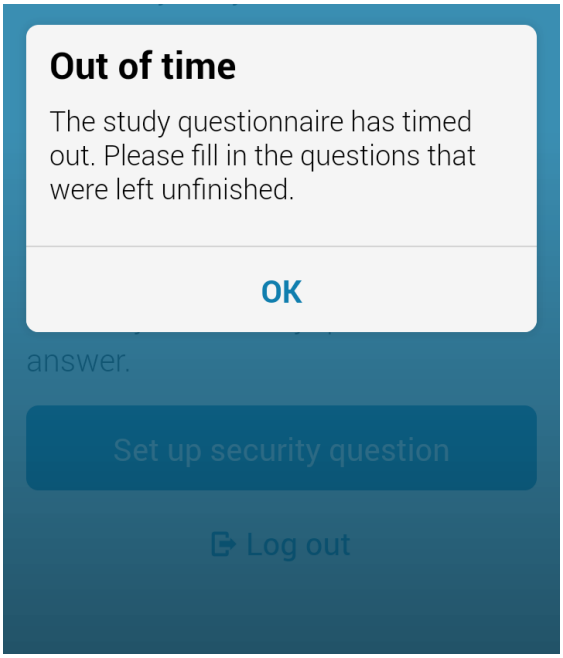

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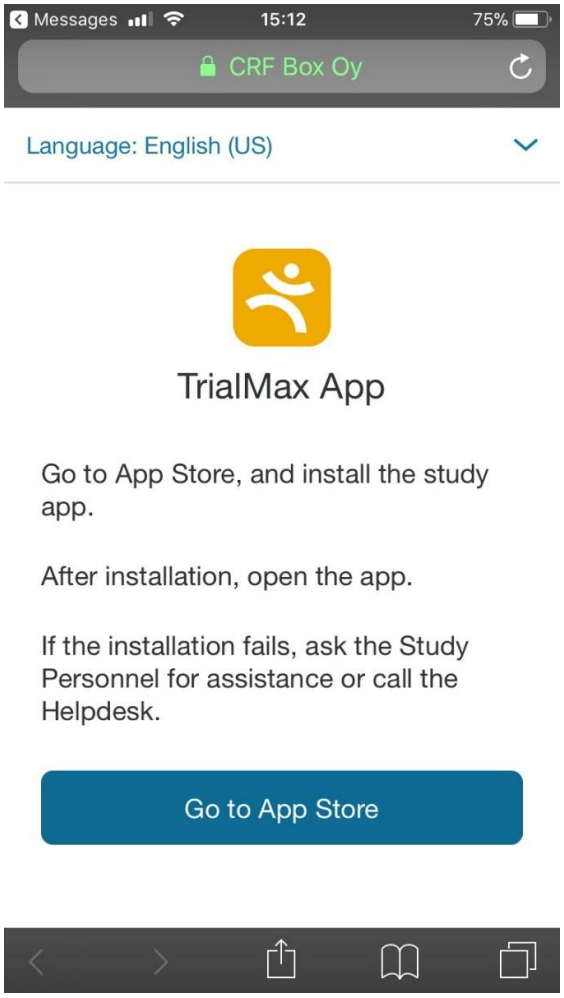

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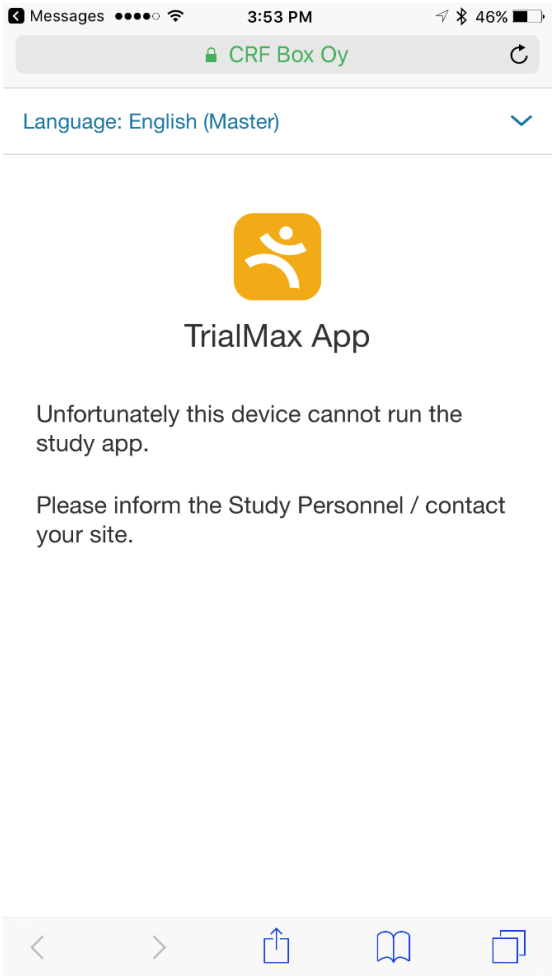

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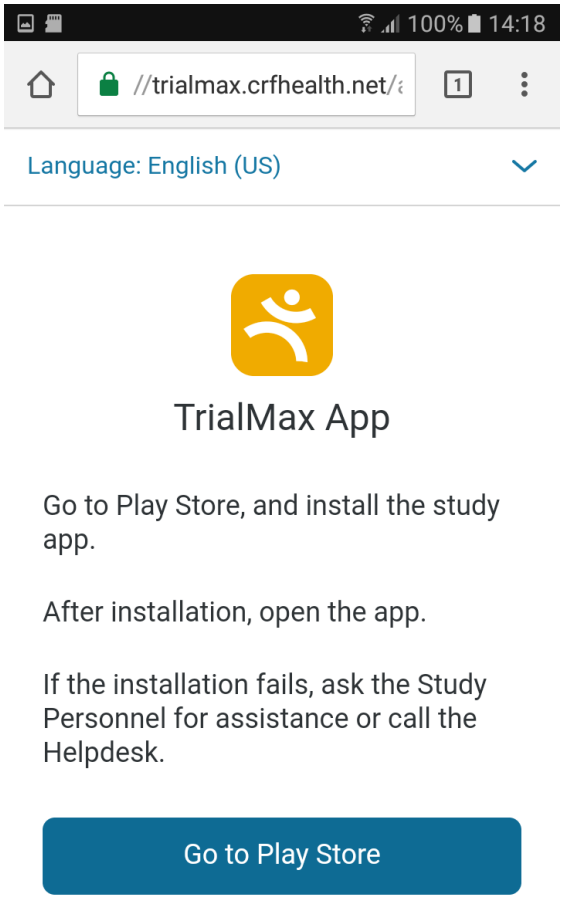

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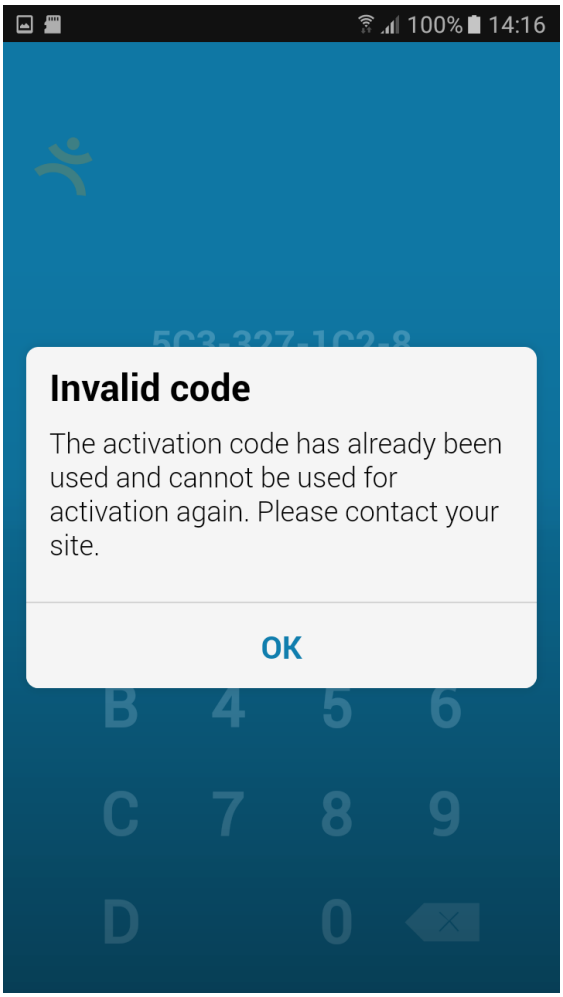

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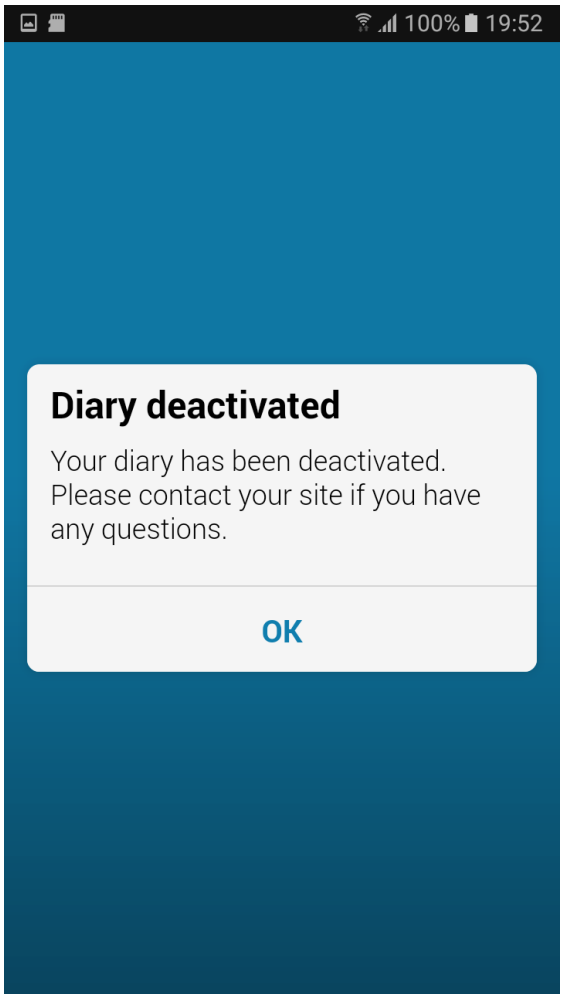

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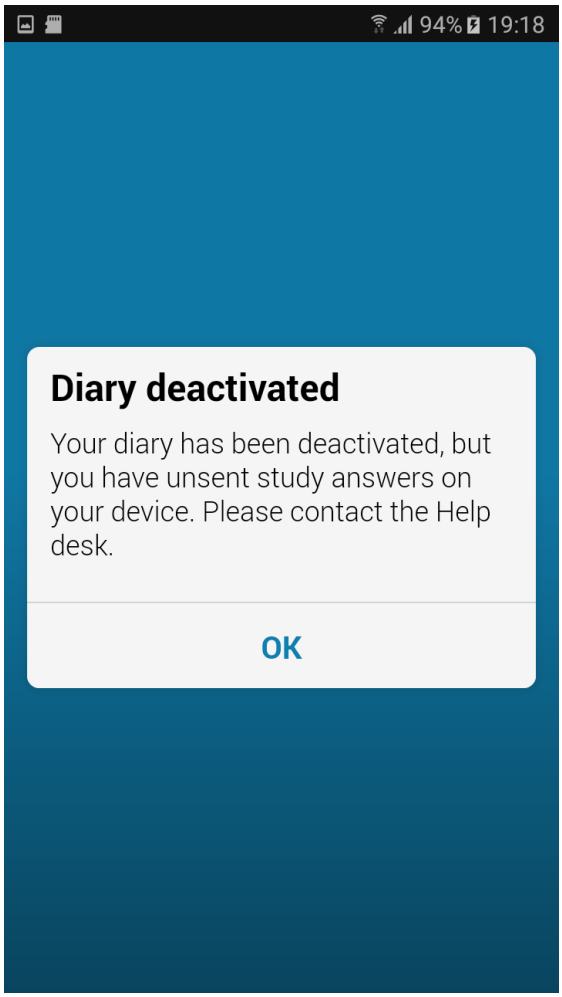
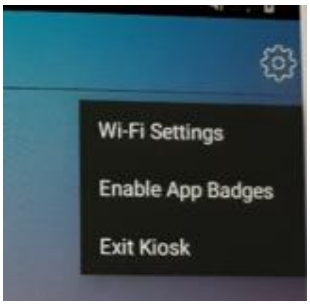


Screen 27

Screen 28



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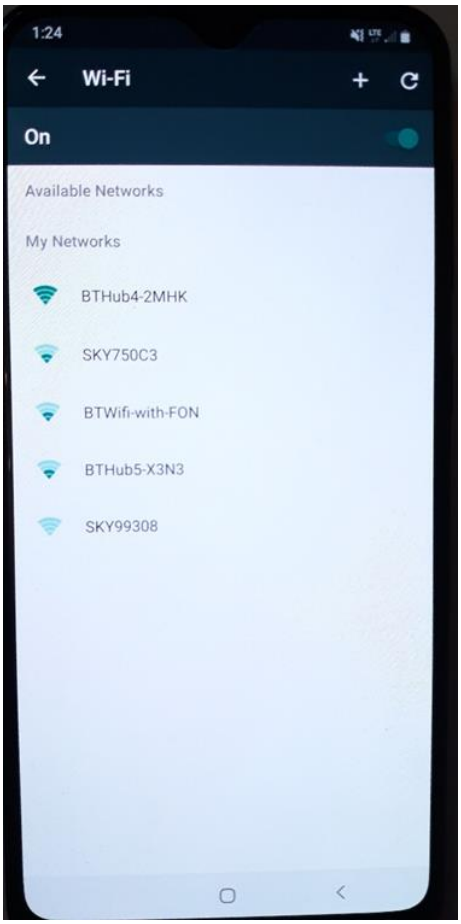

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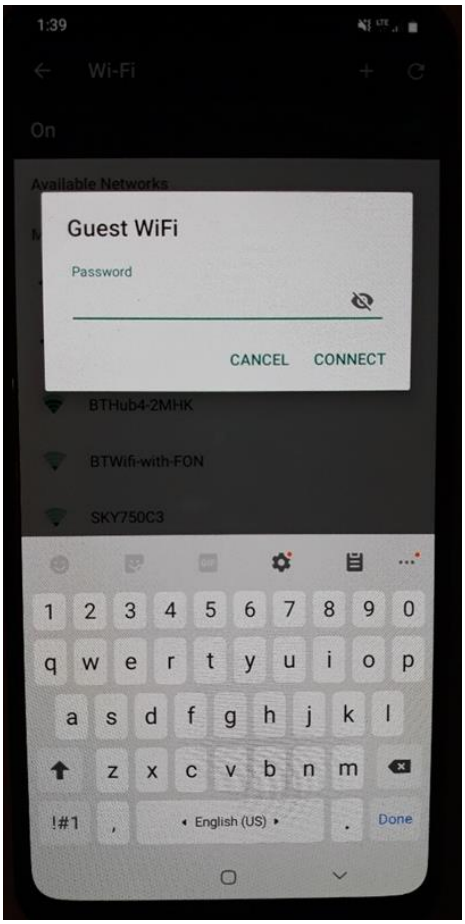

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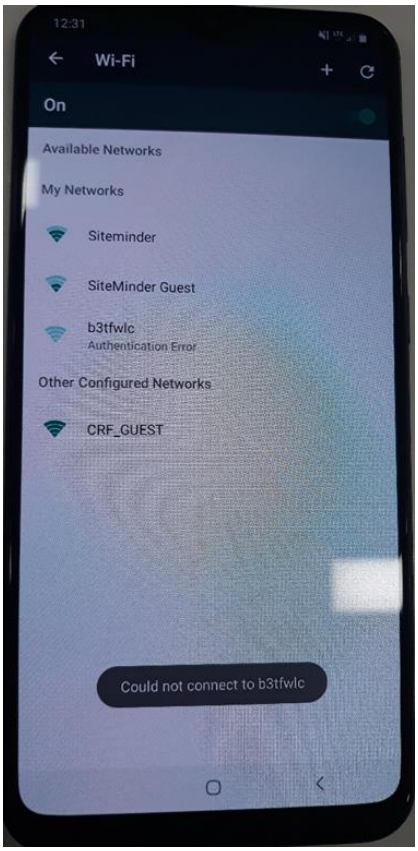

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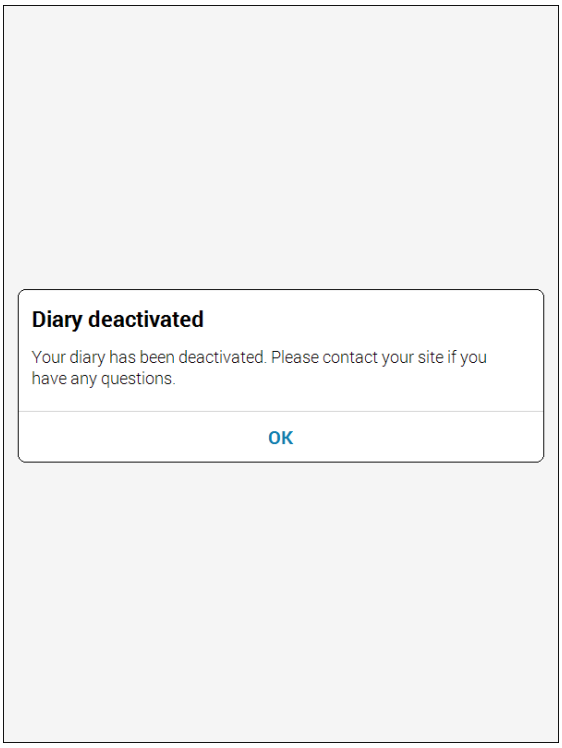


Message 1

Note: Other messages that could appear on the device include:

'Invalid PIN'

'Installing study questions'

'Securing study questions'

'Unsent answers'

'There are a lot of unsent study answers. Please make sure your device is connected to the Internet.'

'The limit of unsent study answers has been reached. Please connect your device to the Internet to fill in the diary again.'

'Oops!'

'Something went wrong, please try again or contact the Help desk.'

'Unsuccessful sending'

'Cannot safely send the study answers, please contact the Help desk.'

'Study ended'

'You no longer need to fill in the diary. Thank you for your help.'

'Updating'

'System is updating, please try again later.'

'Connection error'

'No Internet connection. Please check your Internet connection and try again.'

'Time out'

'Please check your Internet connection and try again.'

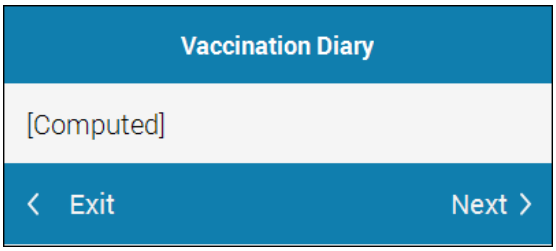
'Low storage space'

'Your device is running out of available storage. Please free some storage space and try again.'

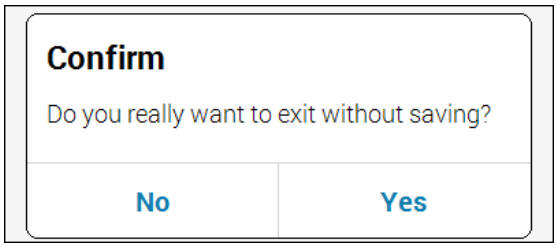
'Error'

'Something went wrong, please contact the Help desk or click OK to try again.'

3 Form: Vaccination Diary



Screen 1



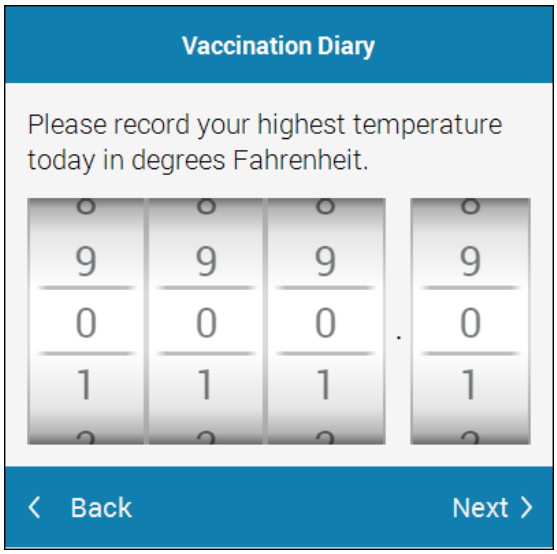
Message 1

[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)."

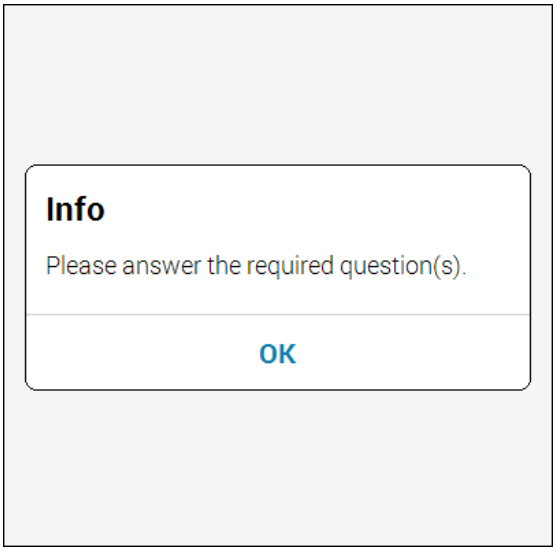
{1} Will display a date

{2} Will display a number of days.

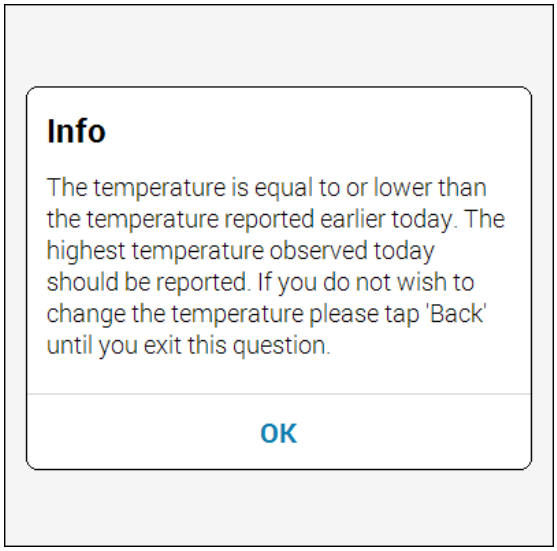
Example: Hello, welcome to the vaccination diary. You will be answering the following questions about how you have been feeling since your vaccination on Mar-27-2020. You will answer these questions for 7 day(s).



Screen 3



Message 1



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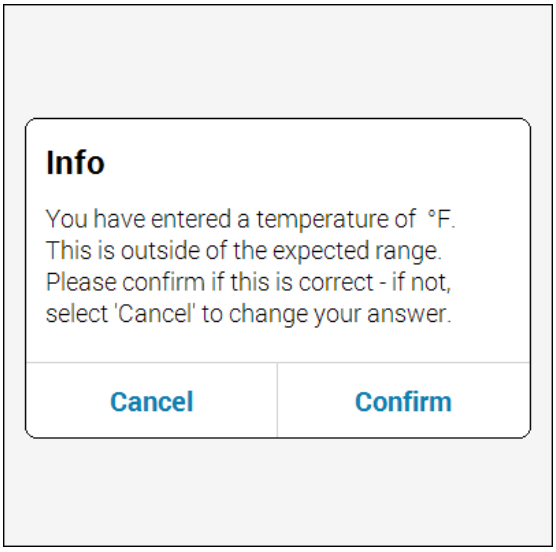
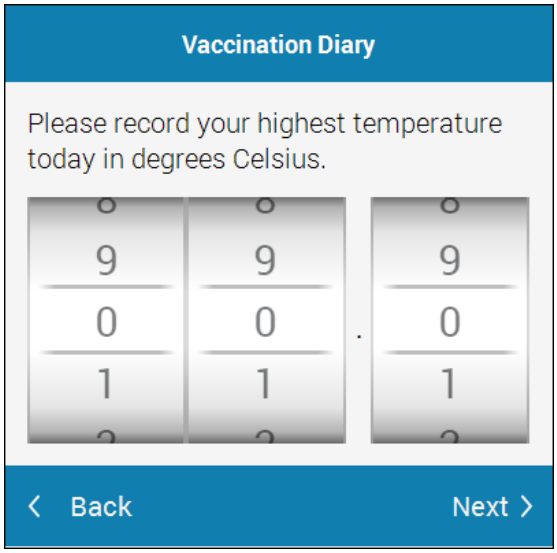
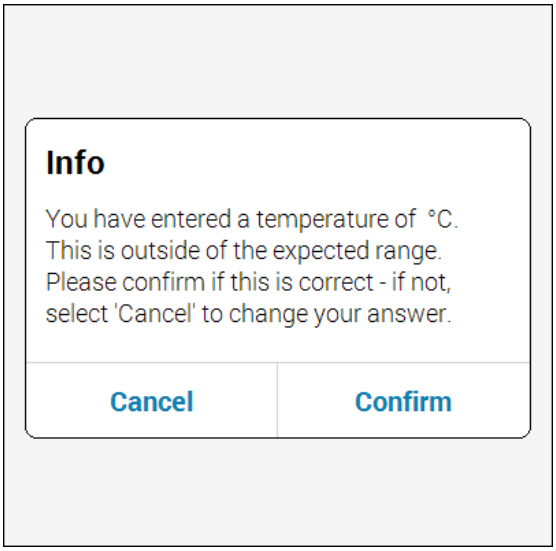


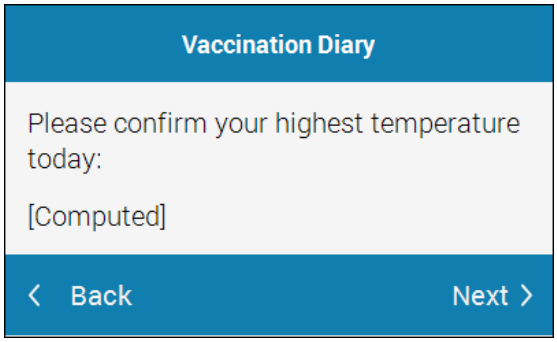
Message 3



Screen 4

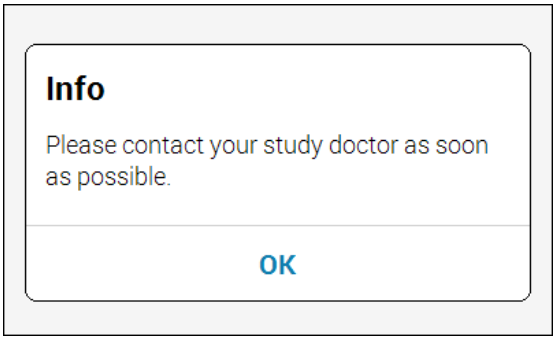


Message 3

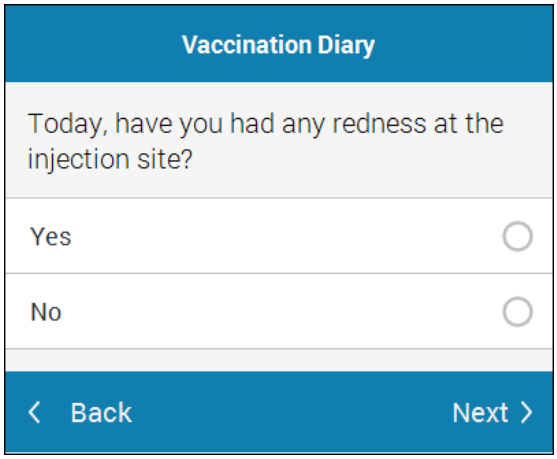


Screen 5

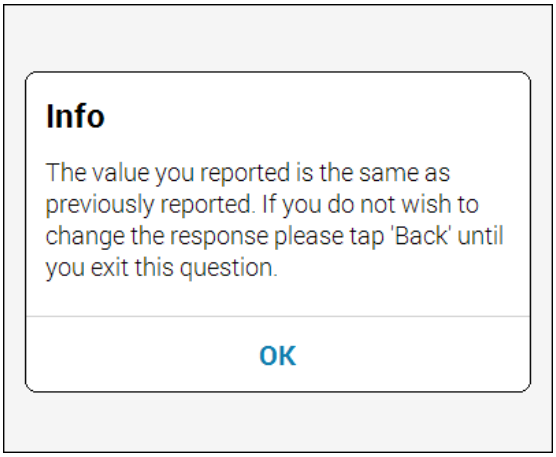
[Computed] will display the temperature selected on Screen 3 or Screen 4



Message 1



Screen 6



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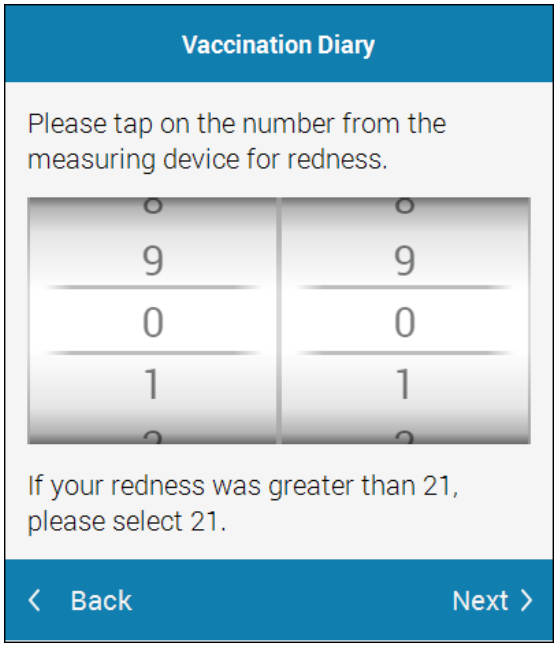
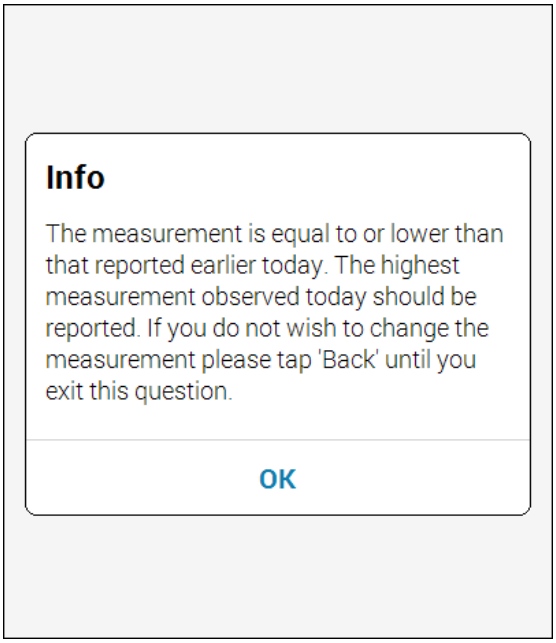


Screen 7



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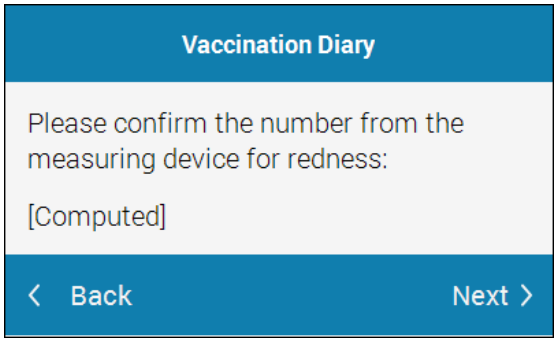
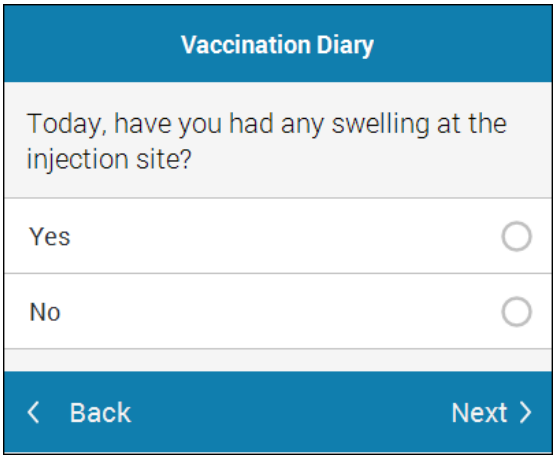
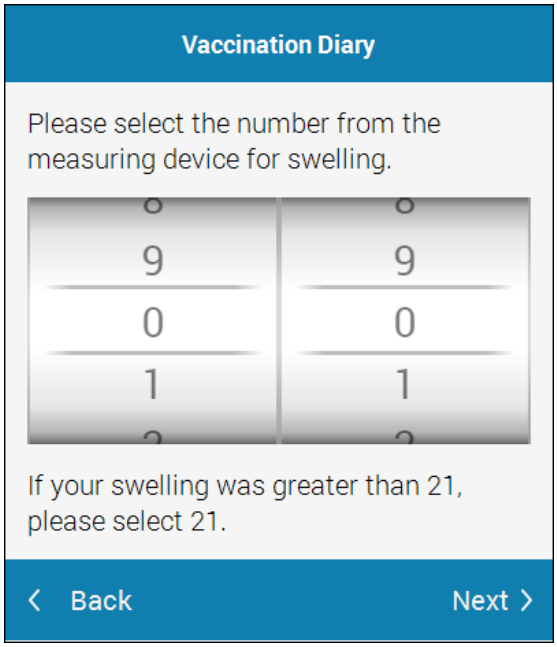


Screen 8

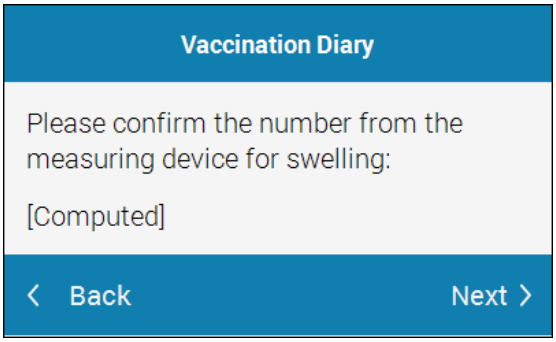
[Computed] will display the number selected on Screen 7.



Screen 9

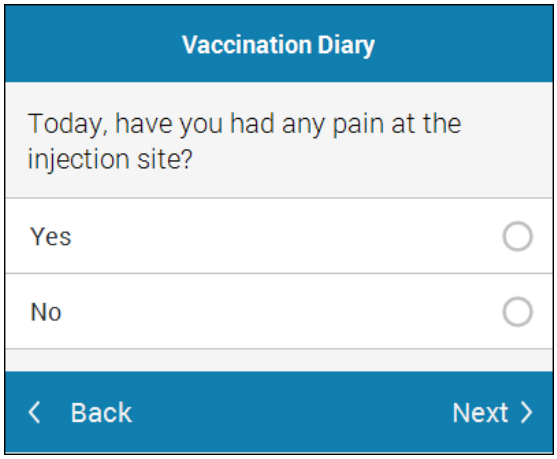


Screen 10

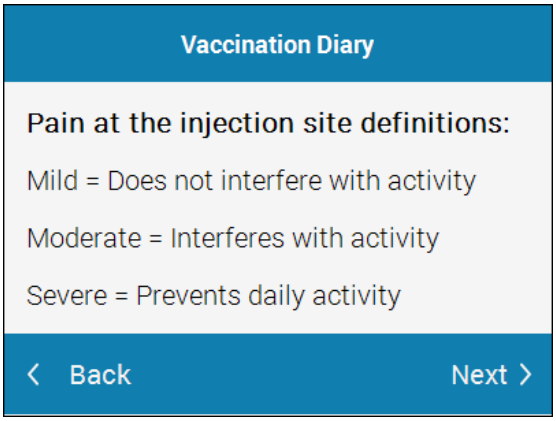


Screen 11

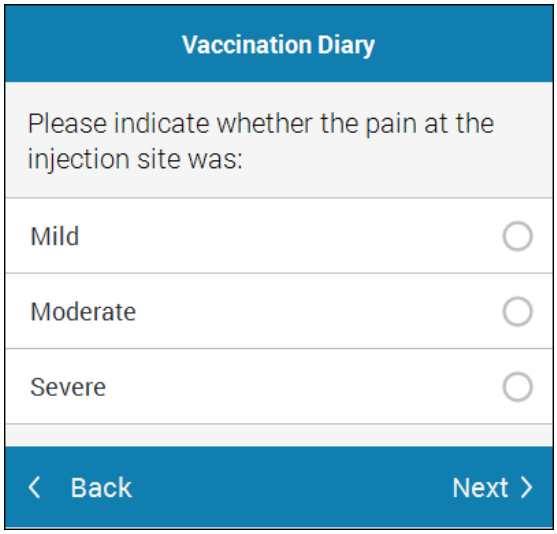
[Computed] will display the number selected on Screen 10.



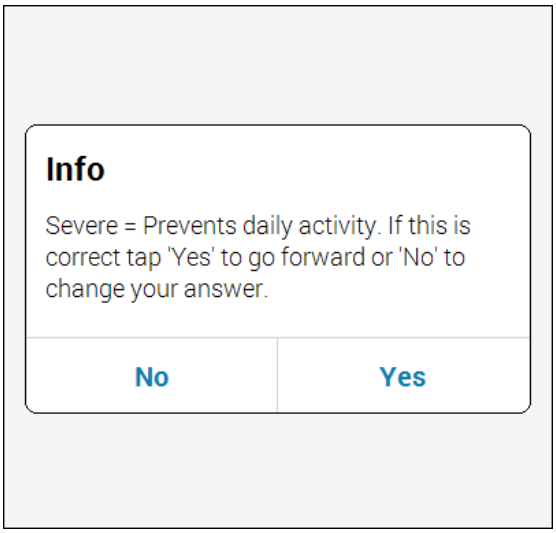
Screen 12



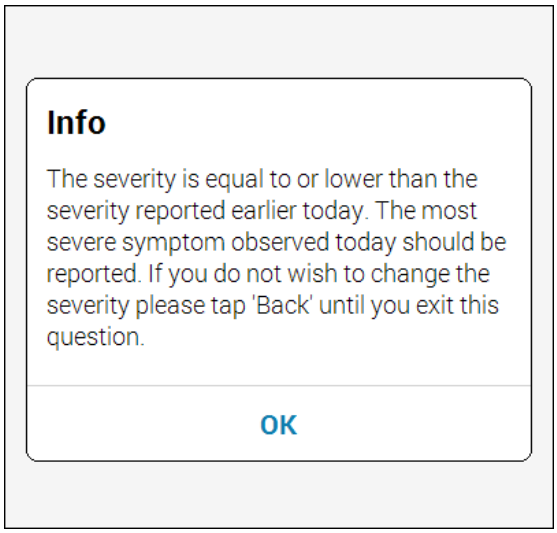
Screen 13



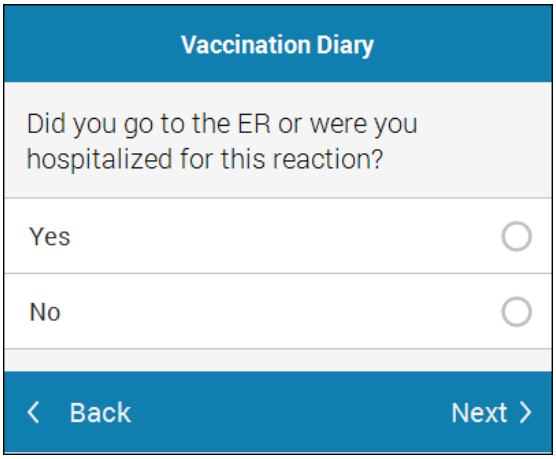
Screen 14



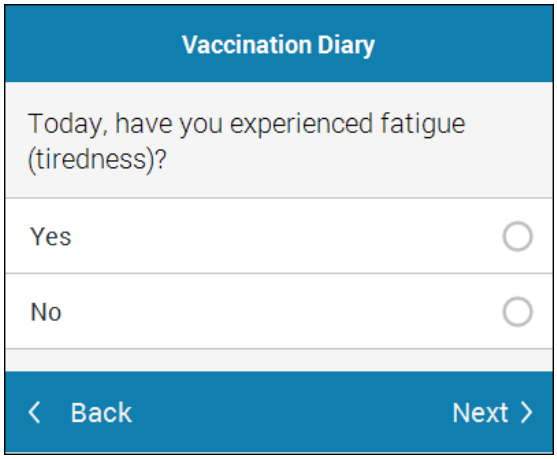
Message 2



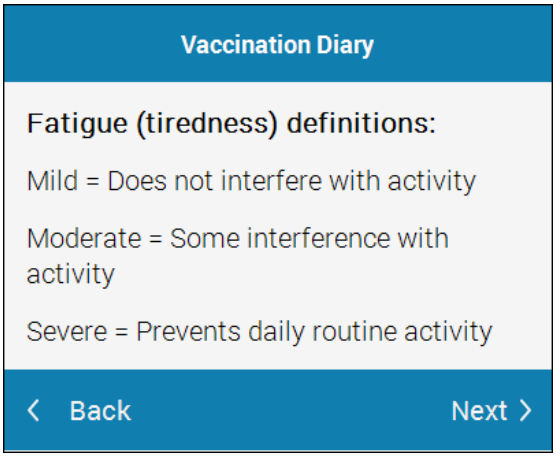
Message 4



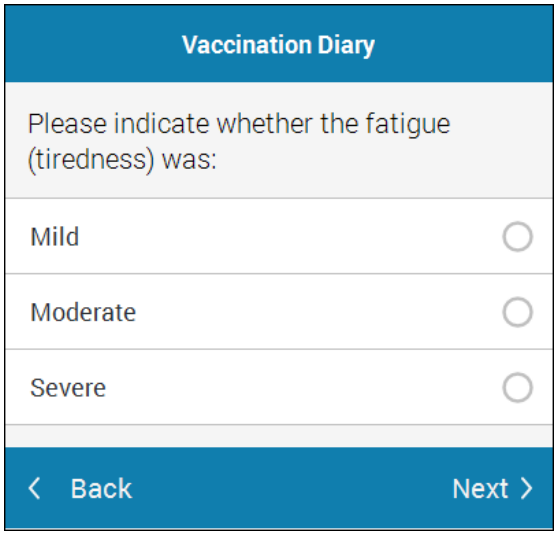
Screen 15



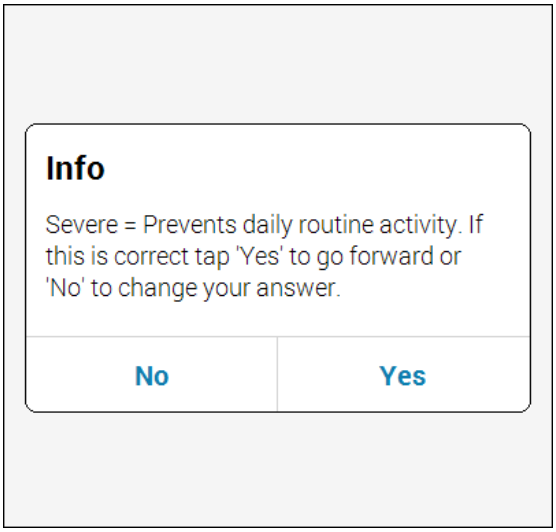
Screen 16



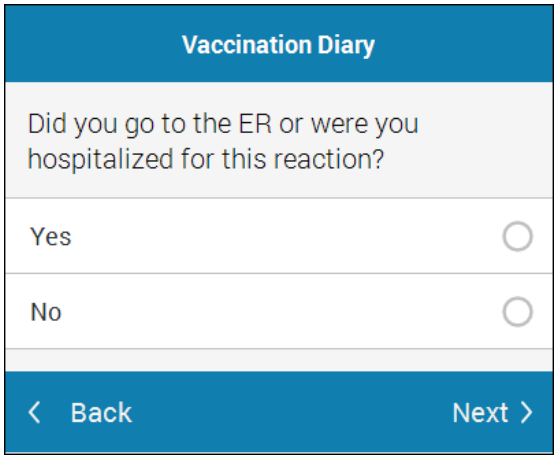
Screen 17



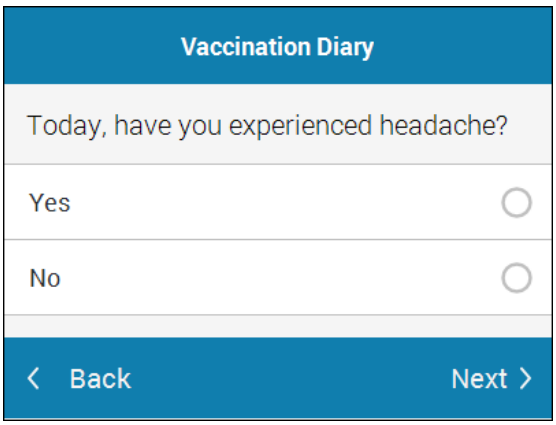
Screen 18



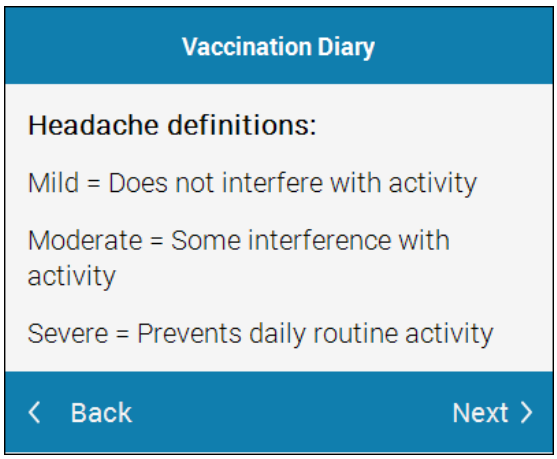
Message 2



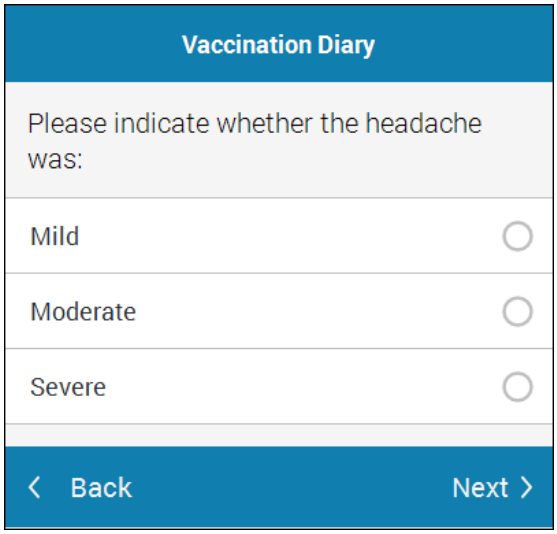
Screen 19



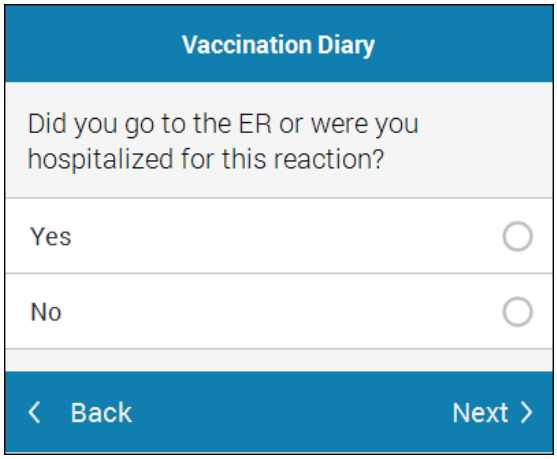
Screen 20



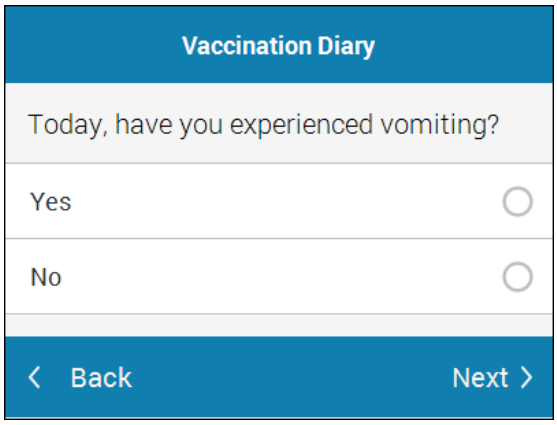
Screen 21



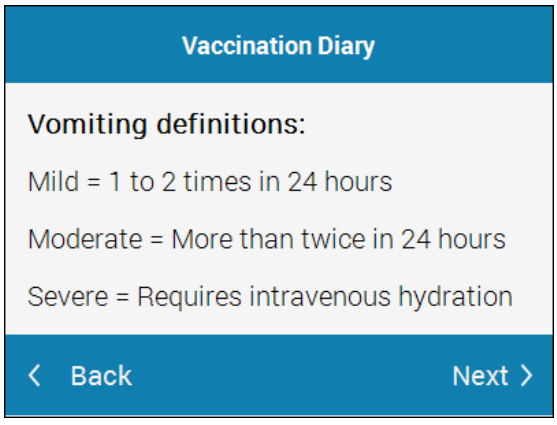
Screen 22



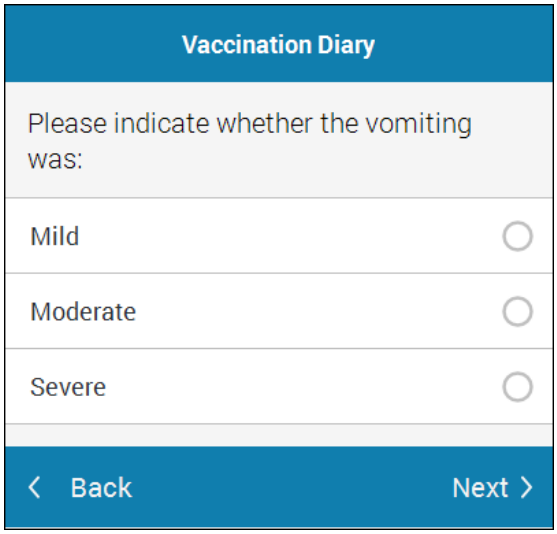
Screen 23



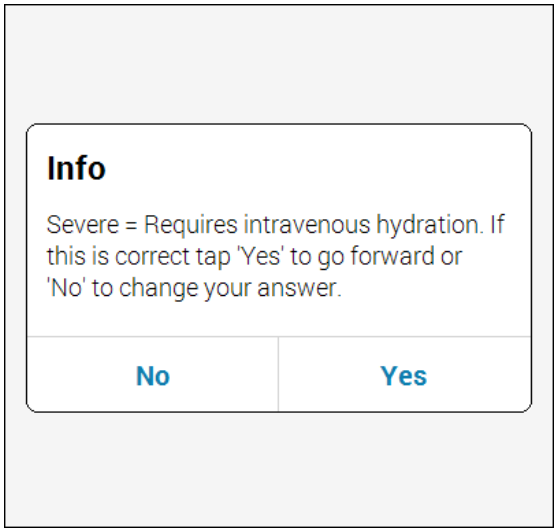
Screen 24



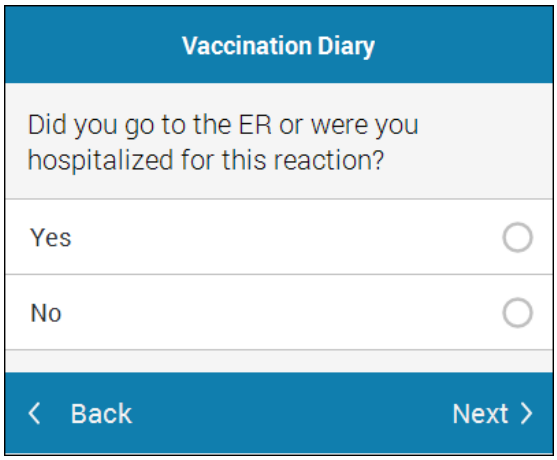
Screen 25



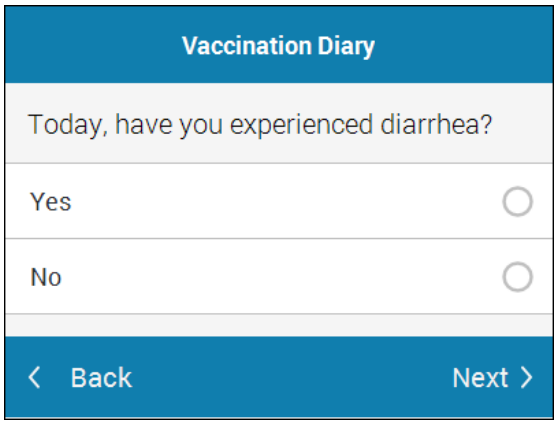
Screen 26



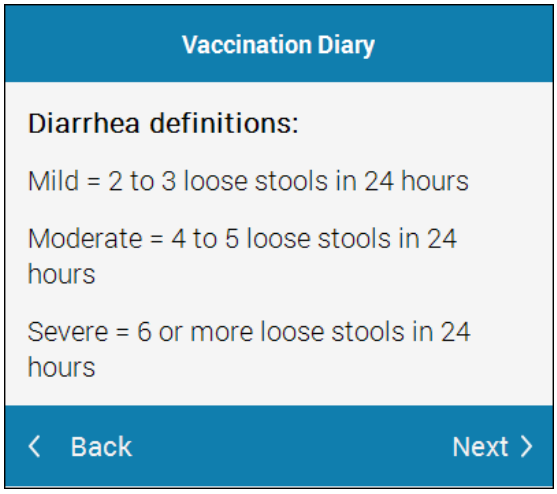
Message 2



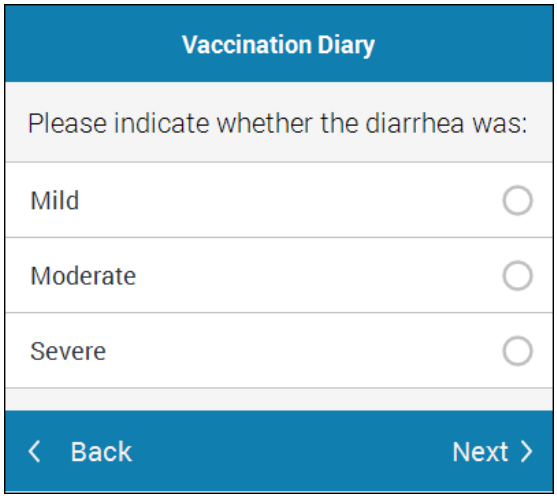
Screen 27



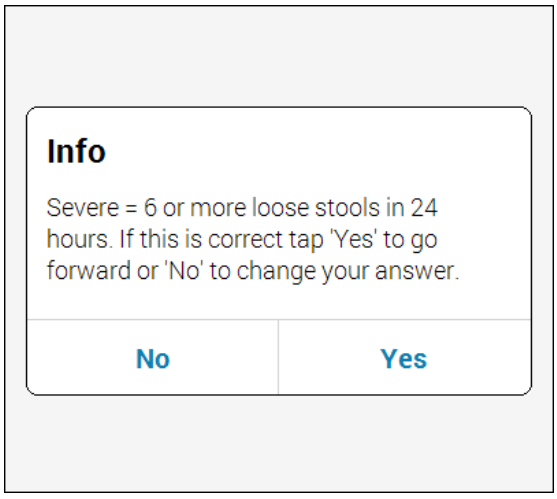
Screen 28



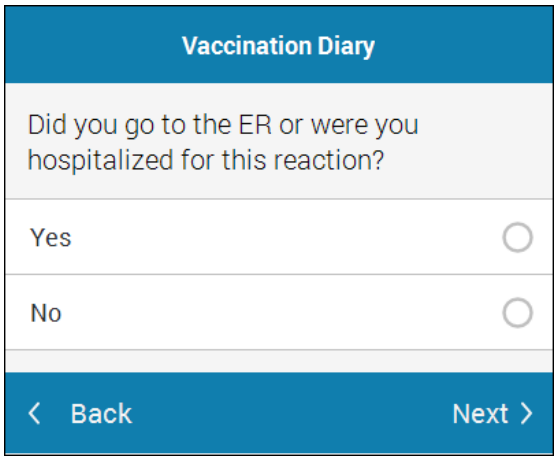
Screen 29



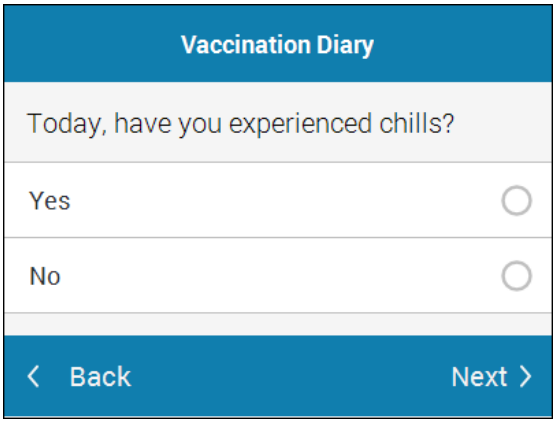
Screen 30



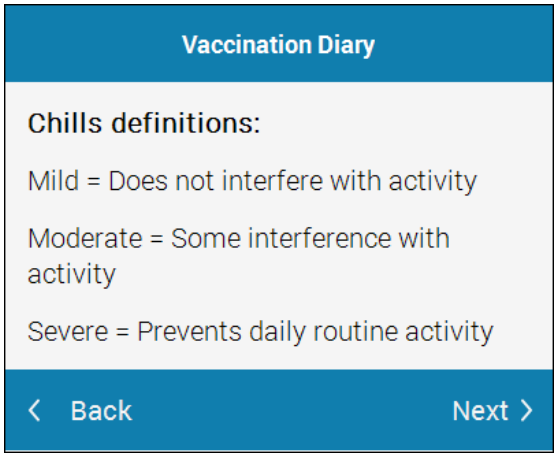
Message 2



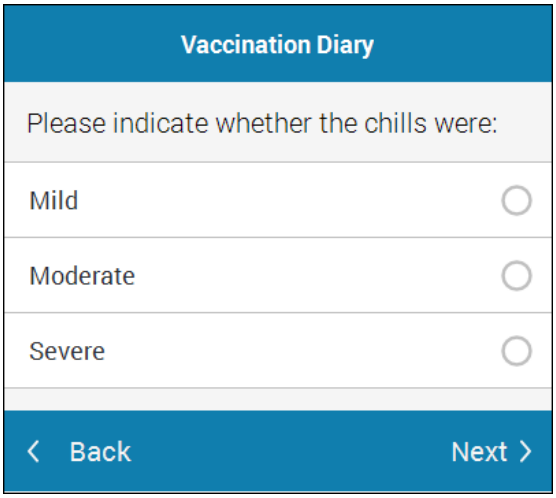
Screen 31



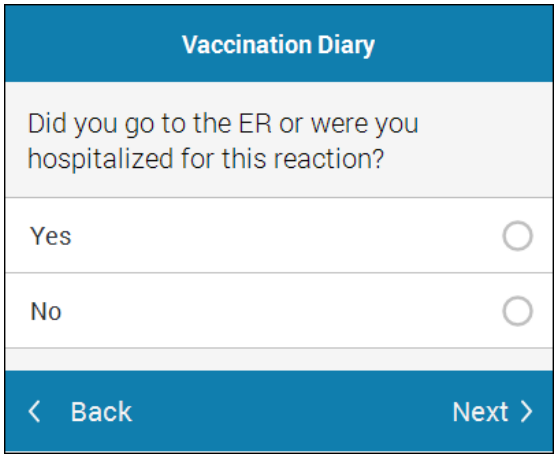
Screen 32



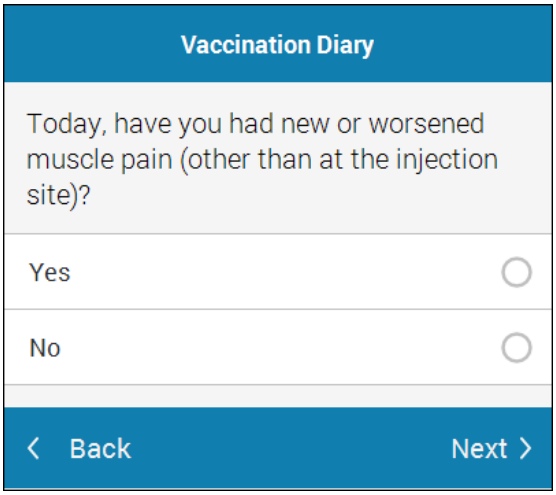
Screen 33



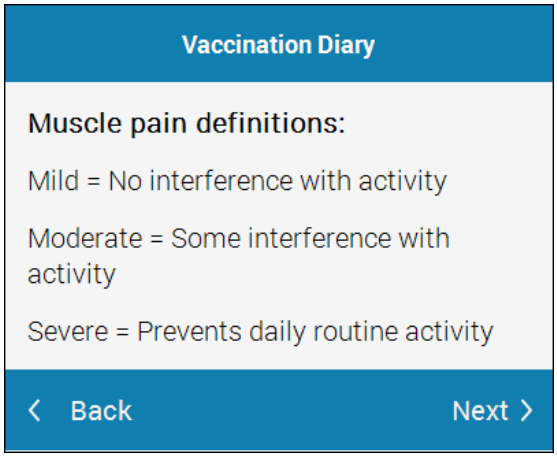
Screen 34



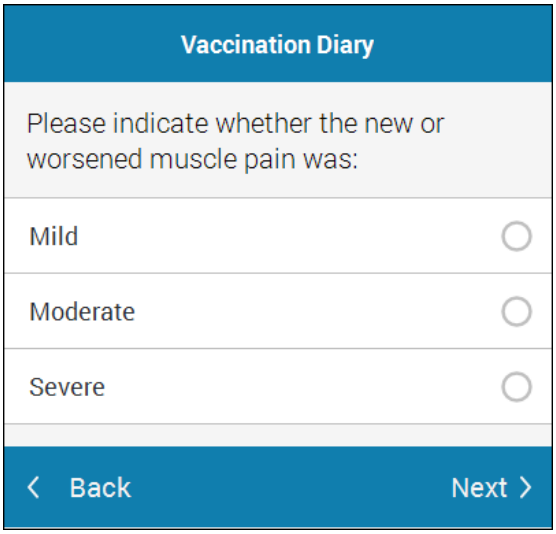
Screen 35



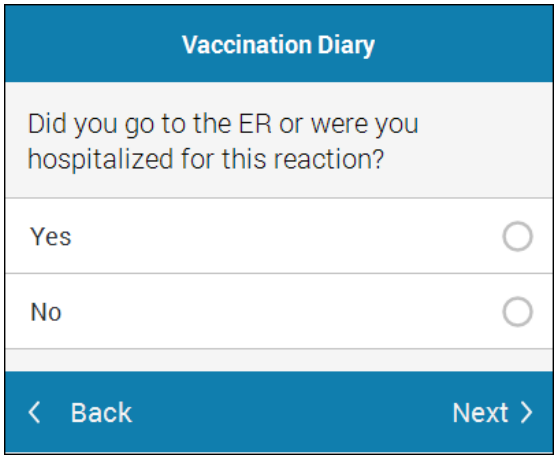
Screen 36



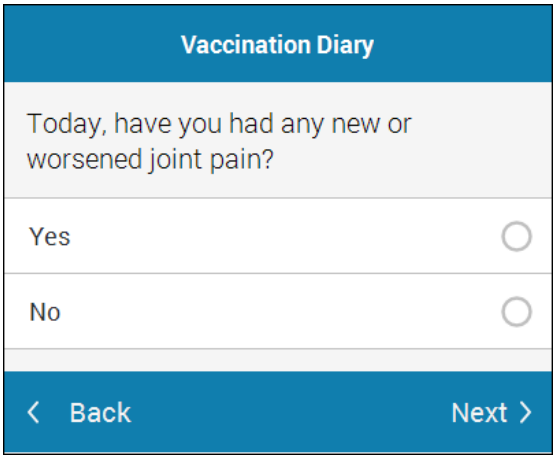
Screen 37



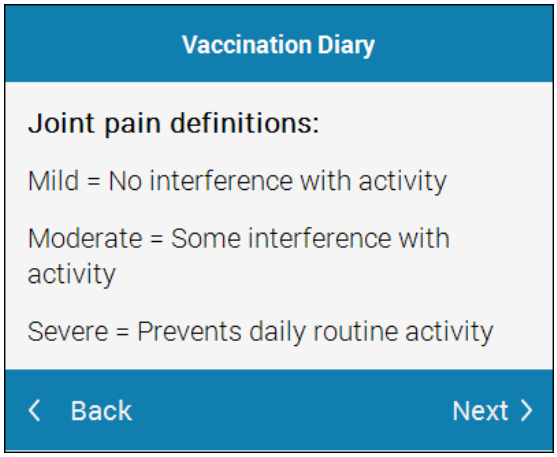
Screen 38



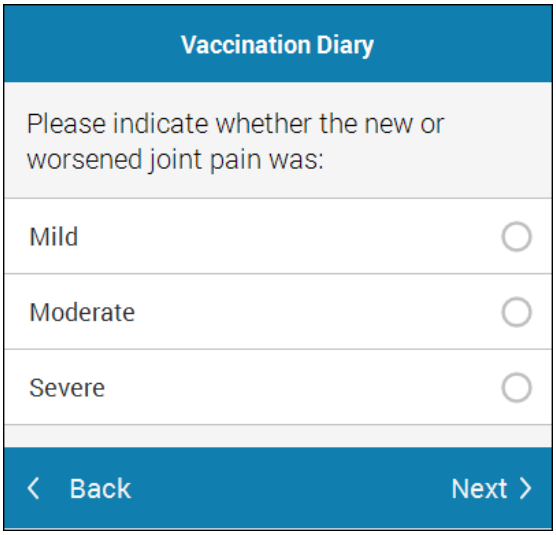
Screen 39



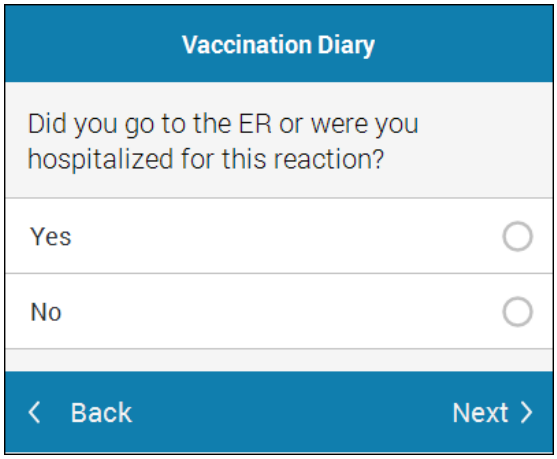
Screen 40



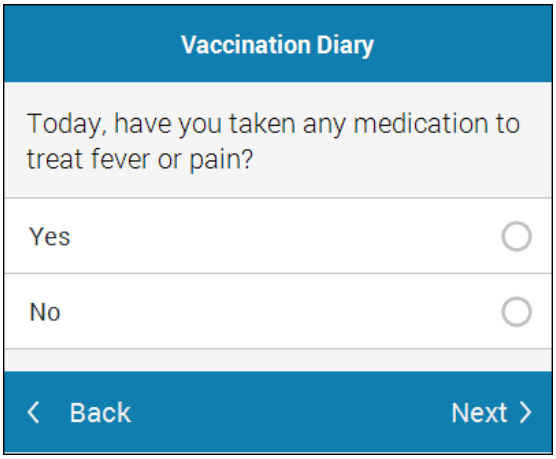
Screen 41



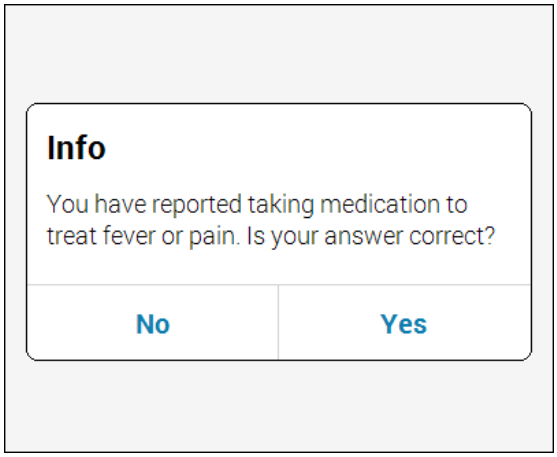
Screen 42



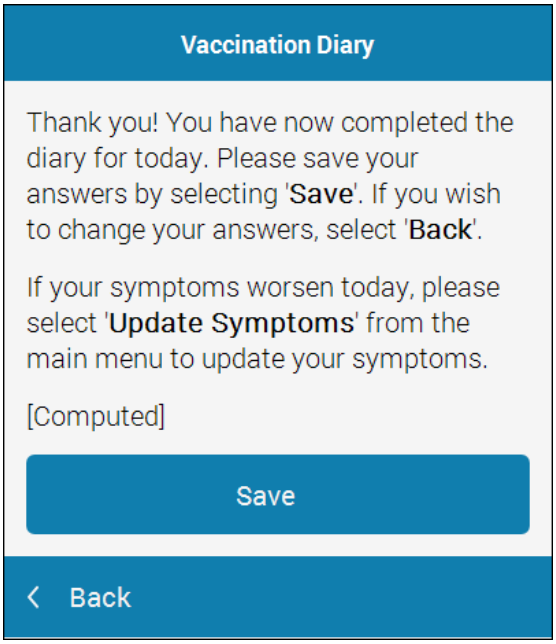
Screen 43



Screen 44



Message 2

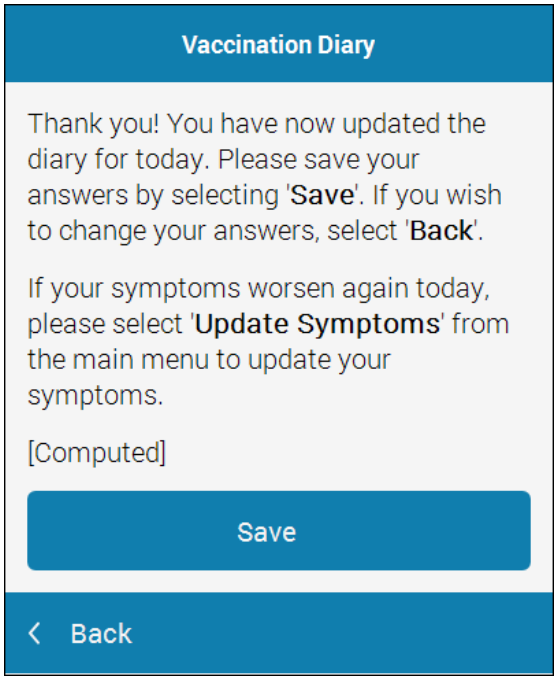


Screen 45

[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).



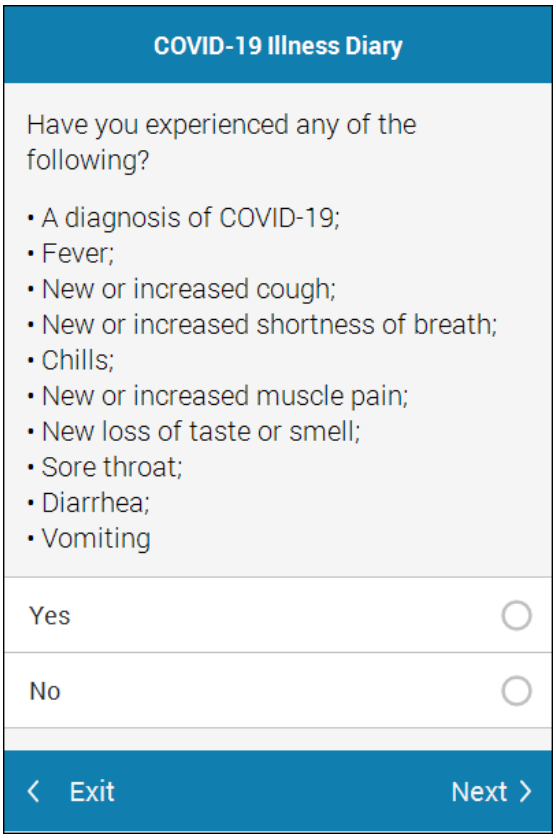
Screen 46

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

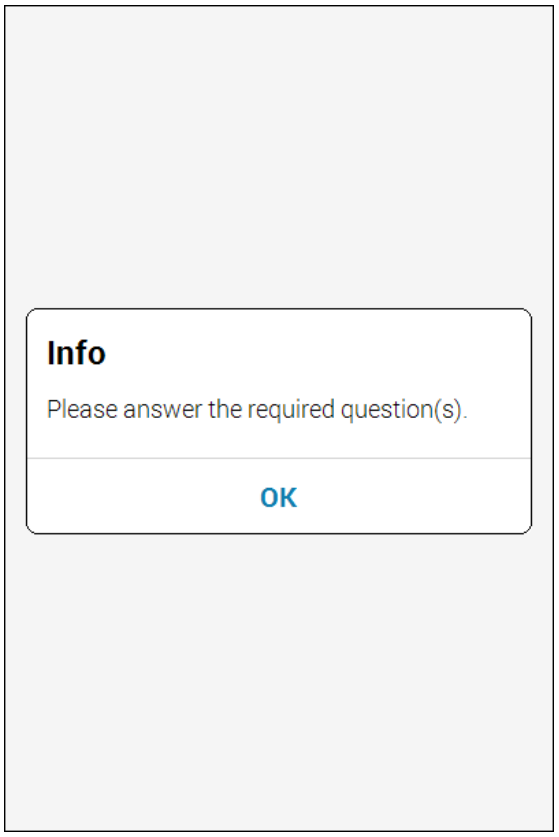
Where {1} = a number of days

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

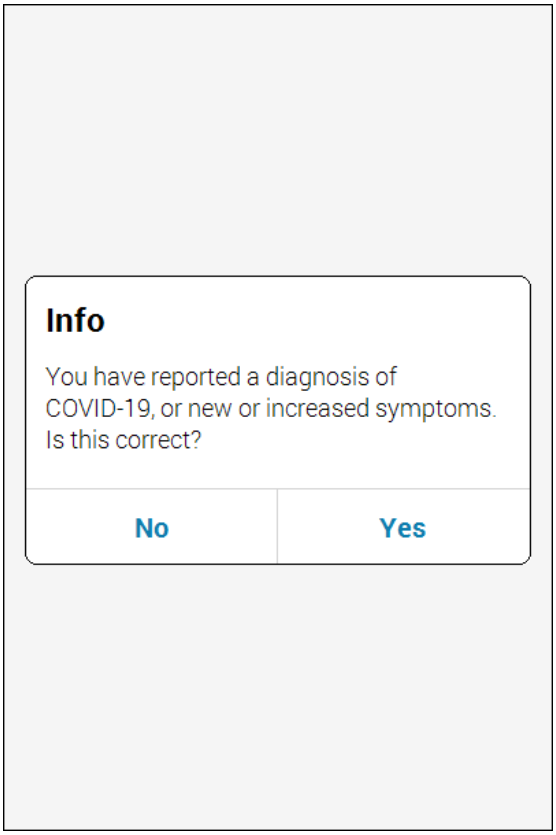
4 Form: COVID-19 Illness Diary



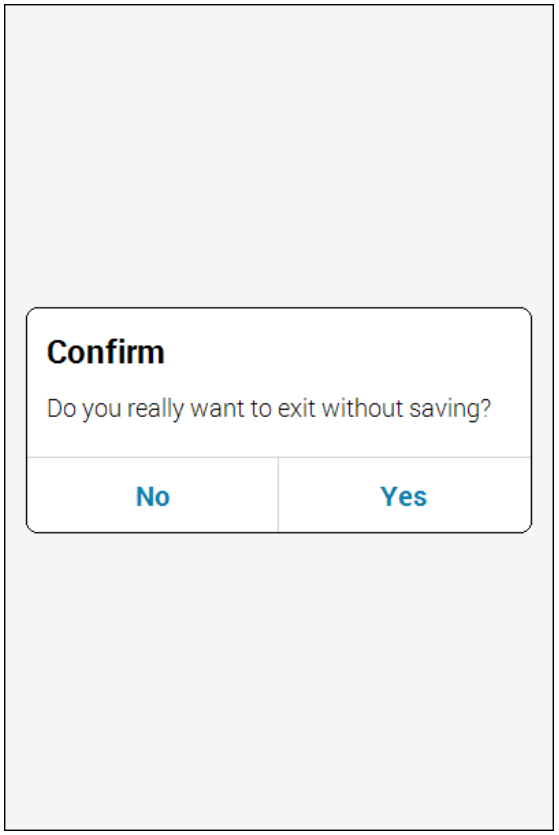
Screen 1



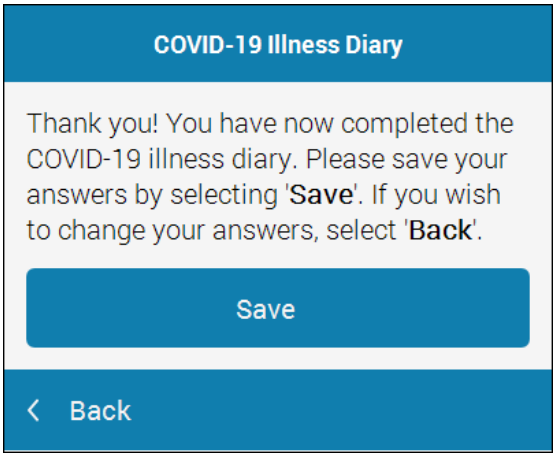
Message 1



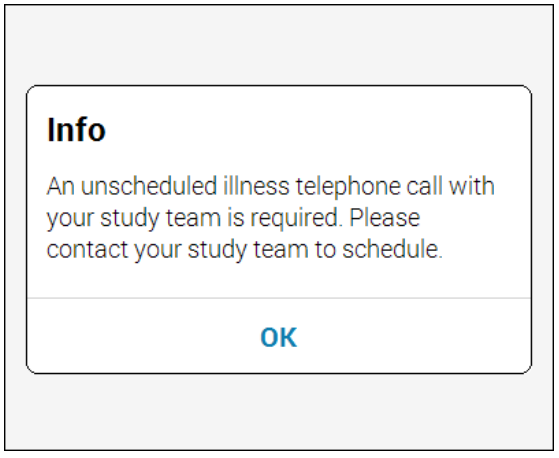
Message 2



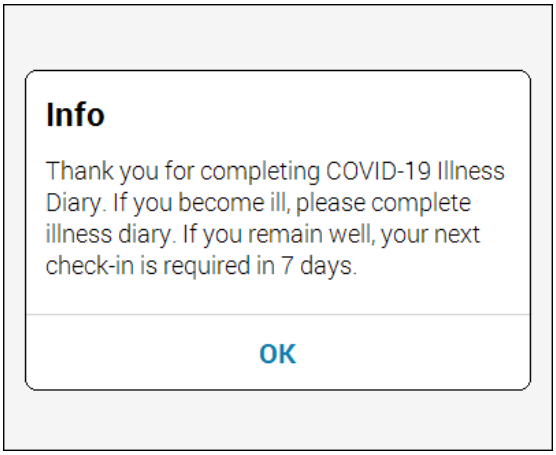
Message 3



Screen 2

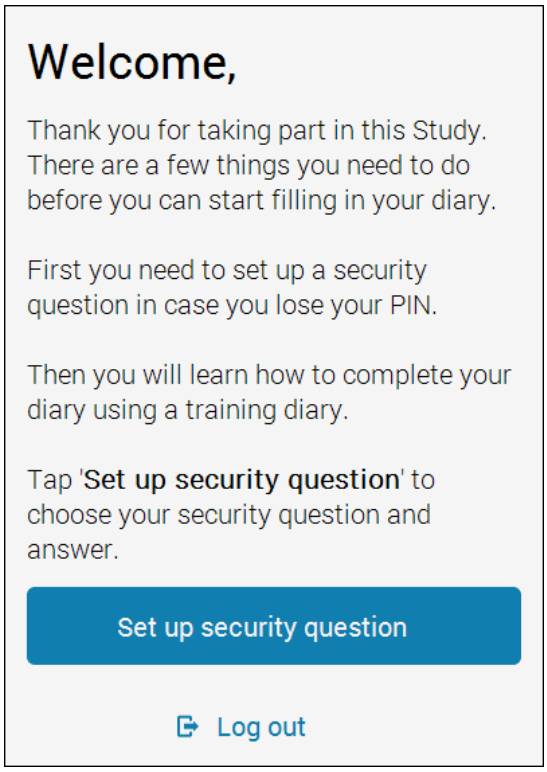


Message 1

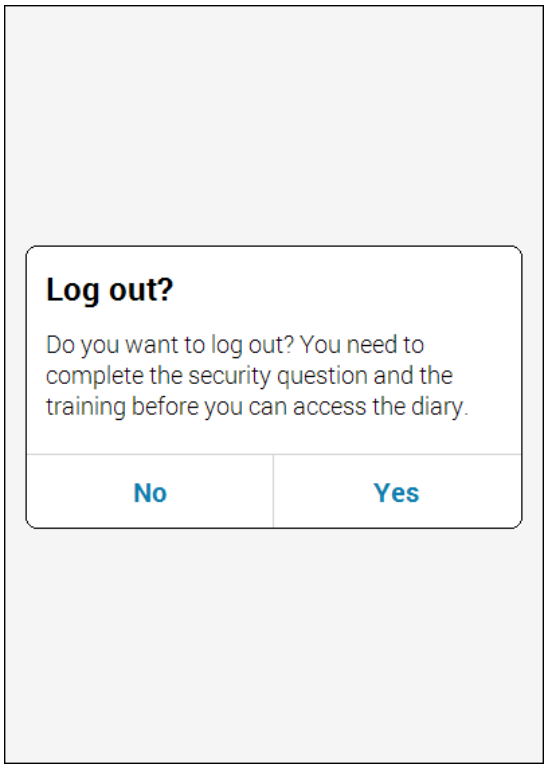


Message 2

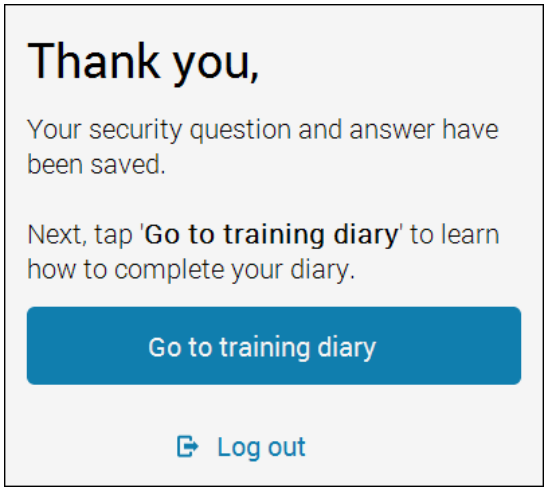
5 Form: Patient main menu



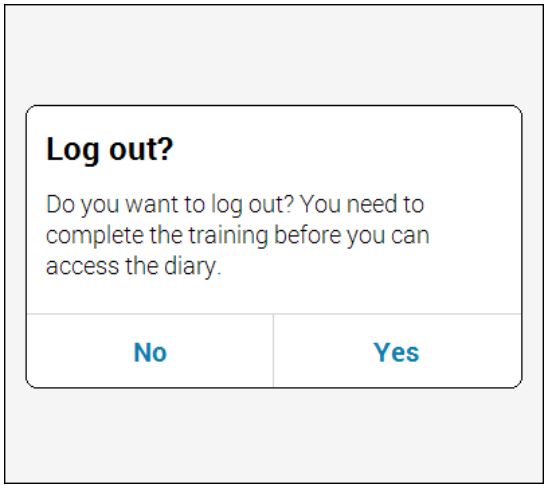
Screen 1



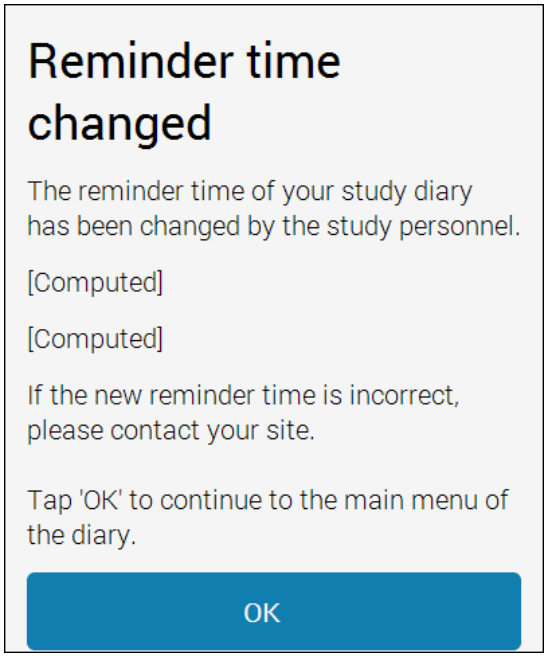
Message 1



Screen 2



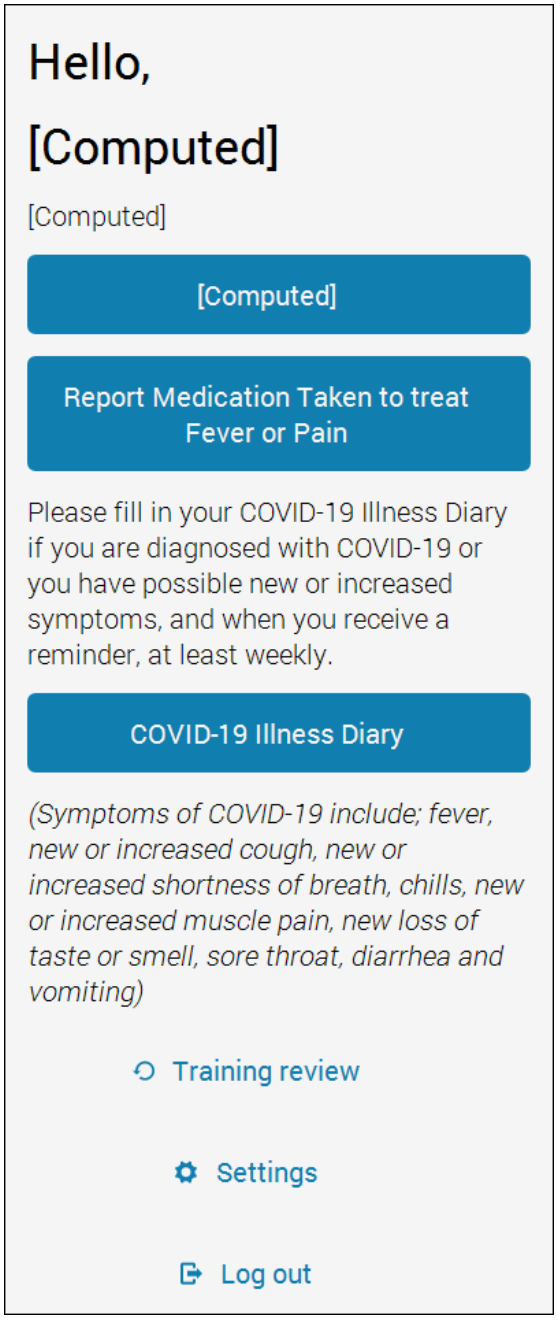
Message 1



Screen 3

First [Computed] will show 'Old reminder time: {1}' where {1} will be the old reminder time

Second [Computed] will show 'New reminder time: {1}' where {1} will be the new reminder time

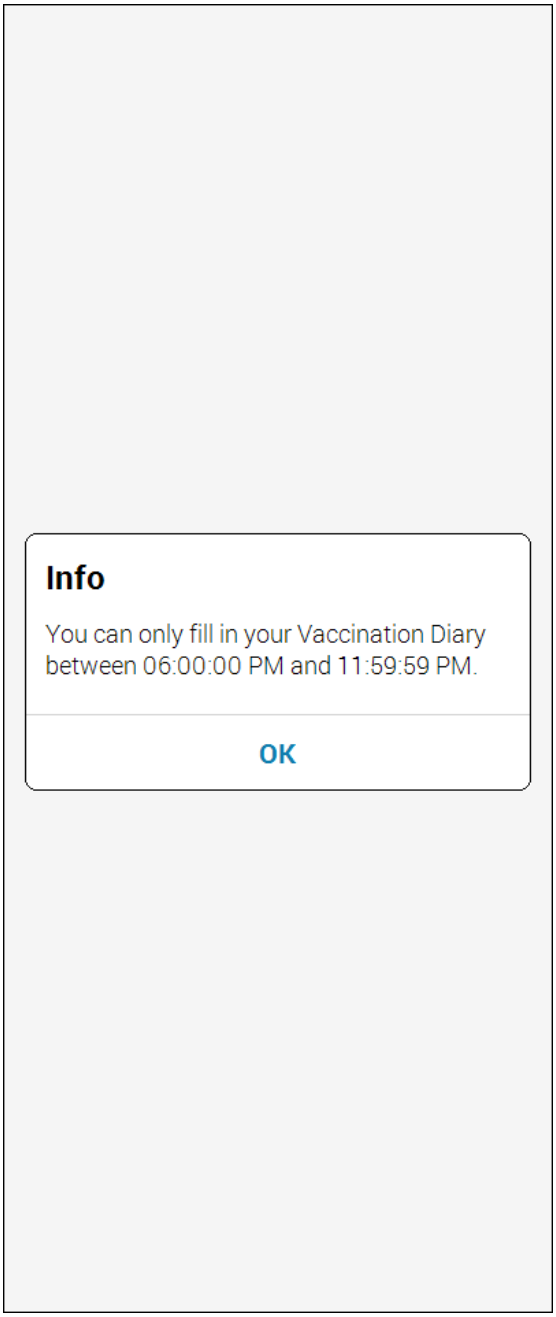


Screen 4

First [Computed] text below Hello, will either display: "You are being reminded to complete your weekly COVID-19 Illness Diary." or "You are being reminded to complete your daily <u>Vaccination Diary</u>."

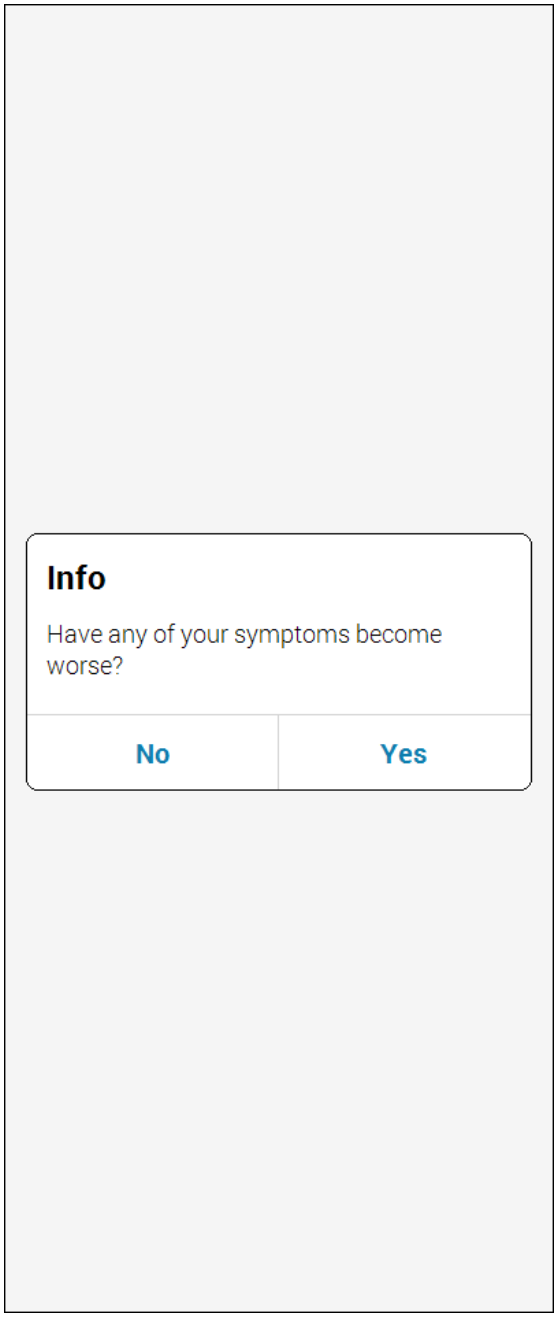
Second [Computed] text below Hello, will either display: “You have completed today's Vaccination Diary.”, “You have completed today's Vaccination Diary. Please remember to log in again tomorrow." or “Please fill in your daily Vaccination Diary before midnight.”

[Computed] text within the button will read: “Update Symptoms” or “Vaccination Diary”

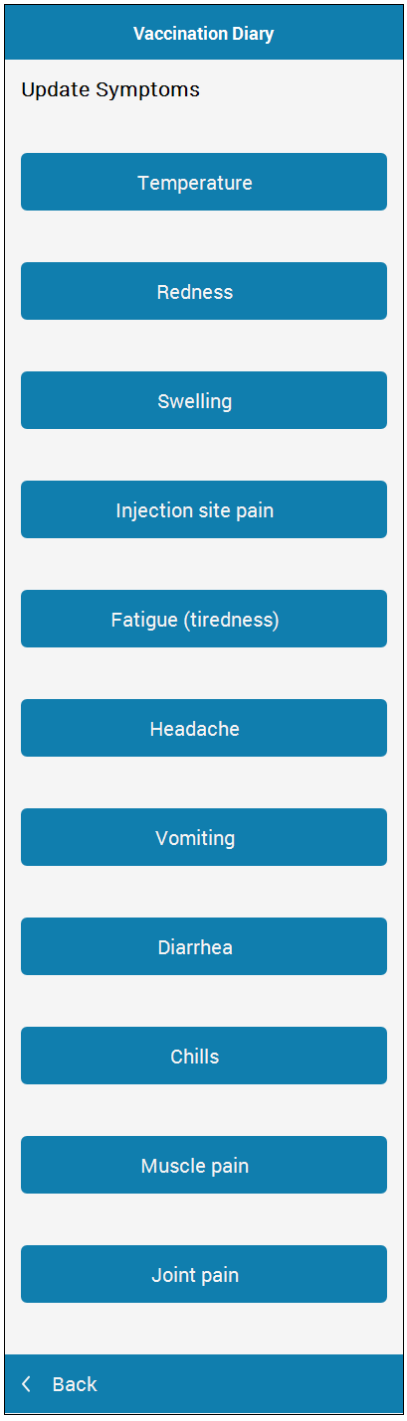


Message 1

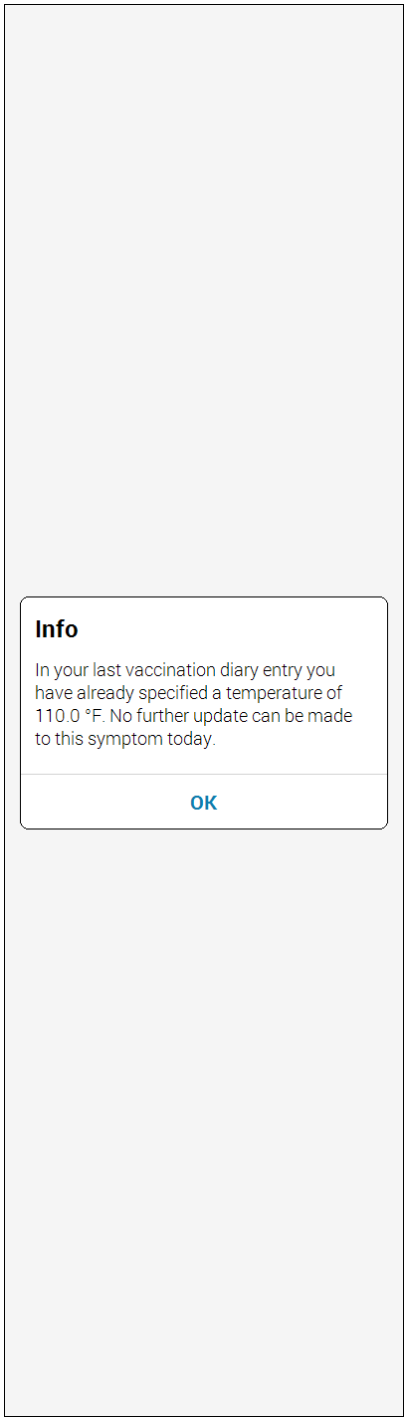
Device text will format out the leading 0's and seconds. Actual popup will read "6:00 PM and 11:59 PM"



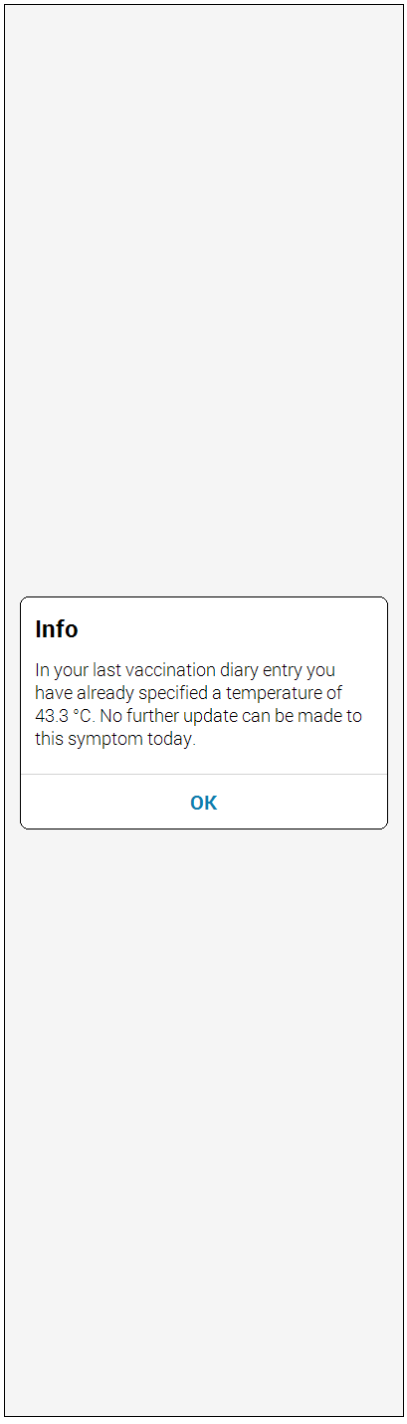
Message 2



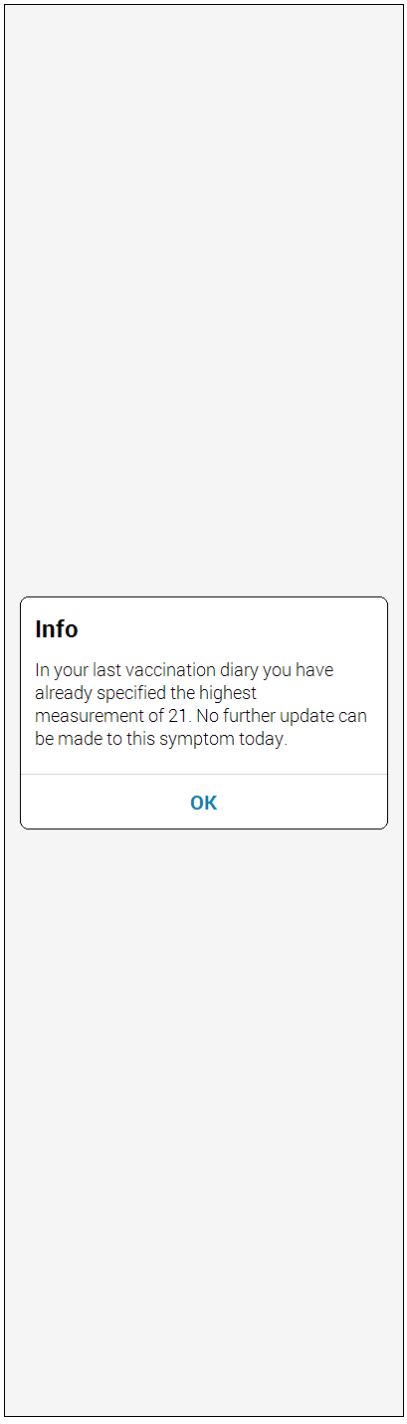
Screen 5



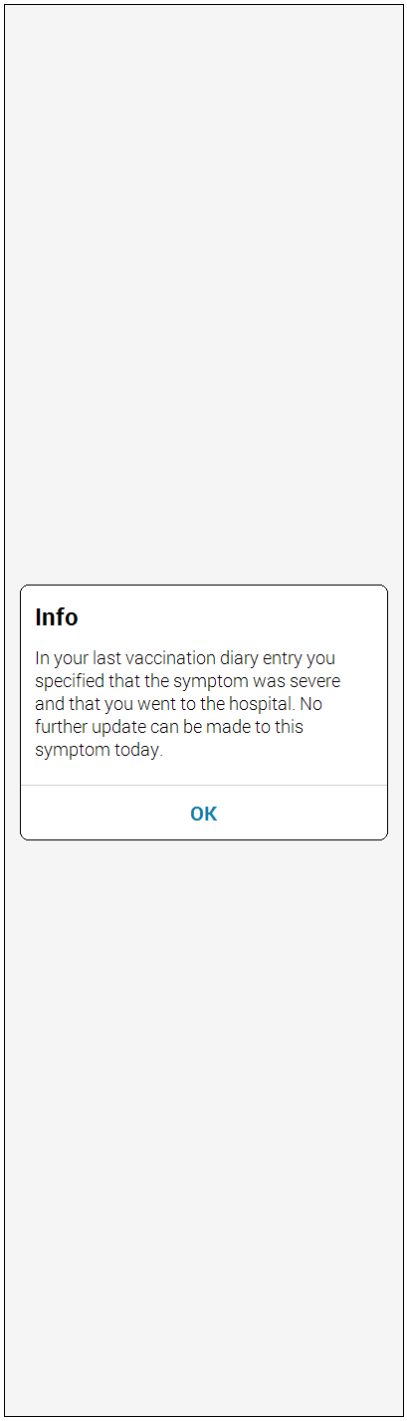
Message 2



Message 3

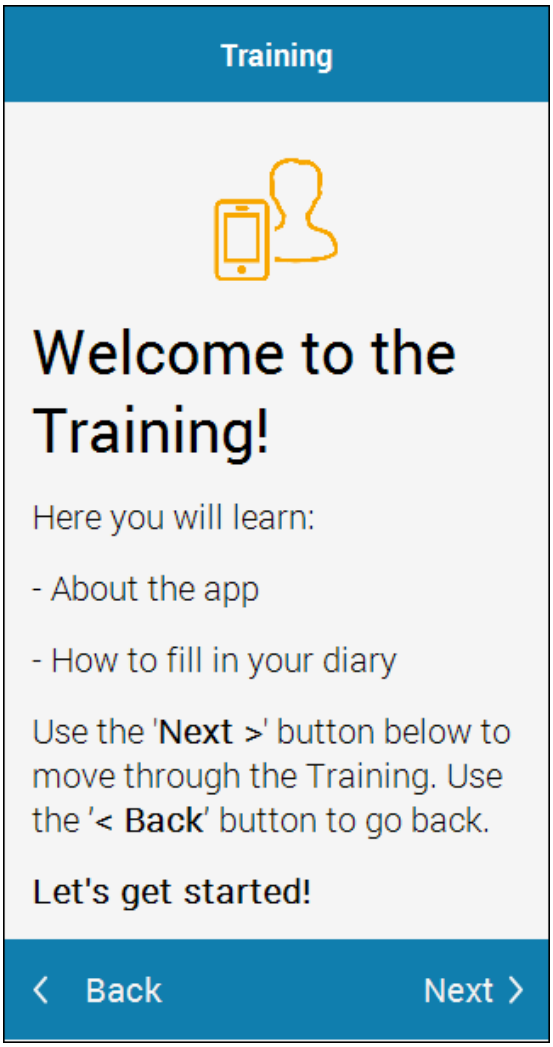


Message 5

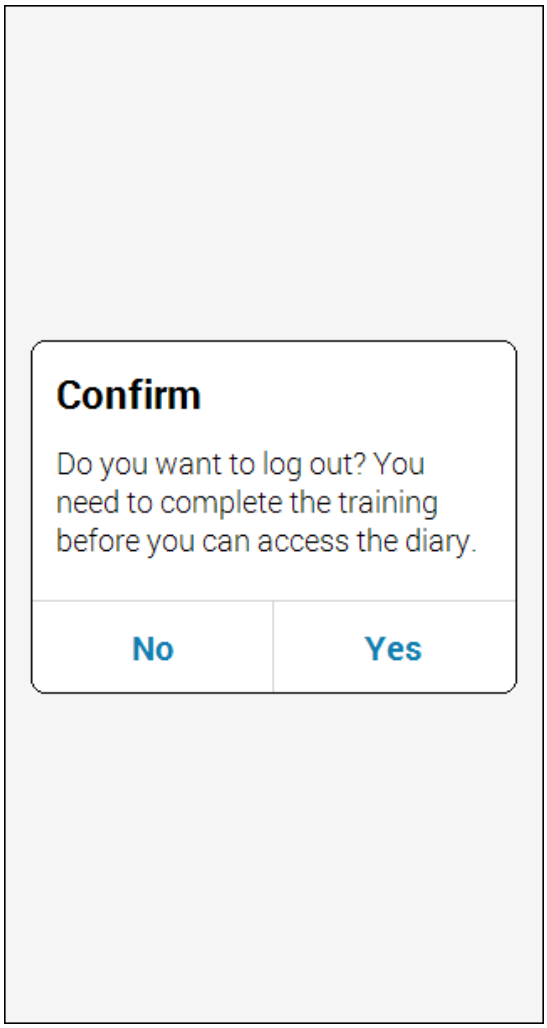


Message 9

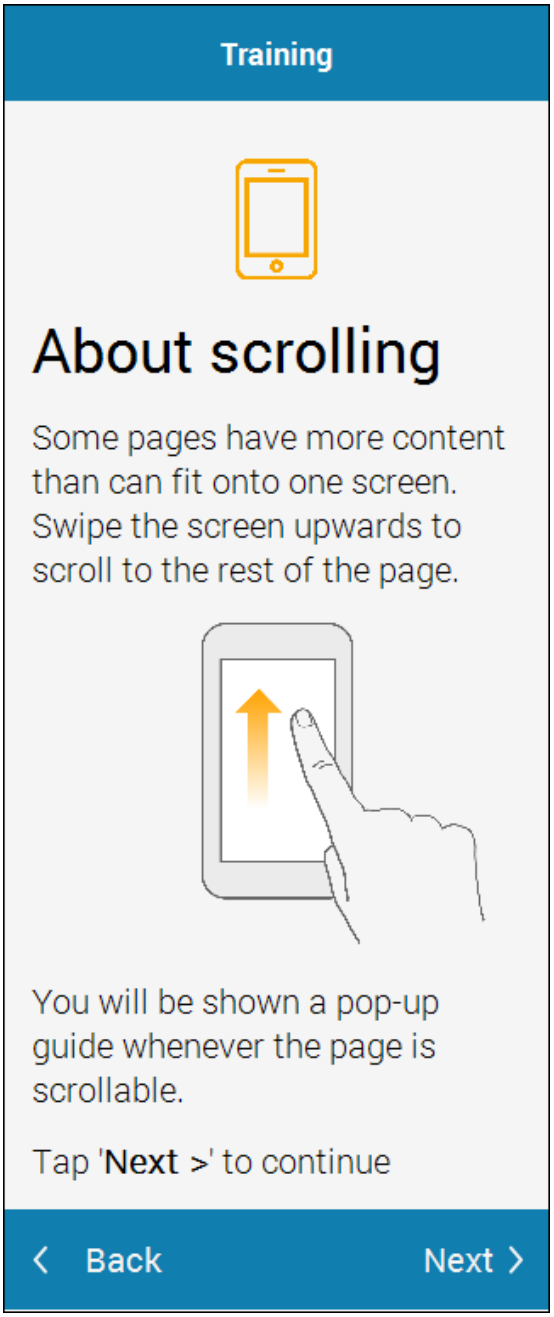
6 Form: Subject training diary



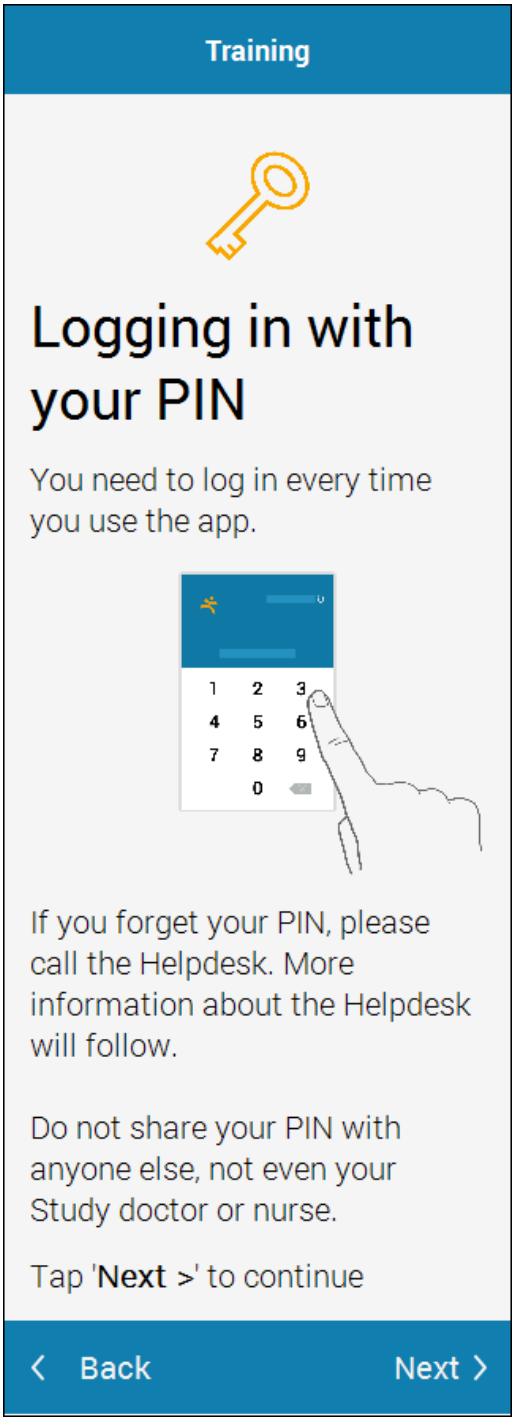
Screen 1



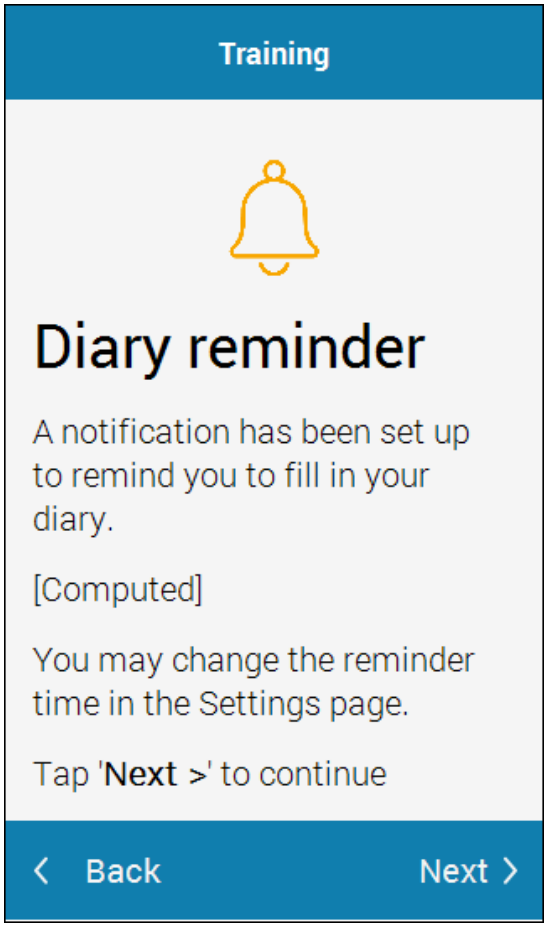
Message 1



Screen 2

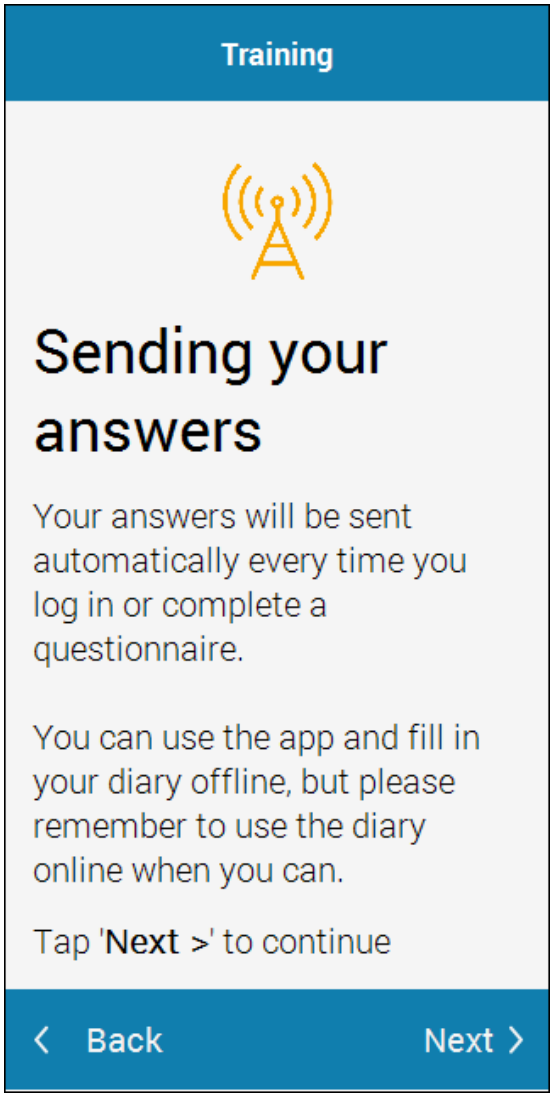


Screen 3

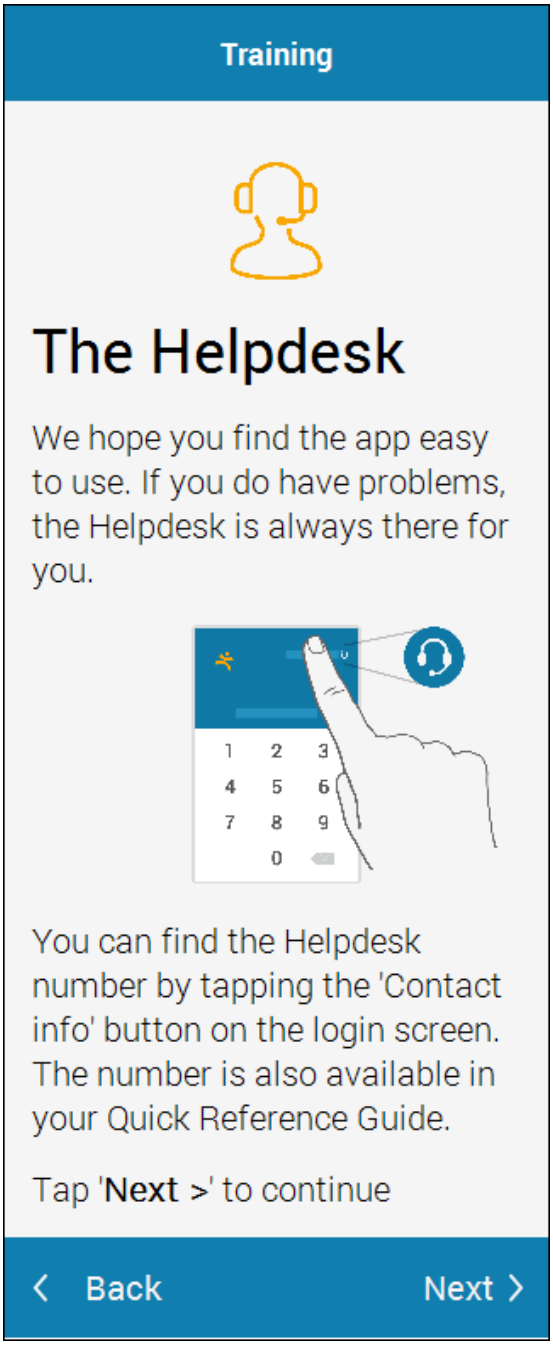


Screen 4

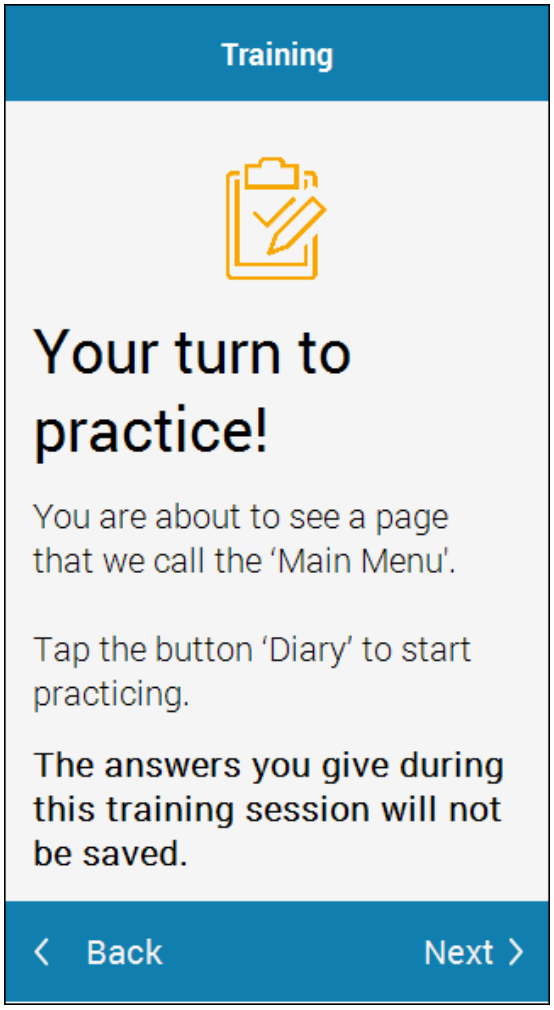
[Computed] will display 'Your reminder time is {1}.', where {1} will be the selected diary reminder time.



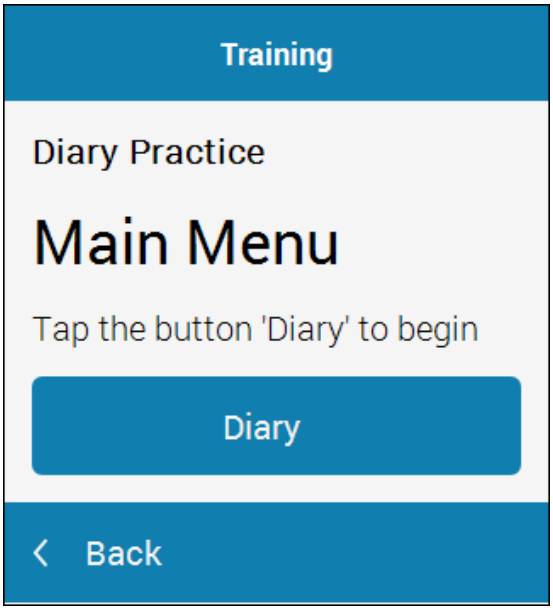
Screen 5



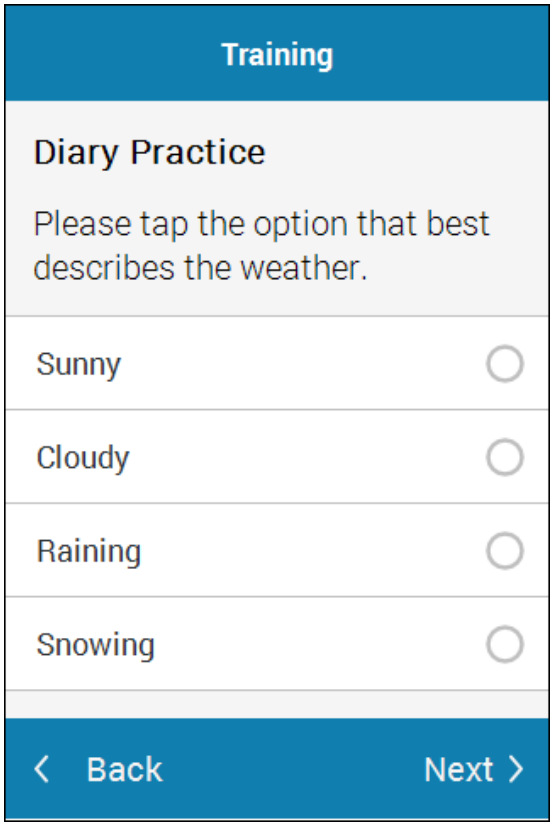
Screen 6



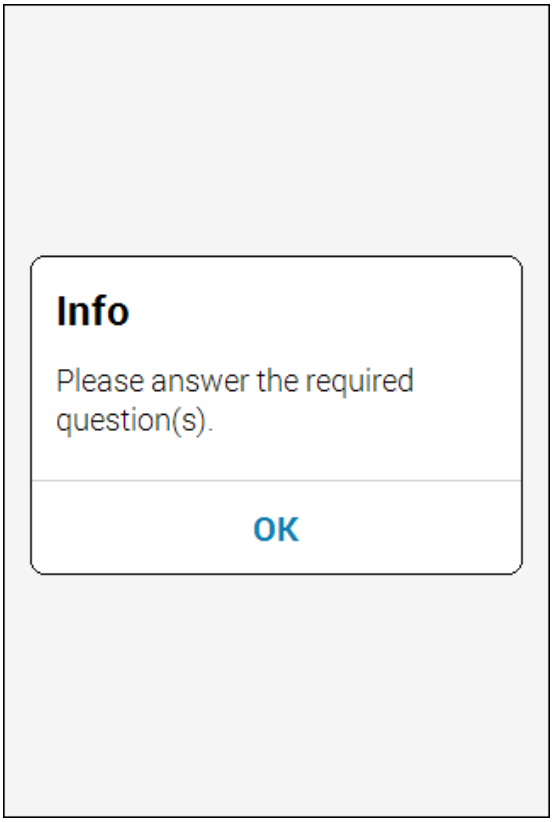
Screen 7



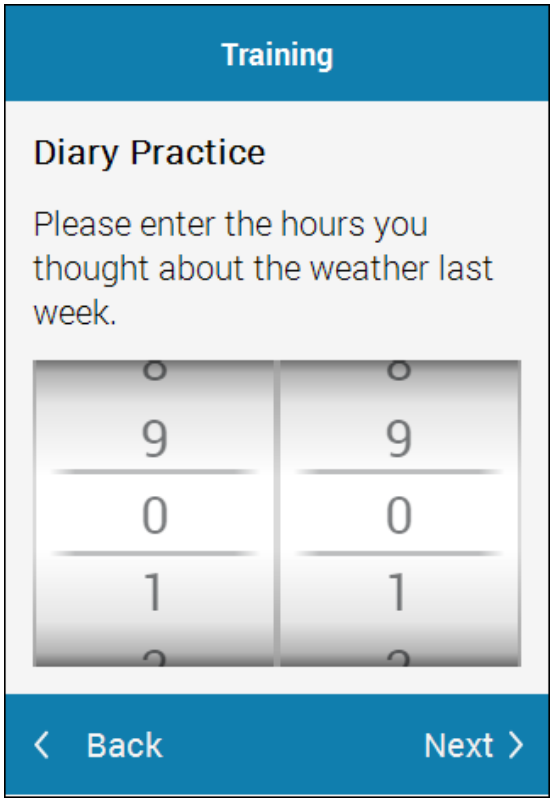
Screen 8



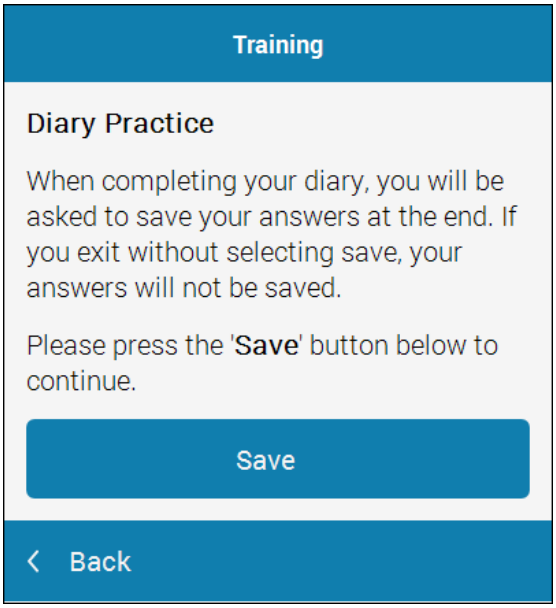
Screen 9



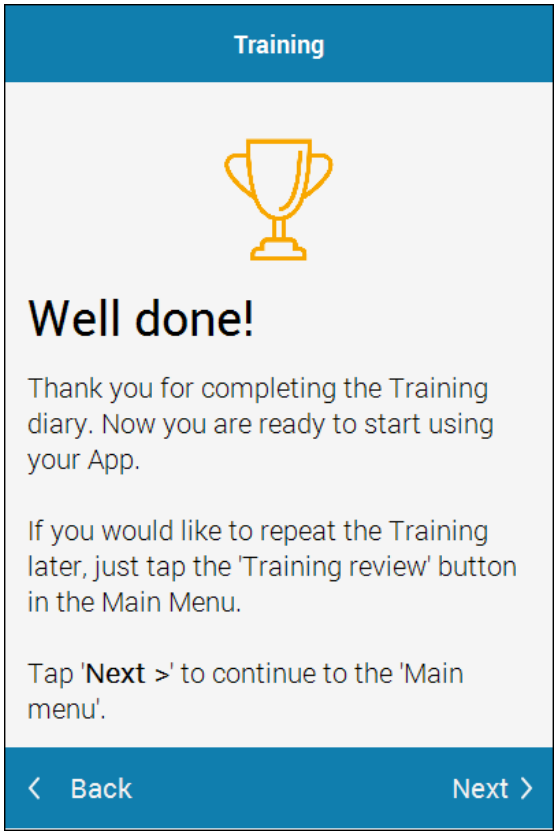
Message 1



Screen 10

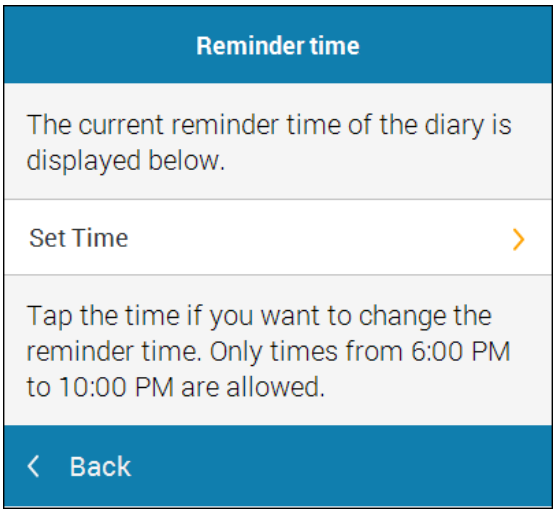


Screen 11

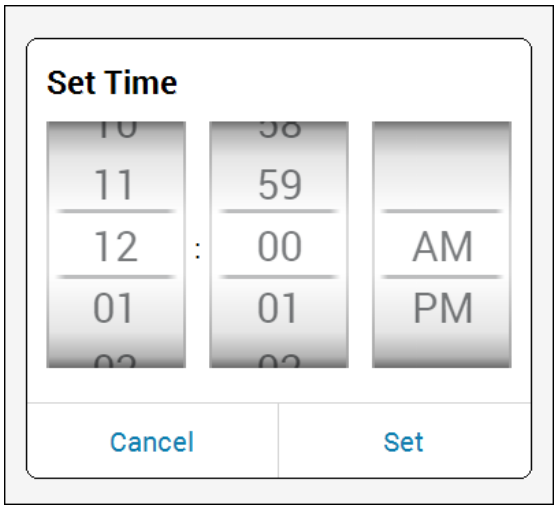


Screen 12

7 Form: Settings

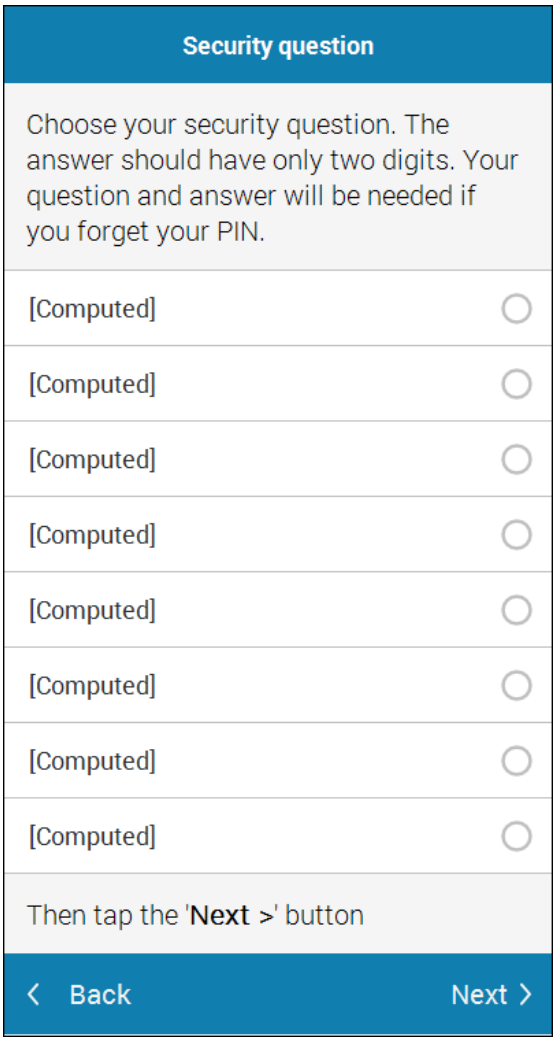


Screen 1

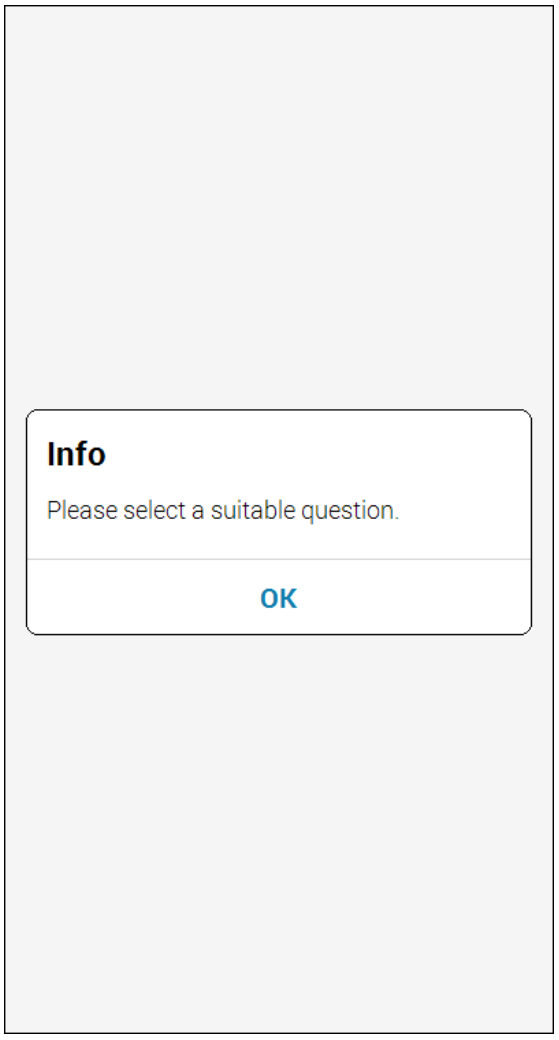


Popup input 1

8 Form: Security question



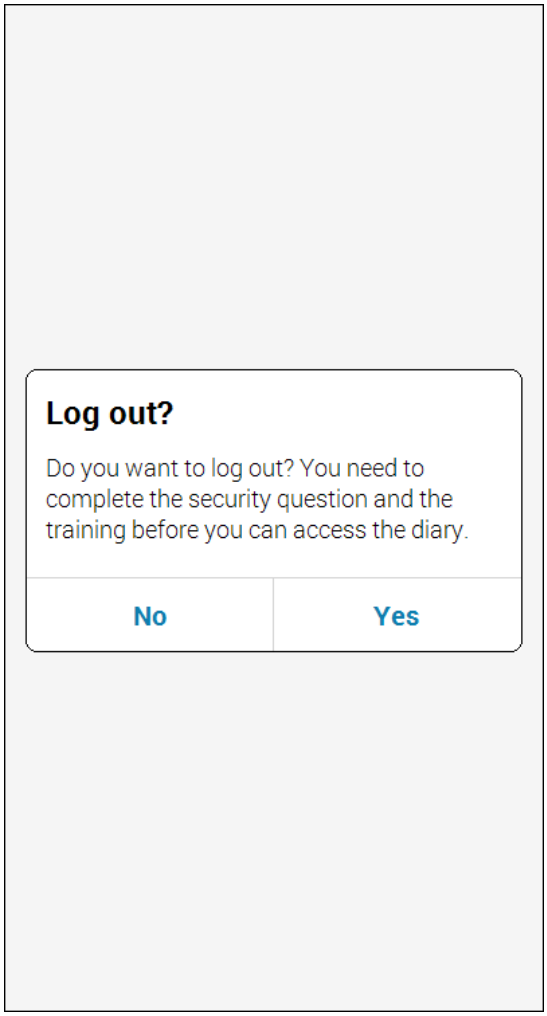
Screen 1



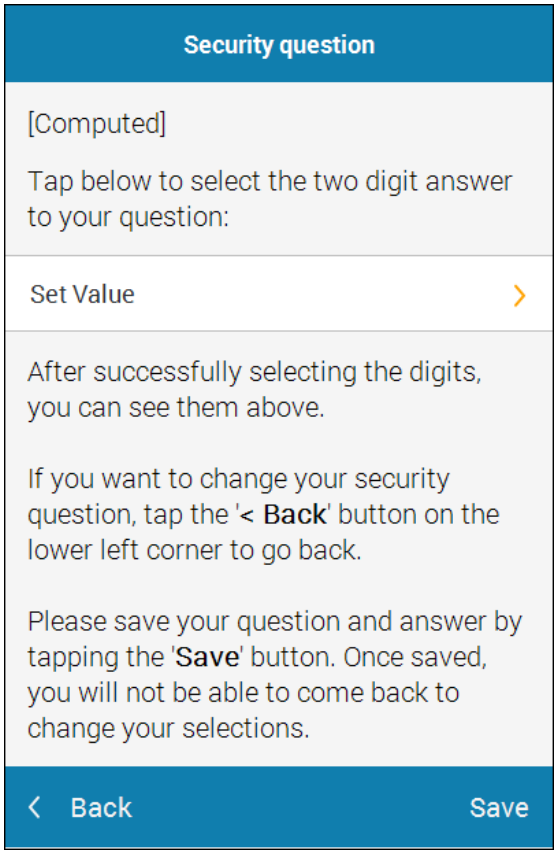
Message 1

[Computed] will show one of the following:

'Your oldest sibling's birth year (YY)'
'Your mother's birth year (YY)'
'Last two digits of your childhood phone number'
'Day of the month of your father's birthday'
'Day of the month of your mother's birthday'
'Childhood home door number (2 digits only)'
'How old were you when you passed your driving test?'
'The year you got married (YY)'



Message 2



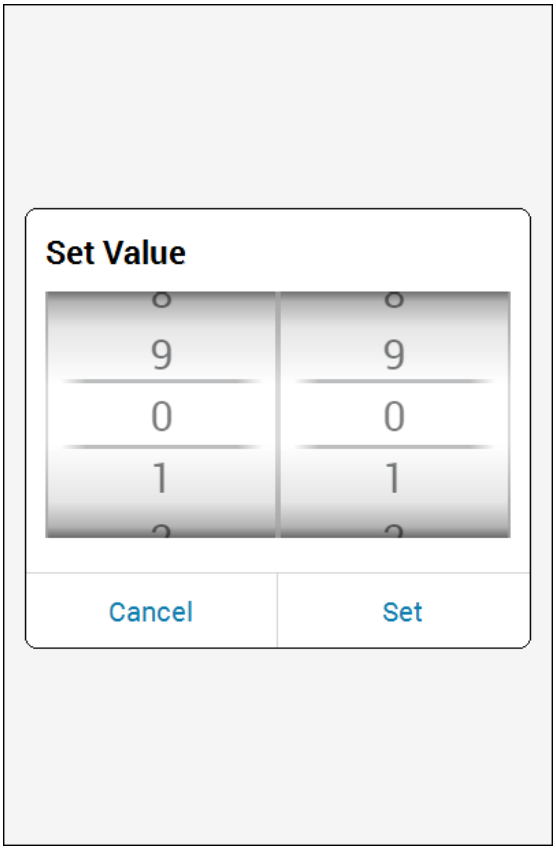
Screen 2

[Computed] will display

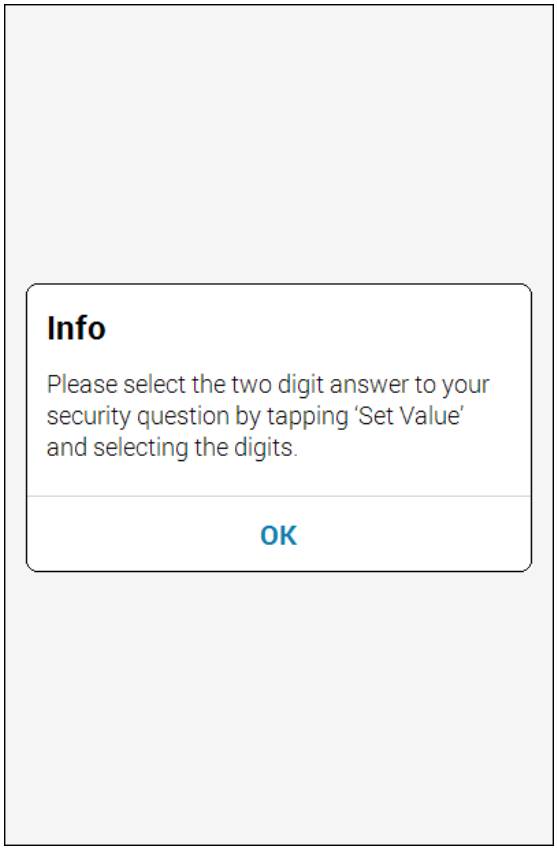
'Your question:

{1}'

{1} will show the question selected on Screen 1



Popup input 1



Message 1