Annotated Study Book for Study Design: C4591001

Study Design Version: 11.0

Sponsor: Pfizer

Protocol: C4591001

Sponsor Drug Name: BLINDED THERAPY

C4591001 - COVID19

Generated by Central Designer TM

October 12, 2020 8:47AM

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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: [Toxicity Grade]	○ 1 ○ 2 ○ 3 ○ 4
7.	Is the adverse event ser ous? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hosp talization or prolongat on of existing hosp talization; Persistent or signif cant disabil ty/incapac ty; Congenital anomaly/birth defect; Important med cal event (i.e. may jeopardize subject and may require med cal/surgical intervention to prevent above outcomes). [Serious]	○ YES Is this ser ous event associated with congenital anomaly or birth defect? ○ YES ○ NO Did this serious event result in death? ○ YES ○ NO Did this serious event require or prolong hospitalization? ○ YES ○ NO Did this serious event result in persistent or significant disabil ty/incapac ty? ○ YES ○ NO Is this ser ous event life threatening? ○ YES ○ NO Other med cally important ser ous event ○ YES ○ NO ○ NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log. [Is AE a Result of a Medication Error]	○ YES ○ NO
9.	Is this event related to study treatment: [Relat onship 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	Latest Action Taken with Study	○ DRUG WITHDRAWN NOT APPLICABLE

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	Treatment: [Act on Taken with Study Treatment]	○
11.	Was a Concomitant Medication given? [Concom tant Med cat 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.	D d the adverse event cause the subject to be discontinued from the study? [Caused Study Discontinuat on]	○ YES ○ NO
15.	Ser ous 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.	D ctionary-Derived Term *[hidden]* [D ctionary-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]	

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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.	Collection Date: [Collect on 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 Un t ○ 10^3/mm3

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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

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

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

Concomitant Medications

1.	What is the medication dentifier? [Sponsor-Defined Identifier]	
2.	Category: [Category for Medication]	◯ GENERAL CONCOMITANT MEDICATIONS
3.	Concomitant Medications Pre-specified: [Concom tant Medications Pre-specified]	◯ NO
4.	Med cation: Prov de the complete gener c drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Med cat on text (e.g., Ingredient(s), route, use, formulation). [Name of Medication]	
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 Med cat on Name - Dict onary derived. *[hidden]* [Standardized Med cat on Name]	
12.	Standardized Med cat on Code - D ctionary derived *[hidden]* [Standardized Med cat on Code]	

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

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

Concomitant Medications

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

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

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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]	

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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]	

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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]	

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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]	

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

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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 Collection: [Date of Collection]	/ /
2.	Specimen Type: [Specimen Type]	○ SWABBED MATERIAL ○ RESPIRATORY SECRETIONS
3.	Specimen Collection 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.	Device Type: [Device 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]	

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C4591001: DEATH DETAILS CODED (DEATH DTL)

Death Details

1.	Date of Collect on / Notification of Death: [Date of Collect on / Notif cat on 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	Dict onary-Derived Term *[hidden]* [Dictionary-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]	

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C4591001: DEMOGRAPHY (DEMOG)		
Demography		
1.	Subject ID [Subject ID]	
2.	Birth Date: [Birth Date]	/ /
3.	Sex: [Sex]	FEMALE MALE
4.	Ethnicity: [Ethnicity]	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

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

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

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

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

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

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

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

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

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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

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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.	Collection Date: [Collect on 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 Un t ◯ /mL

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C4591001: HEALTH CARE UTILIZATION (HLTHCARE)

Health Care Utilization

1.	Evaluation Interval: *[hidden]* [Evaluation 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	Physician or Healthcare Professional: [Type of Practitioner]	◯ SPECIALIST ◯ EMERGENCY ROOM ◯ PRIMARY CARE PHYSICIAN ◯ URGENT CARE ◯ TELEPHONE CONSULTATION ◯ OTHER
3.3	Occurrence of Visits or Contacts: [Occurrence of Vis ts or Contacts]	◯ YES Number of Vis ts or Contacts: [ ] ◯ NO

Health Care Utilization Other

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

Health Care Utilization

5.	Has the subject been hospitalized 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

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C4591001: HOSPITALIZATION DETAILS (HOSP) - Repeating Form				
#	Hospitalization Category	Hospitalization Term	Admission Date	Ongoing
1				

Hospitalization Details		
1.	Hosp talization Category: [Hospitalization Category]	◯ HOSPITALIZATION STATUS
2.	Hosp talization 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 Clin cal 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: [Toxicity 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.	D ctionary Derived Term *[hidden]* [D ctionary 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]	

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

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

Illness Details

1.	Category of Clinical Event: [Category of Clin cal Event:]	◯ SEVERE COVID-19 ILLNESS
2.	Subcategory of Clin cal Event: [Subcategory of Clin cal 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: [Toxicity 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.	D ctionary Derived Term *[hidden]* [D ctionary 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]	

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C4591001: ILLNESS DETAILS - SEVERE (ILL SEVERE)

Illness Details

1.	Category of Clinical Event: [Category of Clin cal Event:]	○ SEVERE COVID-19 ILLNESS
2.	Subcategory of Clin cal Event: [Subcategory of Clin cal 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: [Toxicity 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.	D ctionary Derived Term *[hidden]* [D ctionary 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]	

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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.	Locat on 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

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C4591001: INCLUSION/EXCLUSION CRITERIA (IN EX STG3)

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

Inclusion Criteria

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

Inclusion Criteria Entry

1.1	Inclusion Number: [Inclusion Number]	◯ 1 ◯ 2 ◯ 3 ◯ 4
1.2	Cr terion Description: [Criter on Descript on]	
1.3	Cr terion met? [Criter on met?]	◯ YES ◯ NO Describe details if relevant
1.4	Cr terion 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 abnormal ty that may increase the risk of study participation		EX01A00
2.b	2	Known infection w th human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)		EX02A00
2.c	3	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)		EX03A00
2.d	4	Receipt of medicat ons intended to prevent COVID-19		EX04A00
2.e	8	Immunocompromised indiv duals w th known or suspected immunodeficiency, as determined by history and/or laboratory/phys cal examination		EX08A00
2.f	9	Individuals with a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention		EX09A00
2.g	10	Bleeding diathesis or condition associated w th prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular inject on		EX10A00
2.h	11	Women who are pregnant or breastfeeding		EX11A00
2.i	12	Previous vaccinat on with any coronavirus vaccine		EX12A00
2.j	13	Individuals who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids. Inhaled/nebulized, Intra-art cular, intrabursal, or topical cort costeroids are permitted		EX13A00
2.k	14	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administrat on or planned receipt throughout the study		EX14A00
2.l	15	Participation in other studies involving study intervention w thin 28 days pr or to study entry and/or during study participation		EX15A00
2.m	16	Previous part cipation in other studies involving study intervent on containing lip d nanopart cles		EX16A00
2.n	21	Investigator s te staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members		EX21A00

Exclusion Criteria Entry

2.1	Exclusion Number: [Exclusion Number]	
2.2	Cr terion Description: [Criter on Descript on]	
2.3	Cr terion met? [Criter on met?]	◯ YES Describe details if relevant

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

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C4591001: INCLUSION/EXCLUSION CRITERIA (IN EX STG3)

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

Inclusion Criteria

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

Inclusion Criteria Entry

1.1	Inclusion Number: [Inclusion Number]	◯ 1 ◯ 2 ◯ 3 ◯ 4
1.2	Cr terion Description: [Criter on Descript on]	
1.3	Cr terion met? [Criter on met?]	◯ YES ◯ NO Describe details if relevant
1.4	Cr terion 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 abnormal ty that may increase the risk of study participation		EX01A00
2.b	2	Known infection w th human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)		EX02A00
2.c	3	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)		EX03A00
2.d	4	Receipt of medicat ons intended to prevent COVID-19		EX04A00
2.e	8	Immunocompromised indiv duals w th known or suspected immunodeficiency, as determined by history and/or laboratory/phys cal examination		EX08A00
2.f	10	Bleeding diathesis or condition associated w th prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular inject on		EX10A00
2.g	11	Women who are pregnant or breastfeeding		EX11A00
2.h	12	Previous vaccinat on with any coronavirus vaccine		EX12A00
2.i	13	Subjects who receive immunosuppressive therapy, such as cytotox c agents or systemic cort costeroids		EX13A01
2.j	15	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administrat on or planned receipt throughout the study		EX14A01
2.k	16	Participation in other studies involving study intervention w thin 28 days pr or to study entry and/or during study participation		EX15A01
2.l	17	Previous part cipation in other studies involving study intervent on containing lip d nanopart cles		EX16A01
2.m	22	Investigator s te staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members		EX21A01

Exclusion Criteria Entry

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

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

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C4591001: INCLUSION/EXCLUSION CRITERIA (IN EX STG3)

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

Inclusion Criteria

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

Inclusion Criteria Entry

1.1	Inclusion Number: [Inclusion Number]	◯ 1 ◯ 2 ◯ 3 ◯ 4
1.2	Cr terion Description: [Criter on Descript on]	
1.3	Cr terion met? [Criter on met?]	◯ YES ◯ NO Describe details if relevant
1.4	Cr terion 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 abnormal ty that may increase the risk of study participation		EX01A00
2.b	2	Known infection w th human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)		EX02A00
2.c	3	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)		EX03A00
2.d	4	Receipt of medicat ons intended to prevent COVID-19		EX04A00
2.e	8	Immunocompromised indiv duals w th known or suspected immunodeficiency, as determined by history and/or laboratory/phys cal examination		EX08A00
2.f	9	Individuals with a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention		EX09A00
2.g	10	Bleeding diathesis or condition associated w th prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular inject on		EX10A00
2.h	11	Women who are pregnant or breastfeeding		EX11A00
2.i	12	Previous vaccinat on with any coronavirus vaccine		EX12A00
2.j	13	Subjects who receive immunosuppressive therapy, such as cytotox c agents or systemic cort costeroids		EX13A01
2.k	15	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administrat on or planned receipt throughout the study		EX14A01
2.l	16	Participation in other studies involving study intervention w thin 28 days pr or to study entry and/or during study participation		EX15A01
2.m	17	Previous part cipation in other studies involving study intervent on containing lip d nanopart cles		EX16A01
2.n	22	Investigator s te staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members		EX21A01

Exclusion Criteria Entry

2.1	Exclusion Number: [Exclusion Number]	
2.2	Cr terion Description: [Criter on Descript on]	
2.3	Cr terion met? [Criter on met?]	◯ YES Describe details if relevant

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

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C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC)

	Criterion Description
1.	

Inclusion Criteria Not Met Entry

1.1	Description of Inclusion Cr terion Not Met [Criter on Descript on]	

	Criterion Description
2.	

Exclusion Criteria Met Entry

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

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C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC NS)

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

Inclusion Criteria

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

Inclusion Criteria Entry

1.1	Inclusion Number: [Inclusion Number]	◯ 1 ◯ 2 ◯ 3 ◯ 4
1.2	Cr terion Description: [Criter on Descript on]	
1.3	Cr terion met? [Criter on met?]	◯ YES ◯ NO Describe details if relevant
1.4	Cr terion 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 abnormal ty that may increase the risk of study participation		EX01A00
2.b	2	Known infection w th human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)		EX02A00
2.c	3	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)		EX03A00
2.d	4	Receipt of medicat ons intended to prevent COVID-19		EX04A00
2.e	5	Stages 1 and 2 only: Prev ous clinical or microbiolog cal diagnosis of COVID-19		EX05A00
2.f	8	Immunocompromised indiv duals w th known or suspected immunodeficiency, as determined by history and/or laboratory/phys cal examination		EX08A00
2.g	10	Bleeding diathesis or condition associated w th prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular inject on		EX10A00
2.h	11	Women who are pregnant or breastfeeding		EX11A00
2.i	12	Previous vaccinat on with any coronavirus vaccine		EX12A00
2.j	13	Subjects who receive immunosuppressive therapy, such as cytotox c agents or systemic cort costeroids		EX13A01
2.k	15	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administrat on or planned receipt throughout the study		EX14A01
2.l	16	Participation in other studies involving study intervention w thin 28 days pr or to study entry and/or during study participation		EX15A01
2.m	17	Previous part cipation in other studies involving study intervent on containing lip d nanopart cles		EX16A01
2.n	22	Investigator s te staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members		EX21A01

Exclusion Criteria Entry

2.1	Exclusion Number: [Exclusion Number]	
2.2	Cr terion Description: [Criter on Descript on]	
2.3	Cr terion met? [Criter on met?]	◯ YES Describe details if relevant ◯ NO

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

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C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC NS)

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

Inclusion Criteria

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

Inclusion Criteria Entry

1.1	Inclusion Number: [Inclusion Number]	◯ 1 ◯ 2 ◯ 3 ◯ 4
1.2	Cr terion Description: [Criter on Descript on]	
1.3	Cr terion met? [Criter on met?]	◯ YES ◯ NO Describe details if relevant
1.4	Cr terion 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 abnormal ty that may increase the risk of study participation		EX01A00
2.b	2	Known infection w th human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)		EX02A00
2.c	3	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)		EX03A00
2.d	4	Receipt of medicat ons intended to prevent COVID-19		EX04A00
2.e	5	Stages 1 and 2 only: Prev ous clinical or microbiolog cal diagnosis of COVID-19		EX05A00
2.f	8	Immunocompromised indiv duals w th known or suspected immunodeficiency, as determined by history and/or laboratory/phys cal examination		EX08A00
2.g	9	Individuals with a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention		EX09A00
2.h	10	Bleeding diathesis or condition associated w th prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular inject on		EX10A00
2.i	11	Women who are pregnant or breastfeeding		EX11A00
2.j	12	Previous vaccinat on with any coronavirus vaccine		EX12A00
2.k	13	Individuals who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids. Inhaled/nebulized, Intra-art cular, intrabursal, or topical cort costeroids are permitted		EX13A00
2.l	14	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administrat on or planned receipt throughout the study		EX14A00
2.m	15	Participation in other studies involving study intervention w thin 28 days pr or to study entry and/or during study participation		EX15A00
2.n	16	Previous part cipation in other studies involving study intervent on containing lip d nanopart cles		EX16A00
2.o	21	Investigator s te staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members		EX21A00

Exclusion Criteria Entry

2.1	Exclusion Number: [Exclusion Number]	
2.2	Cr terion Description: [Criter on Descript on]	
2.3	Cr terion met? [Criter on met?]	◯ YES Describe details if relevant

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

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C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC NS)

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

Inclusion Criteria

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

Inclusion Criteria Entry

1.1	Inclusion Number: [Inclusion Number]	◯ 1 ◯ 2 ◯ 3 ◯ 4
1.2	Cr terion Description: [Criter on Descript on]	
1.3	Cr terion met? [Criter on met?]	◯ YES ◯ NO Describe details if relevant
1.4	Cr terion 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 abnormal ty that may increase the risk of study participation		EX01A00
2.b	2	Known infection w th human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)		EX02A00
2.c	3	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)		EX03A00
2.d	4	Receipt of medicat ons intended to prevent COVID-19		EX04A00
2.e	5	Stages 1 and 2 only: Prev ous clinical or microbiolog cal diagnosis of COVID-19		EX05A00
2.f	8	Immunocompromised indiv duals w th known or suspected immunodeficiency, as determined by history and/or laboratory/phys cal examination		EX08A00
2.g	9	Individuals with a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention		EX09A00
2.h	10	Bleeding diathesis or condition associated w th prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular inject on		EX10A00
2.i	11	Women who are pregnant or breastfeeding		EX11A00
2.j	12	Previous vaccinat on with any coronavirus vaccine		EX12A00
2.k	13	Subjects who receive immunosuppressive therapy, such as cytotox c agents or systemic cort costeroids		EX13A01
2.l	15	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administrat on or planned receipt throughout the study		EX14A01
2.m	16	Participation in other studies involving study intervention w thin 28 days pr or to study entry and/or during study participation		EX15A01
2.n	17	Previous part cipation in other studies involving study intervent on containing lip d nanopart cles		EX16A01
2.o	22	Investigator s te staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members		EX21A01

Exclusion Criteria Entry

2.1	Exclusion Number: [Exclusion Number]	
2.2	Cr terion Description: [Criter on Descript on]	
2.3	Cr terion met? [Criter on met?]	◯ YES Describe details if relevant

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

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C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC S)

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

Inclusion Criteria

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

Inclusion Criteria Entry

1.1	Inclusion Number: [Inclusion Number]	◯ 1 ◯ 2 ◯ 3 ◯ 4
1.2	Cr terion Description: [Criter on Descript on]	
1.3	Cr terion met? [Criter on met?]	◯ YES ◯ NO Describe details if relevant
1.4	Cr terion 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 abnormal ty that may increase the risk of study participation		EX01A00
2.b	2	Known infection w th human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)		EX02A00
2.c	3	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)		EX03A00
2.d	4	Receipt of medicat ons intended to prevent COVID-19		EX04A00
2.e	5	Stages 1 and 2 only: Prev ous clinical or microbiolog cal diagnosis of COVID-19		EX05A00
2.f	6	Sentinel participants in Stage 1 only: Individuals at high risk for severe COVID-19 (full details in protocol)		EX06A01
2.g	7	Sentinel participants in Stage 1 only: Individuals currently working in occupations with high risk of exposure to SARS-CoV-2 (eg, healthcare worker, emergency response personnel)		EX07A00
2.h	8	Immunocompromised indiv duals w th known or suspected immunodeficiency, as determined by history and/or laboratory/phys cal examinat on		EX08A00
2.i	9	Sentinel participants in Stage 1 only: Individuals w th a history of autoimmune disease or an active autoimmune disease requiring therapeut c intervention		EX09A04
2.j	10	Bleeding diathesis or condition associated w th prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular inject on		EX10A00
2.k	11	Women who are pregnant or breastfeeding		EX11A00
2.l	12	Previous vaccinat on with any coronavirus vaccine		EX12A00
2.m	13	Subjects who receive immunosuppressive therapy, such as cytotox c agents or systemic cort costeroids		EX13A01
2.n	14	Sentinel participants in Stage 1 only: Regular receipt of inhaled/nebulized corticosteroids		EX22A01
2.o	15	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administrat on or planned receipt throughout the study		EX14A01
2.p	16	Participation in other studies involving study intervention w thin 28 days pr or to study entry and/or during study participation		EX15A01
2.q	17	Previous part cipation in other studies involving study intervent on containing lip d nanopart cles		EX16A01
2.r	18	Sentinel part cipants in Stage 1 only: Positive serological test for SARS-CoV-2 IgM and/or IgG antibodies at the screening visit		EX17A01
2.s	19	Sentinel part cipants in Stage 1 only: Screening hematology/blood chemistry lab >=Grade 1 abnormality. Except Bilirubin, other stable Grade1 abnormalities may be considered eligible by Investigator		EX18A01
2.t	20	Sentinel part cipants in Stage 1 only: Positive test for HIV, hepat tis B surface antigen		EX19A01

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		(HBsAg), hepat tis B core antibodies (HBc Abs), or hepatitis C virus antibodies (HCV Abs) at screening vis t		
2.u	21	Sentinel participants in Stage 1 only: SARS-CoV-2 NAAT-positive nasal swab within 24 hours before receipt of study intervention		EX20A01
2.v	22	Investigator s te staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members		EX21A01

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

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C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC S)

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

Inclusion Criteria

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

Inclusion Criteria Entry

1.1	Inclusion Number: [Inclusion Number]	◯ 1 ◯ 2 ◯ 3 ◯ 4
1.2	Cr terion Description: [Criter on Descript on]	
1.3	Cr terion met? [Criter on met?]	◯ YES ◯ NO Describe details if relevant
1.4	Cr terion 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 abnormal ty that may increase the risk of study participation		EX01A00
2.b	2	Known infection w th human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)		EX02A00
2.c	3	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)		EX03A00
2.d	4	Receipt of medicat ons intended to prevent COVID-19		EX04A00
2.e	5	Stages 1 and 2 only: Prev ous clinical or microbiolog cal diagnosis of COVID-19		EX05A00
2.f	6	Sentinel participants in Stage 1 only: Individuals at high risk for severe COVID-19		EX06A00
2.g	7	Sentinel participants in Stage 1 only: Individuals currently working in occupations with high risk of exposure to SARS-CoV-2 (eg, healthcare worker, emergency response personnel)		EX07A00
2.h	8	Immunocompromised indiv duals w th known or suspected immunodeficiency, as determined by history and/or laboratory/phys cal examinat on		EX08A00
2.i	9	Individuals w th a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention		EX09A00
2.j	10	Bleeding diathesis or condition associated w th prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular inject on		EX10A00
2.k	11	Women who are pregnant or breastfeeding		EX11A00
2.l	12	Previous vaccinat on with any coronavirus vaccine		EX12A00
2.m	13	Individuals who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids. Inhaled/nebulized, Intra-art cular, intrabursal, or topical cort costeroids are permitted		EX13A00
2.n	14	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administrat on or planned receipt throughout the study		EX14A00
2.o	15	Participation in other studies involving study intervention w thin 28 days pr or to study entry and/or during study participation		EX15A00
2.p	16	Previous part cipation in other studies involving study intervent on containing lip d nanopart cles		EX16A00
2.q	17	Sentinel part cipants in Stage 1 only: Positive serological test for SARS-CoV-2 IgM and/or IgG antibodies at the screening visit		EX17A00
2.r	18	Sentinel part cipants in Stage 1 only: Screening hematology/blood chemistry lab >=Grade 1 abnormality. Except Bilirubin, other stable Grade1 abnormalities may be considered eligible by Investigator		EX18A00
2.s	19	Sentinel part cipants in Stage 1 only: Positive test for HIV, hepat tis B surface antigen (HBsAg), hepat tis B core antibodies (HBc Abs), or hepatitis C virus antibodies (HCV Abs) at screening vis t		EX19A00

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2.t	20	Sentinel participants in Stage 1 only: SARS-CoV-2 NAAT-positive nasal swab within 24 hours before receipt of study intervention		EX20A00
2.u	21	Investigator s te staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members		EX21A00

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

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C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC S)

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

Inclusion Criteria

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

Inclusion Criteria Entry

1.1	Inclusion Number: [Inclusion Number]	◯ 1 ◯ 2 ◯ 3 ◯ 4
1.2	Cr terion Description: [Criter on Descript on]	
1.3	Cr terion met? [Criter on met?]	◯ YES ◯ NO Describe details if relevant
1.4	Cr terion 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 abnormal ty that may increase the risk of study participation		EX01A00
2.b	2	Known infection w th human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)		EX02A00
2.c	3	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)		EX03A00
2.d	4	Receipt of medicat ons intended to prevent COVID-19		EX04A00
2.e	5	Stages 1 and 2 only: Prev ous clinical or microbiolog cal diagnosis of COVID-19		EX05A00
2.f	6	Sentinel participants in Stage 1 only: Individuals at high risk for severe COVID-19 (full details in protocol)		EX06A01
2.g	7	Sentinel participants in Stage 1 only: Individuals currently working in occupations with high risk of exposure to SARS-CoV-2 (eg, healthcare worker, emergency response personnel)		EX07A00
2.h	8	Immunocompromised indiv duals w th known or suspected immunodeficiency, as determined by history and/or laboratory/phys cal examinat on		EX08A00
2.i	9	Individuals w th a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention		EX09A00
2.j	10	Bleeding diathesis or condition associated w th prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular inject on		EX10A00
2.k	11	Women who are pregnant or breastfeeding		EX11A00
2.l	12	Previous vaccinat on with any coronavirus vaccine		EX12A00
2.m	13	Subjects who receive immunosuppressive therapy, such as cytotox c agents or systemic cort costeroids		EX13A01
2.n	14	Sentinel participants in Stage 1 only: Regular receipt of inhaled/nebulized corticosteroids		EX22A01
2.o	15	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administrat on or planned receipt throughout the study		EX14A01
2.p	16	Participation in other studies involving study intervention w thin 28 days pr or to study entry and/or during study participation		EX15A01
2.q	17	Previous part cipation in other studies involving study intervent on containing lip d nanopart cles		EX16A01
2.r	18	Sentinel part cipants in Stage 1 only: Positive serological test for SARS-CoV-2 IgM and/or IgG antibodies at the screening visit		EX17A01
2.s	19	Sentinel part cipants in Stage 1 only: Screening hematology/blood chemistry lab >=Grade 1 abnormality. Except Bilirubin, other stable Grade1 abnormalities may be considered eligible by Investigator		EX18A01
2.t	20	Sentinel part cipants in Stage 1 only: Positive test for HIV, hepat tis B surface antigen		EX19A01

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		(HBsAg), hepat tis B core antibodies (HBc Abs), or hepatitis C virus antibodies (HCV Abs) at screening vis t		
2.u	21	Sentinel participants in Stage 1 only: SARS-CoV-2 NAAT-positive nasal swab within 24 hours before receipt of study intervention		EX20A01
2.v	22	Investigator s te staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members		EX21A01

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

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

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C4591001: CENTRAL LAB SAMPLE COLLECTION (LAB)

Central Lab Sample Collection

1.	Collection Date: [Collect on 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

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

Central Lab Sample Collection

1.	Collection Date: [Collect on 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

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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.	Collection Date: [Collect on 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 Un t

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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.	Collection Date: [Collect on 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 Un t

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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.	Collection Date: [Collect on 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 Un t

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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.	Collection Date: [Collect on 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		Chor ogonadotropin 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

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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.	Medication Error (Type of Medication Error): [Med cat 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 med cation error still ongoing? [Is the med cat on error Still Ongoing]	○ YES ○ NO End Date: / /
6.	Latest Action Taken with Study Treatment: [Study Medication Errors Act on]	○ NO ACTION TAKEN ○ PERMANENTLY DISCONTINUED
7.	Was a Concomitant Med cation given? [Concom tant Med cat on Given]	○ YES ○ NO
8.	Was a Non-Drug Treatment given? [Non-Drug Treatment Given]	○ YES ○ NO
9.	D d the Medication Error cause the subject to be discontinued from the study? [Caused Study Discontinuat on]	○ YES ○ NO
10.	Was this medication error associated with any adverse events? [Med cat on Error Associated With AE]	○ YES AE ID: AE ID: AE ID: AE ID: AE ID: ○ NO
11.	Ser ous 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.	D ctionary-Derived Term *[hidden]* [D ctionary-Derived Term]	

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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]	

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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	Dict onary Derived Term *[hidden]* [Dictionary 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]	

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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 (Fraction of Inhaled Oxygen)]	

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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 clinically signif cant, record on the Medical History or Adverse Event CRF as appropriate). Are there clinically signif cant findings? ◯ YES ◯ NO ◯ NOT DONE

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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 provide reason: [Reason sample not collected]	

	Sample ID
5.	

Aliquot Entry		
Please enter barcode for each aliquot.		
5.1	Sample ID [Sample ID]	

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

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

Concomitant Medications

1.	What is the medication dentifier? [Sponsor-Defined Identifier]	
2.	Category: [Category for Medication]	◯ CONCOMITANT IMMUNOSUPPRESSIVE THERAPY ◯ CORTICOSTEROIDS ◯ IMMUNOGLOBULINS
3.	Concomitant Medications Pre-specified: [Concom tant Medications Pre-specified]	◯ NO
4.	Med cation: Prov de the complete gener c drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Med cat on text (e.g., Ingredient(s), route, use, formulation). [Name of Medication]	
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 Med cat on Name - Dict onary derived. *[hidden]* [Standardized Med cat on Name]	
13.	Standardized Med cat on Code - D ctionary derived *[hidden]* [Standardized Med cat on Code]	

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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.	D ctionary Derived Term *[hidden]* [D ctionary 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]	

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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 Saturation]	

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

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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

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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.	Injection Site Location [Injection S te Location]	◯ DELTOID MUSCLE
4.	Injection Site Body S de: [Injection S te Body Side]	◯ LEFT ◯ RIGHT

Reaction

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

Reaction Entry

5.1	Reaction: [React on:]	◯ REDNESS ◯ SWELLING
5.2	Reaction Present: [React on Present:]	◯ YES Maximum Diameter (cm): Minimum Diameter (cm): Meets Grade 4 Reaction Cr teria: ◯ 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

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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.	D ctionary Derived Term *[hidden]* [D ctionary 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]	

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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.	D ctionary Derived Term *[hidden]* [D ctionary 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]	

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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 provide reason: [Reason sample not collected]	
	Sample ID	
5.		
Aliquot Entry		
Please enter barcode for each aliquot.		
5.1	Sample ID [Sample ID]	

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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 provide reason: [Reason sample not collected]	

	Sample ID
5.	

Aliquot Entry

Please enter barcode for each aliquot.

5.1	Sample ID [Sample ID]	

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

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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 provide reason: [Reason sample not collected]	

	Sample ID
5.	

Aliquot Entry		
Please enter barcode for each aliquot.		
5.1	Sample ID [Sample ID]	

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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	Dict onary Derived Term *[hidden]* [Dictionary 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	

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	Code]	

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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	Dict onary Derived Term *[hidden]* [Dictionary 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	

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	Code]	

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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)

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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-Mid dose level (20mcg)
4.	Select appropriate response - Randomizat on Dose Group *[hidden]* [Trigger Response 6]	◯ 21 Day 2-dose group ◯ 60 Day 2-dose group ◯ 1-dose group
5.	Select appropriate response - Randomizat on Dose Group [Trigger Response 8]	◯ 21 Day ◯ 60 Day
6.	Select appropriate response - BNT Number [Trigger Response 7]	◯ (BNT162a1 or PBO) ◯ (BNT162b1 or PBO) ◯ (BNT162b2 or PBO) ◯ (BNT162c2 or PBO) ◯ (BNT162b3 or PBO)

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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)

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C4591001: SUBJECT STATUS (SUB STATU)		
Subject Status		
1.	Subject Status [Subject Status]	
2.	Subject Status Date [Status Date]	/ /

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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 provide reason: [Reason sample not collected]	

	Sample ID
5.	

Aliquot Entry		
Please enter barcode for each aliquot.		
5.1	Sample ID [Sample ID]	

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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 Collection: [Date of Collection]	/ /
2.	Specimen Type: [Specimen Type]	◯ SWABBED MATERIAL
3.	Specimen Collection Location: [Specimen Collection Location]	◯ NASAL CAVITY
4.	Assay Code and Description: [Assay Code and Description]	◯ SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type: [Device 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:]	

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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 system c symptoms present on the last day the Subject Diary was completed? [Were fever or systemic symptoms present on the last day the Subject Diary was completed?]	◯ YES Ongoing? ◯ YES ◯ NO Stop Date: [ ] / [ ] / [ ] ◯ NO
3.	Injection Site Location: [Injection S te Location:]	◯ DELTOID MUSCLE
4.	Injection Site Body S de: [Injection 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 React on: [Injection Site Reaction:]	◯ REDNESS ◯ SWELLING ◯ PAIN AT INJECTION SITE
5.2	Were injection s te reactions present on the last day the Subject Diary was completed? [Were inject on site reactions present on the last day the Subject Diary was completed?]	◯ YES Ongoing? ◯ YES ◯ NO Stop Date: [ ] / [ ] / [ ] ◯ NO

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C4591001: TRANSFUSIONS (TRANSFUSE) - Repeating Form

#	Transfusion Type	Date of Transfusion
1		

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

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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:

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

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C4591001: VACCINATION (VACIN TRT)

Vaccination

1.	Was there a temporary delay of vaccinat on? [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: [Anatomical Locat on:]	◯ DELTOID MUSCLE
6.	Body Side: [Body S de:]	◯ LEFT ◯ RIGHT
7.	Route: [Route:]	◯ INTRAMUSCULAR
8.	Container Number: *[hidden]* [PAC / K t Number:]	
9.	Actual Dose: [Actual Dose:]	
10.	Unit: [Unit:]	◯ mL
11.	Timeframe Subject Was Observed [Timeframe Subject Was Observed]	◯ THE PROTOCOL SPECIFIED OBSERVATION PERIOD
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 Med cation Name - D ctionary Derived. *[hidden]* [Standardized Med cation Name]	
15.	Standardized Med cation Code - D ctionary Derived *[hidden]*	

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	[Standardized Med cation Code]	

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C4591001: VACCINATION (VACIN TRT)

Vaccination

1.	Was there a temporary delay of vaccinat on? [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: [Anatomical Locat on:]	◯ DELTOID MUSCLE
6.	Body Side: [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 administration? [Observed Post Dose For Specified Time]	◯ YES ◯ NO If No, specify reason:
15.	Comparison Term *[hidden]* [Comparison Term]	
16.	Standardized Med cation Name -	

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	D ctionary Derived. *[hidden]* [Standardized Med cation Name]	
17.	Standardized Med cation Code - D ctionary Derived *[hidden]* [Standardized Med cation Code]	

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

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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	Unit: [Temperature Unit]	○ F ○ C
2.4	Temperature Location: [Temperature Location:]	○ ORAL CAVITY ○ EAR ○ RECTUM ○ AXILLA ○ FOREHEAD

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C4591001: VITAL SIGNS - BASELINE (VITALS BSL)

Vital Signs

1.	Date: [Date:]	/ /
2.	Weight: [Weight]	
3.	Un t: [Weight Unit]	kg LB
4.	Height: [Height]	
5.	Un t: [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	Unit: [Temperature Unit]	C F
7.4	Temperature Location: [Temperature Location:]	ORAL CAVITY EAR RECTUM AXILLA FOREHEAD

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C4591001: VITAL SIGNS - BASELINE (VITALS BSL)

Vital Signs

1.	Date: [Date:]	/ /
2.	Weight: [Weight]	
3.	Un t: [Weight Unit]	kg LB
4.	Height: [Height]	
5.	Un t: [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	Unit: [Temperature Unit]	C F
7.4	Temperature Location: [Temperature Location:]	ORAL CAVITY EAR RECTUM AXILLA FOREHEAD
7.5	Systol c: [Systolic:]	
7.6	Diastol c: [Diastol c:]	
7.7	BP Posit on: [BP Position]	SITTING
7.8	Pulse: [Pulse:]	

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

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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	Unit: [Temperature Unit]	○ F ○ C
2.4	Temperature Location: [Temperature Location:]	○ ORAL CAVITY ○ EAR ○ RECTUM ○ AXILLA ○ FOREHEAD
2.5	Systol c: [Systolic:]	
2.6	Diastol c: [Diastol c:]	
2.7	BP Posit on: [BP Position]	○ SITTING
2.8	Pulse: [Pulse:]	

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

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

Localized texts are displayed in English (US).

Contents

1 Notifications / Subject card 2
2 Common 5
3 Form: Vaccination Diary 22
4 Form: COVID-19 Illness Diary 37
5 Form: Patient main menu 40
6 Form: Subject training diary 47
7 Form: Settings 54
8 Form: Security question 55

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

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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:

090177e195746b2f\Approved\Approved On: 06-Nov-2020 14:14 (GMT)

[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: [----------
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,

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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 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. **]**

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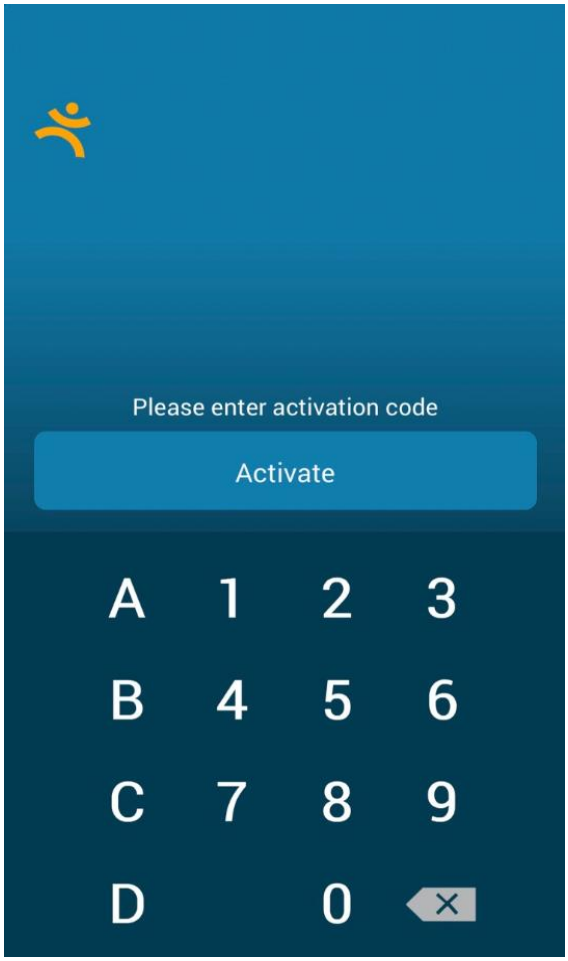
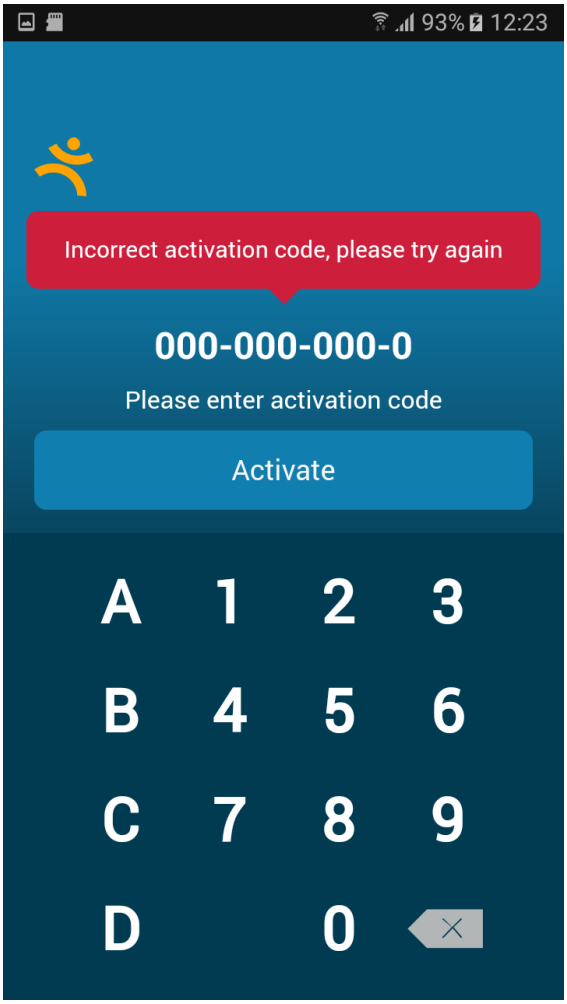
2 Common

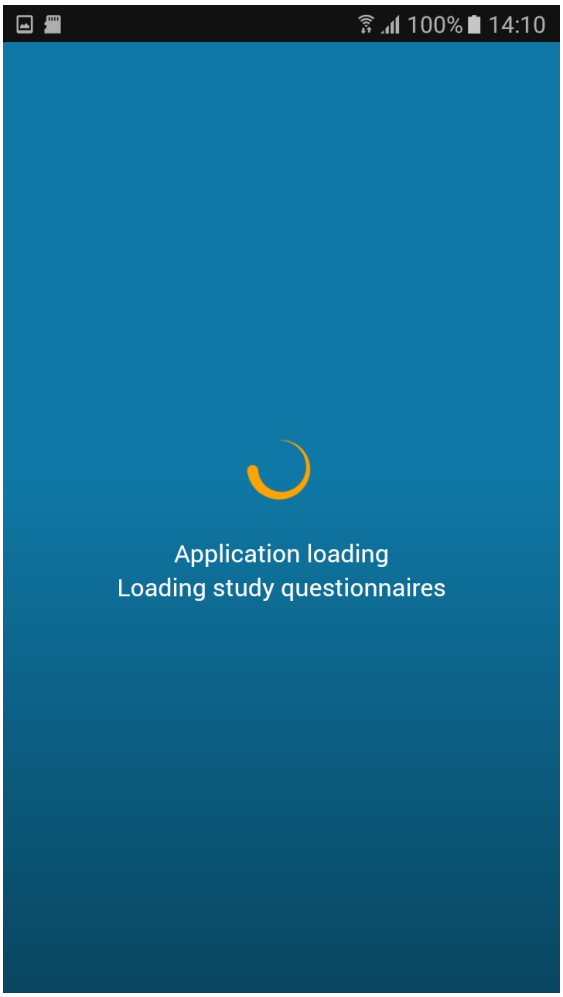


Screen 1

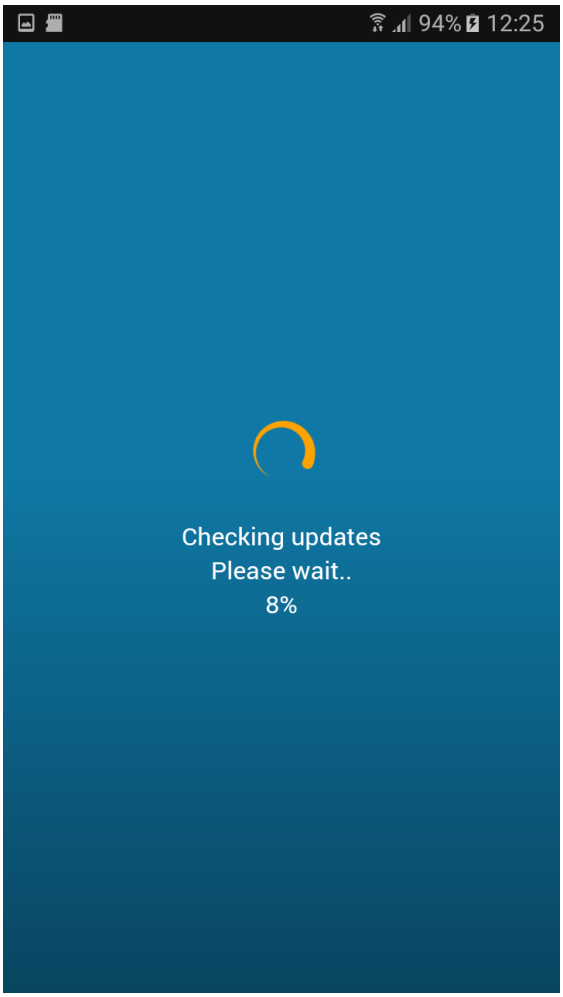


Screen 2

090177e195746b2f\Approved\Approved On: 06-Nov-2020 14:14 (GMT)



Screen 3



Screen 4

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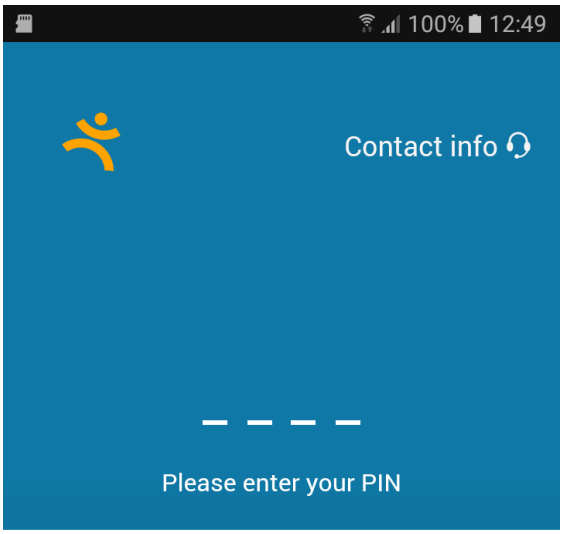
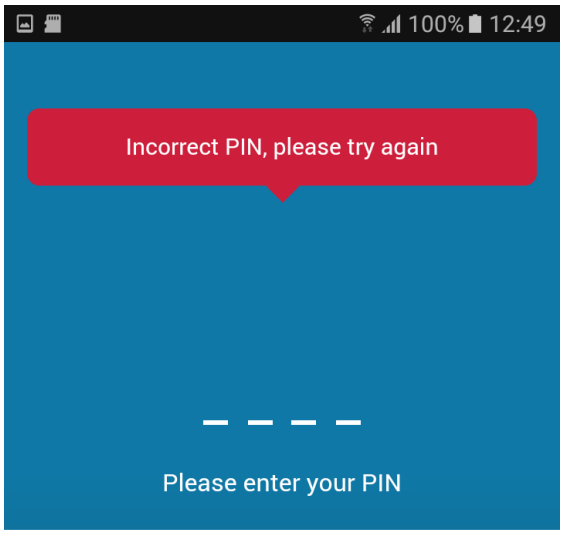


Screen 5



Screen 6

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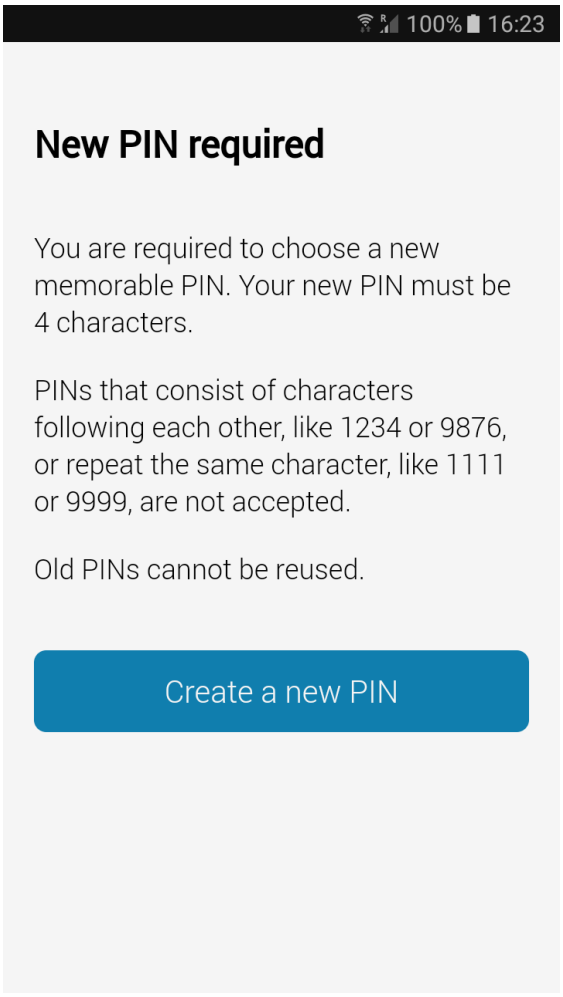
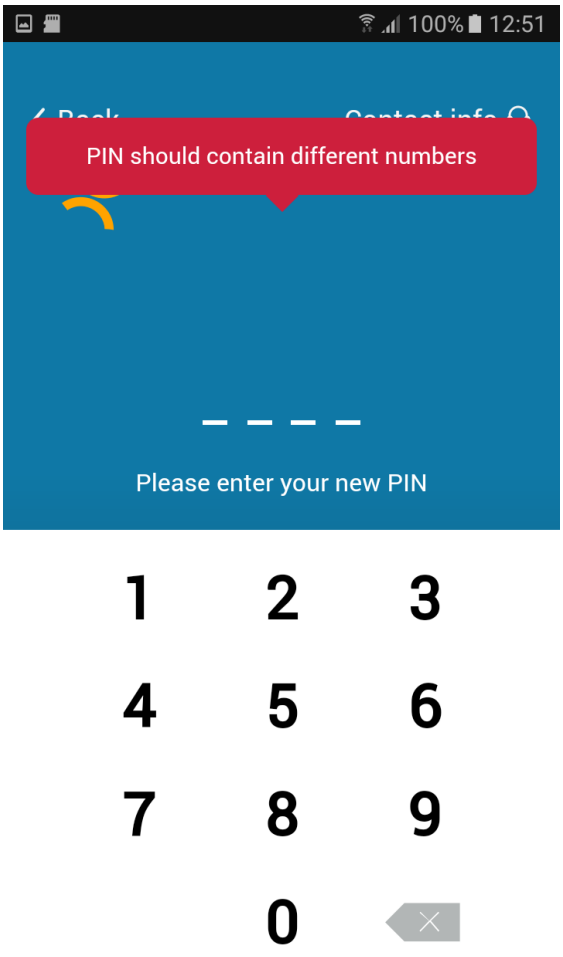


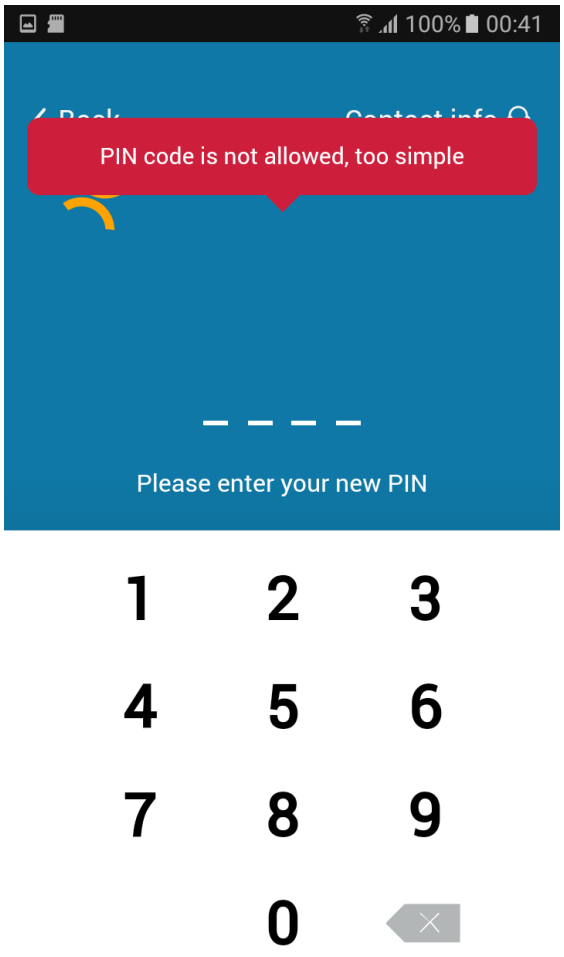
Screen 7

Screen 8

090177e195746b2f\Approved\Approved On: 06-Nov-2020 14:14 (GMT)



Screen 9



Screen 10

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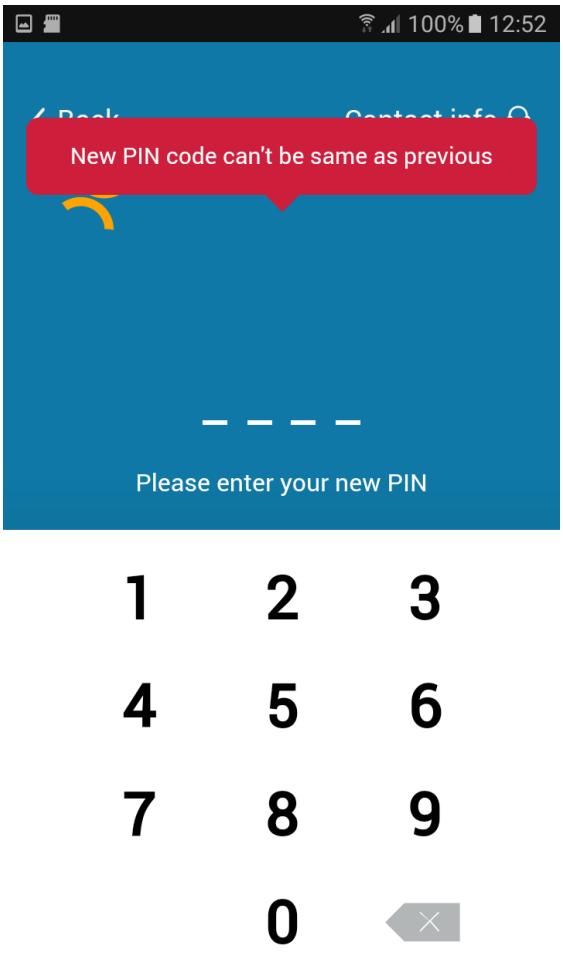
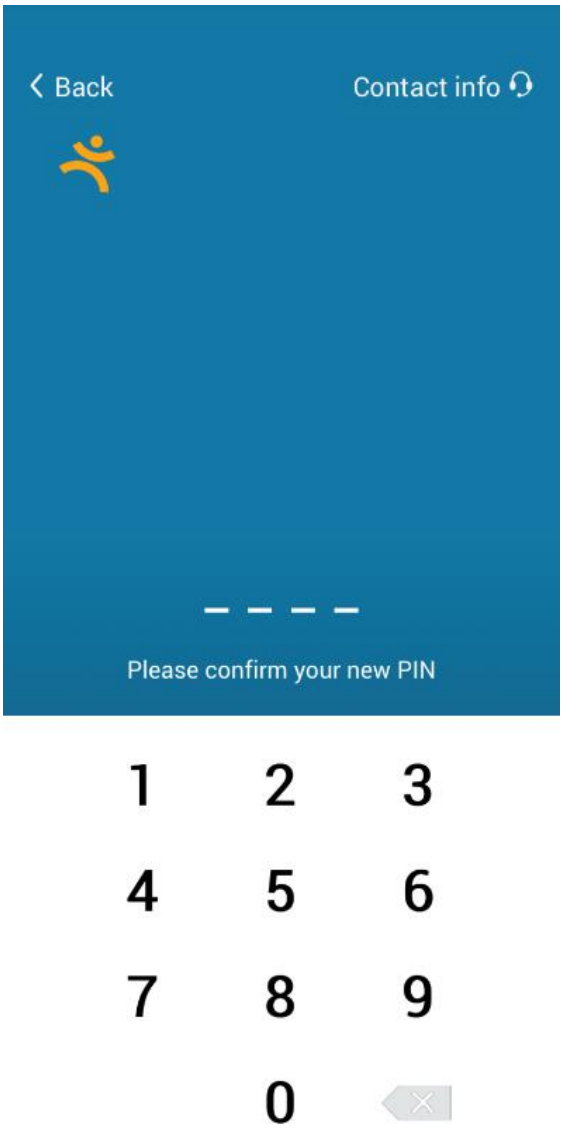


Screen 11



Screen 12

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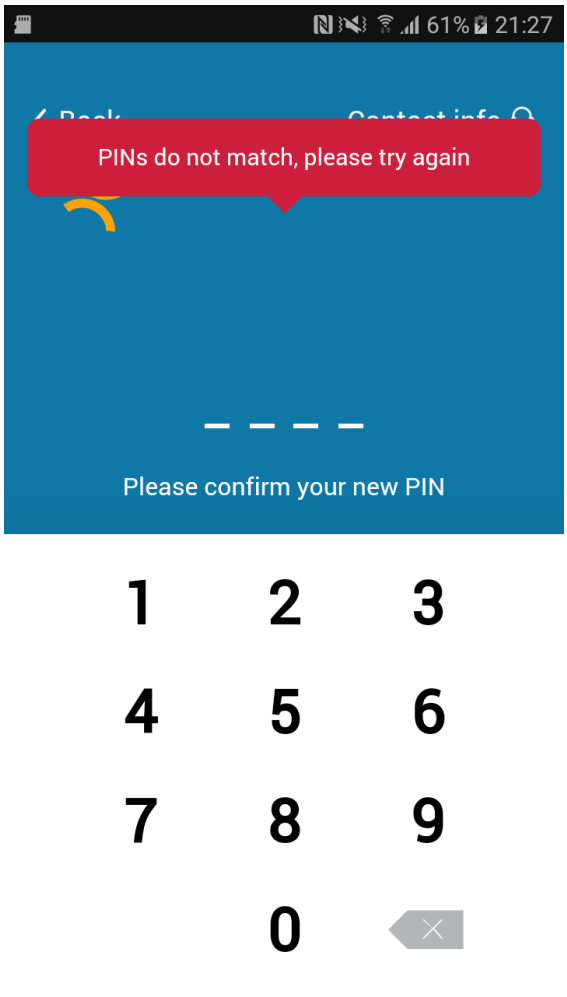
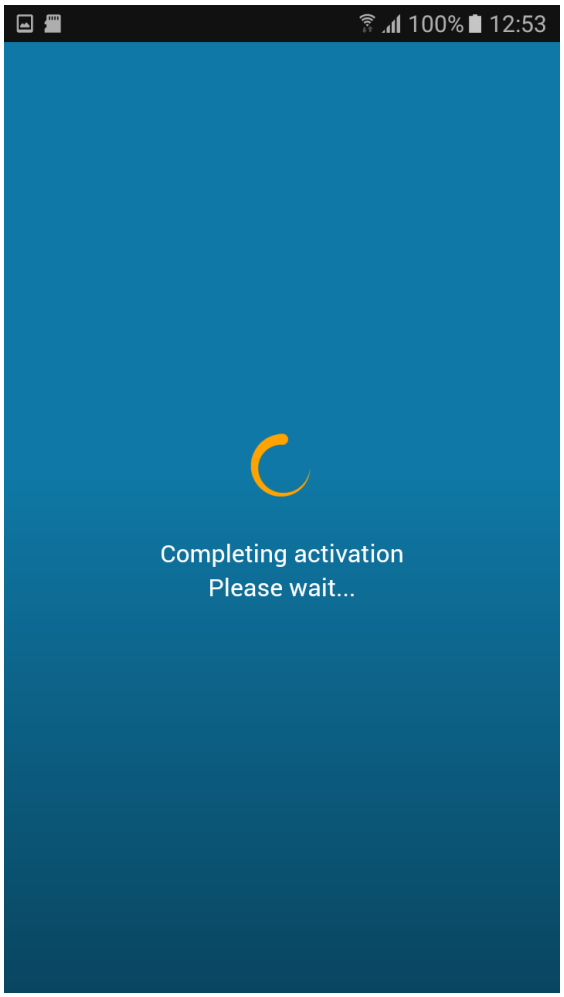
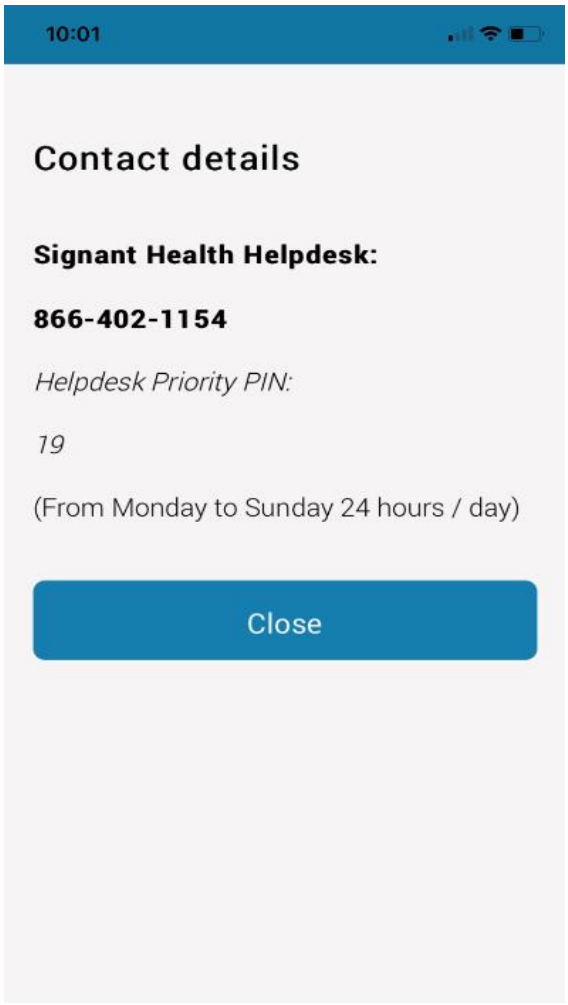


Screen 13

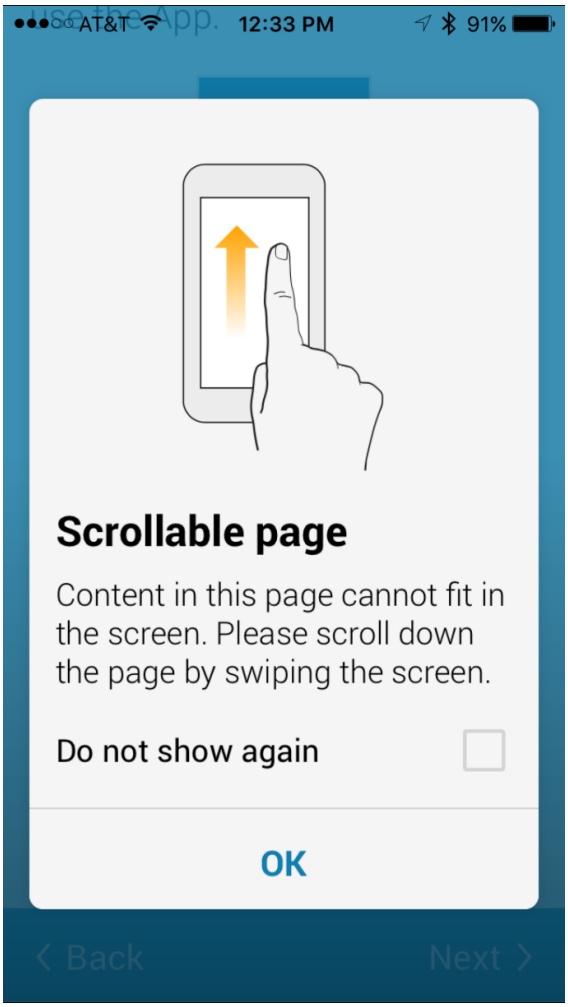


Screen 14

090177e195746b2f\Approved\Approved On: 06-Nov-2020 14:14 (GMT)

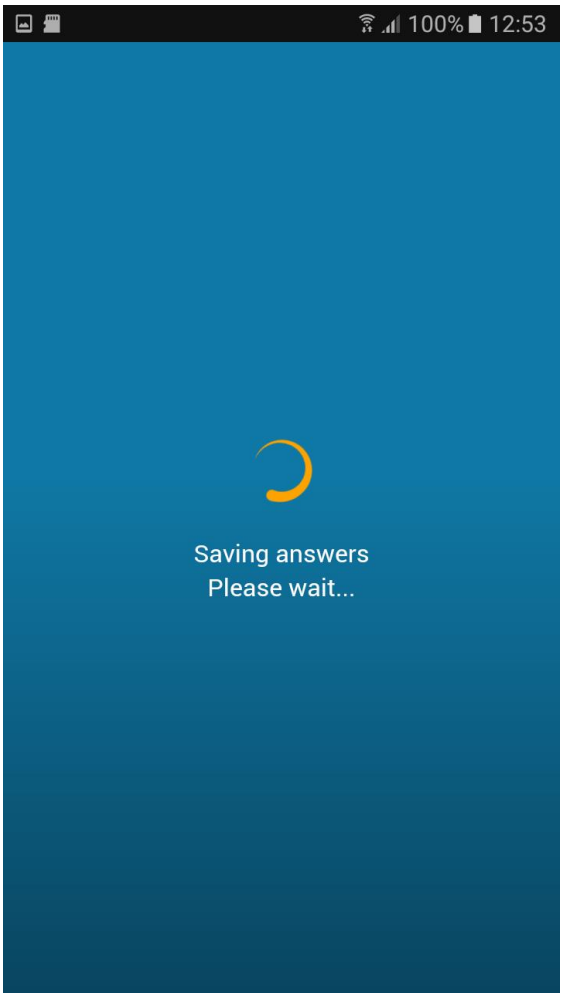


Screen 15

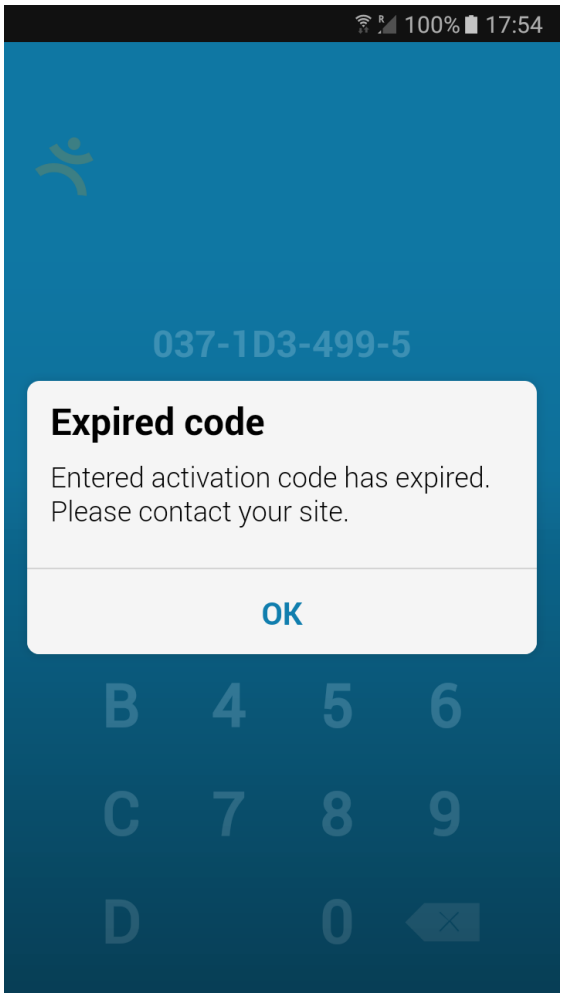


Screen 16

090177e195746b2f\Approved\Approved On: 06-Nov-2020 14:14 (GMT)

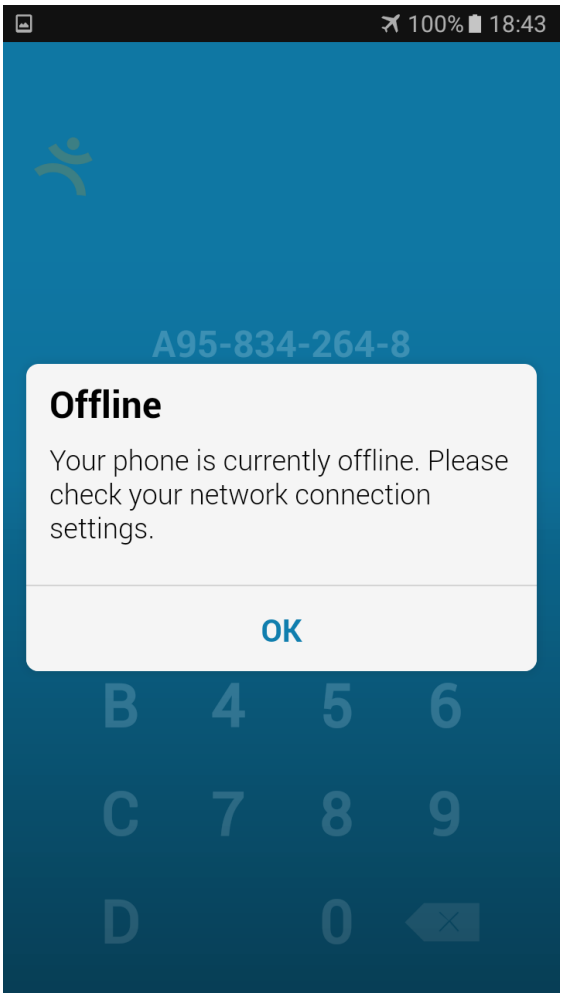


Screen 17

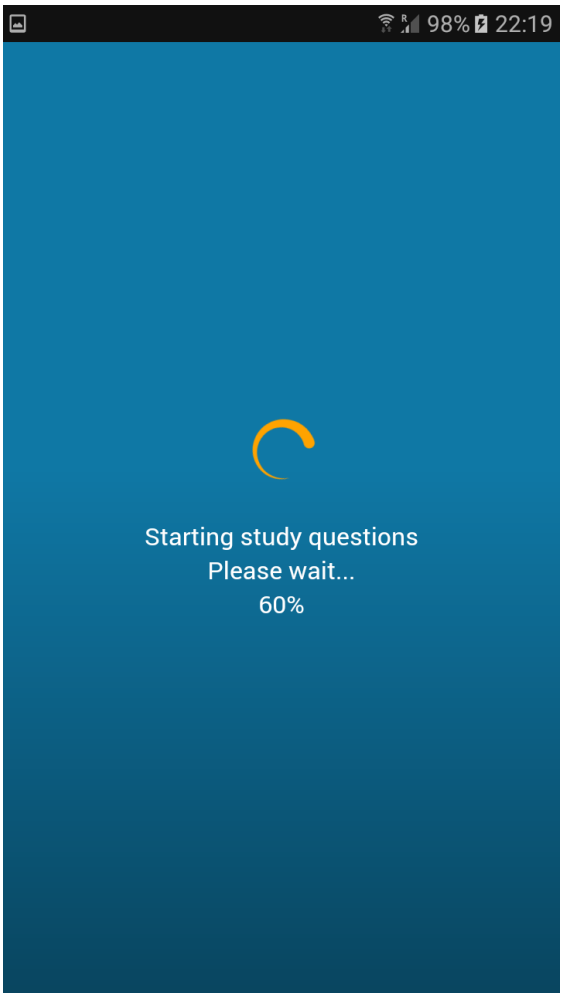


Screen 18

090177e195746b2f\Approved\Approved On: 06-Nov-2020 14:14 (GMT)



Screen 19



Screen 20

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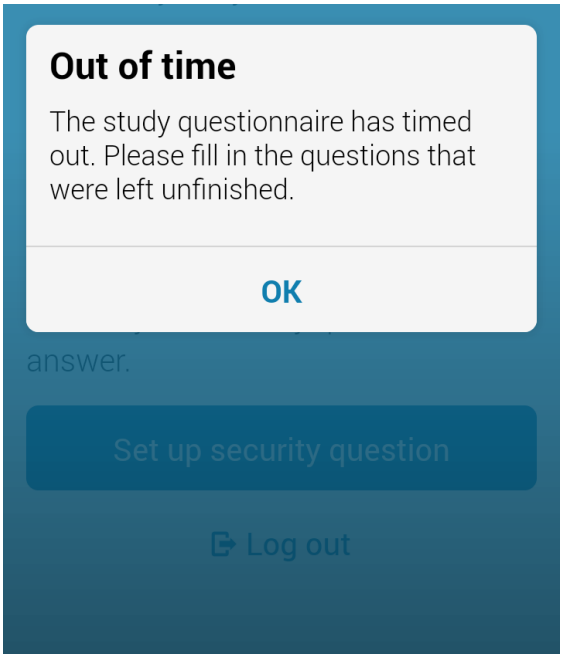
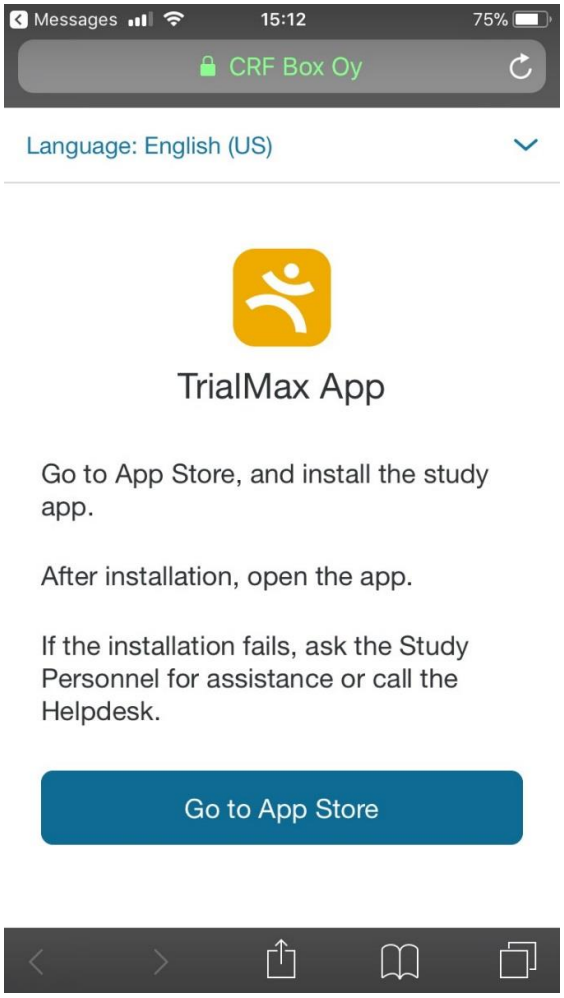
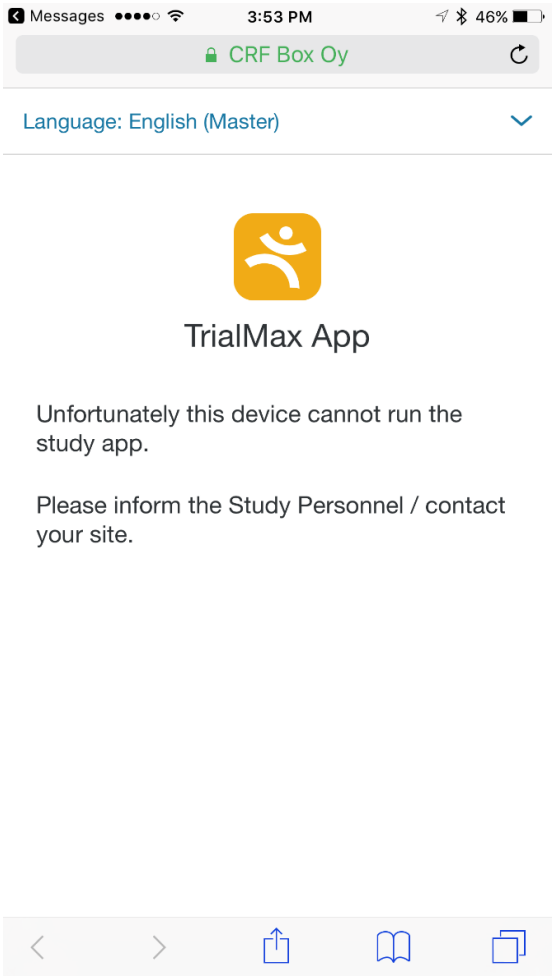


Screen 21

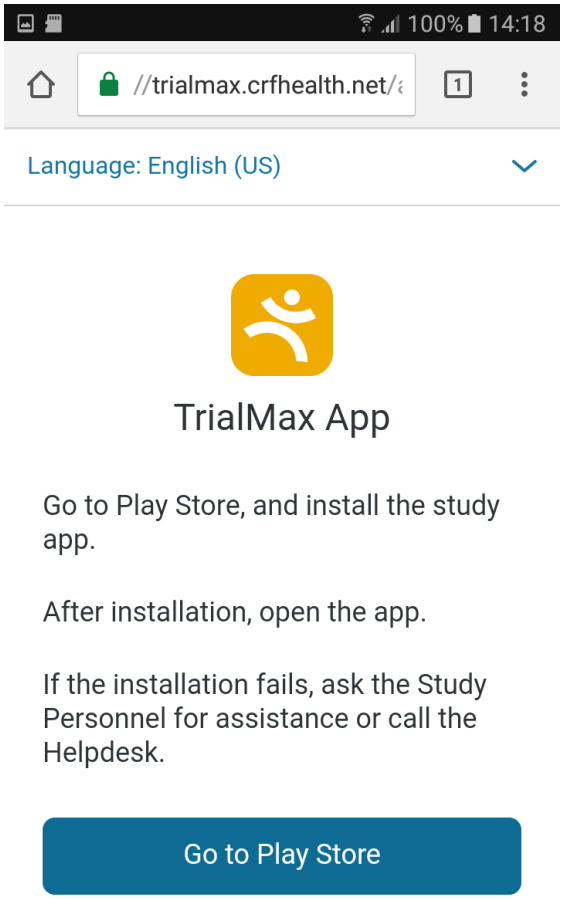


Screen 22

090177e195746b2f\Approved\Approved On: 06-Nov-2020 14:14 (GMT)

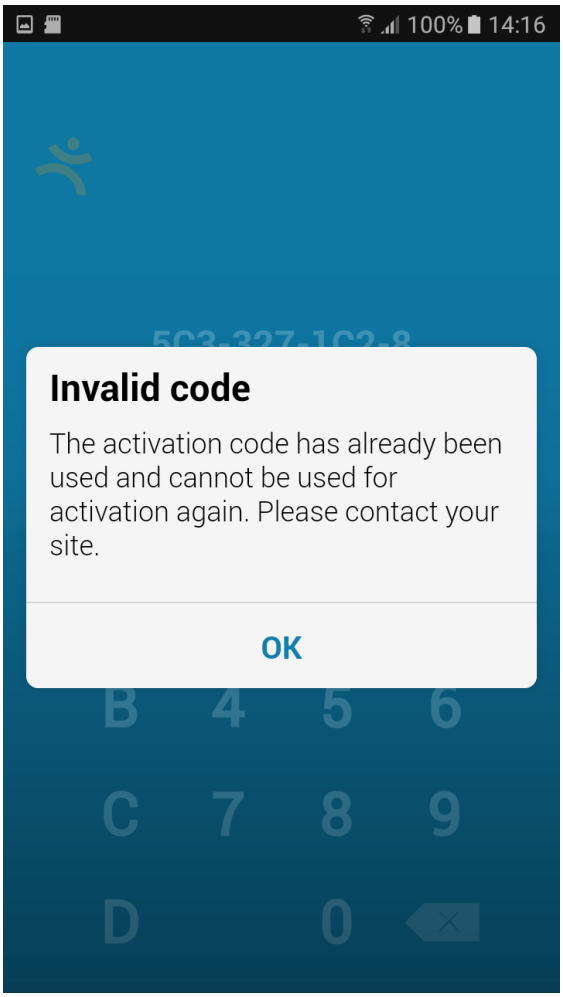


Screen 23

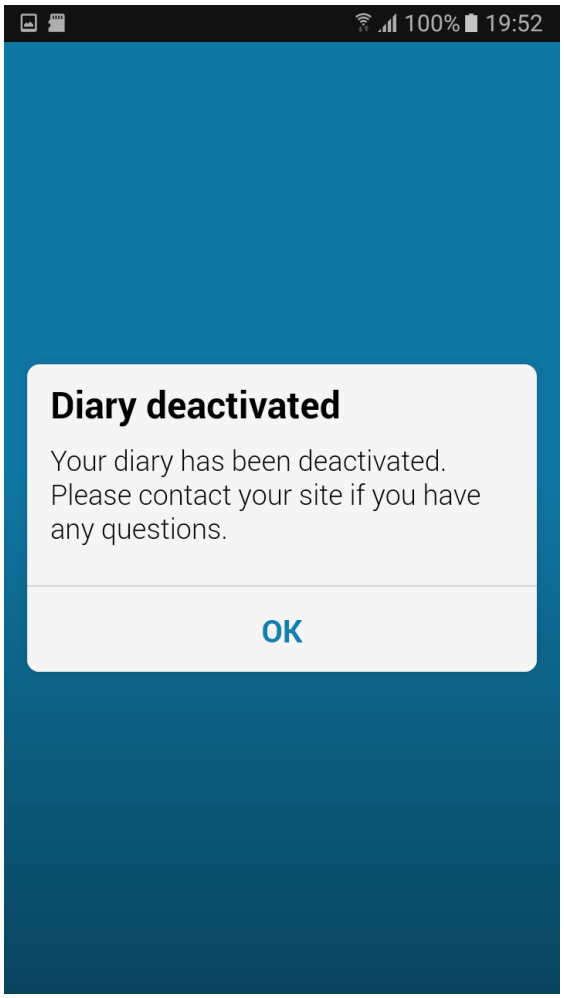


Screen 24

090177e195746b2f\Approved\Approved On: 06-Nov-2020 14:14 (GMT)

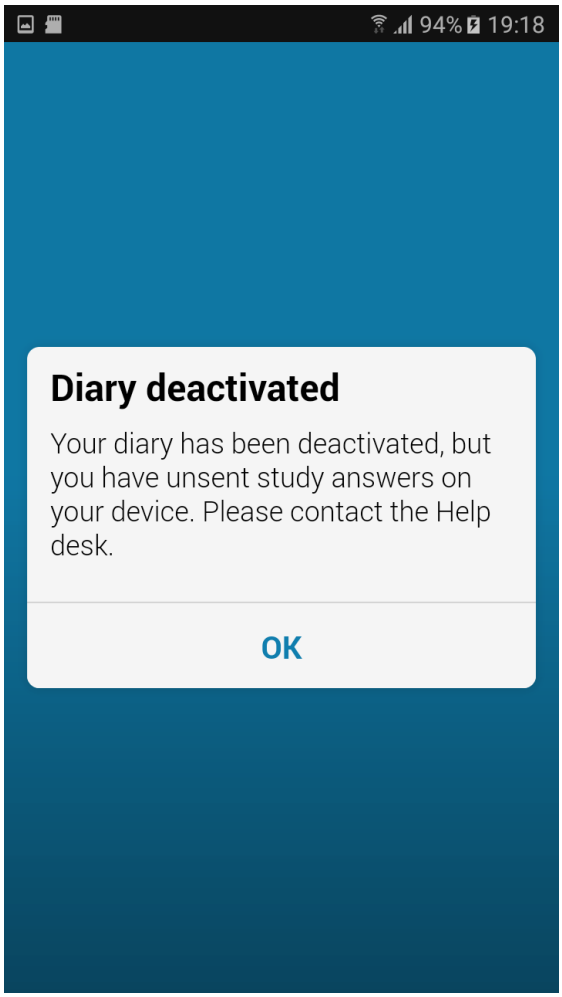


Screen 25



Screen 26

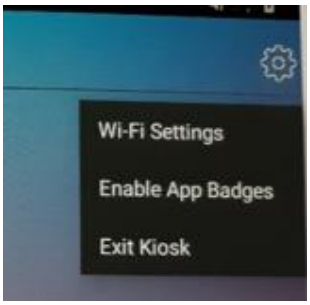
090177e195746b2f\Approved\Approved On: 06-Nov-2020 14:14 (GMT)



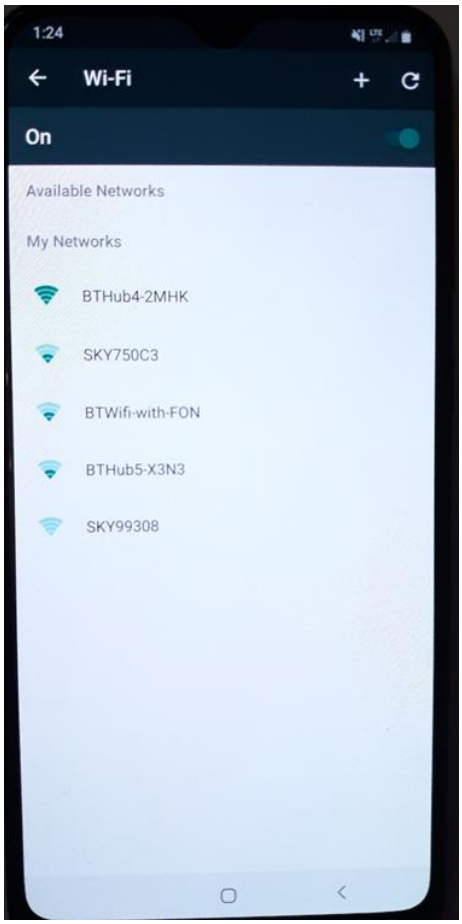
Screen 27

Screen 28

090177e195746b2f\Approved\Approved On: 06-Nov-2020 14:14 (GMT)

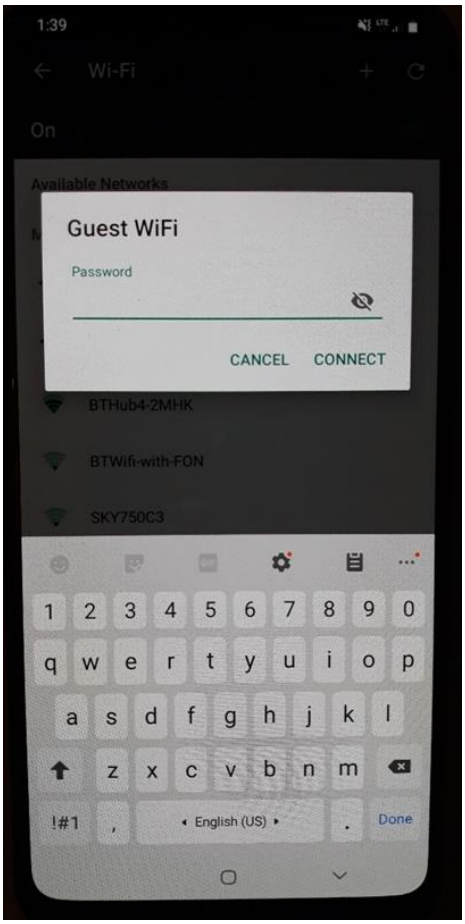


Screen 29

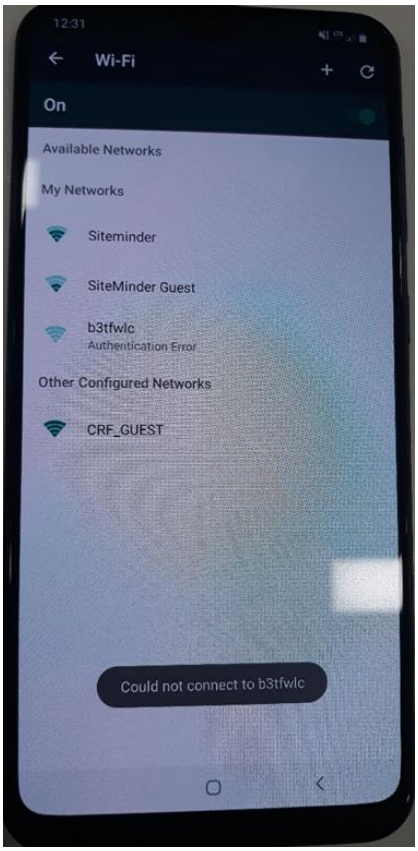


Screen 30

090177e195746b2f\Approved\Approved On: 06-Nov-2020 14:14 (GMT)

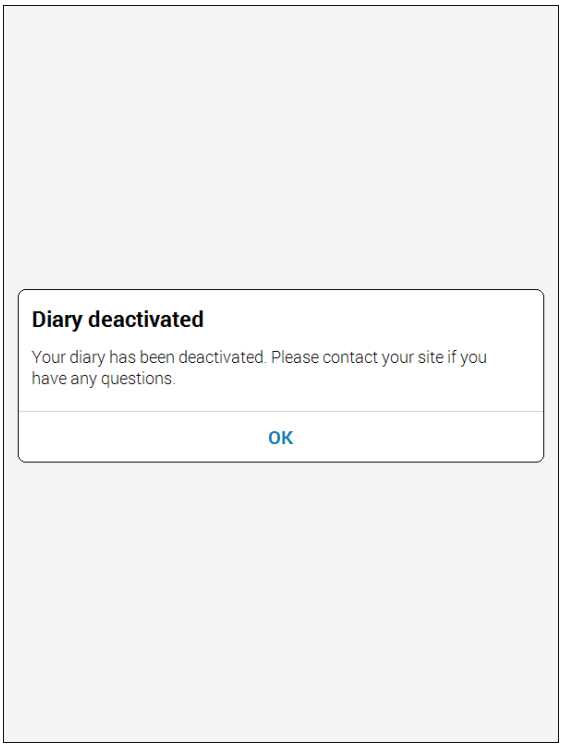


Screen 31



Screen 32

090177e195746b2f\Approved\Approved On: 06-Nov-2020 14:14 (GMT)



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.'

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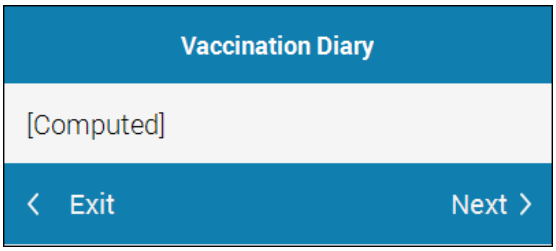
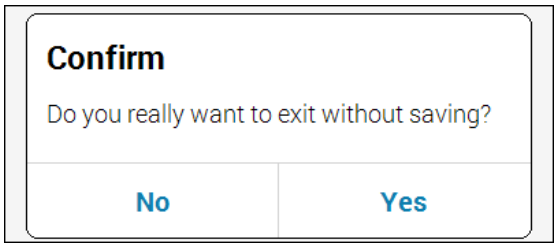
3 Form: Vaccination Diary



Screen 1



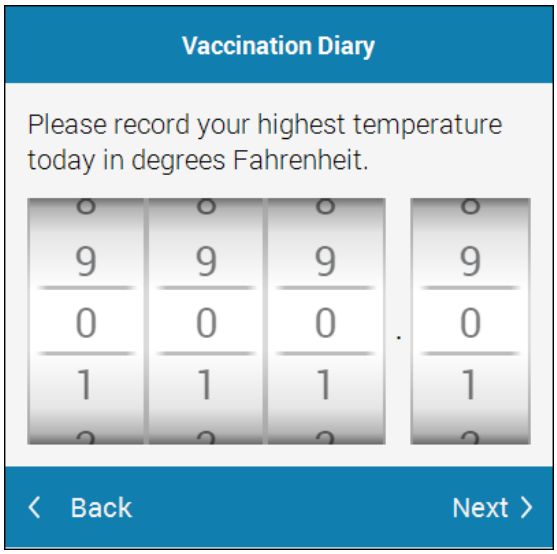
Message 1

[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

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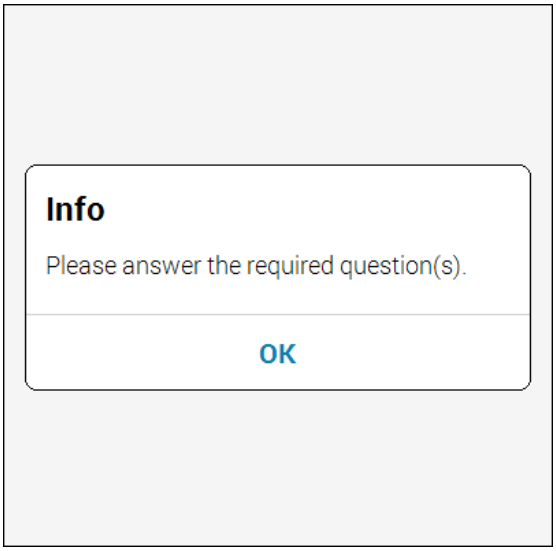
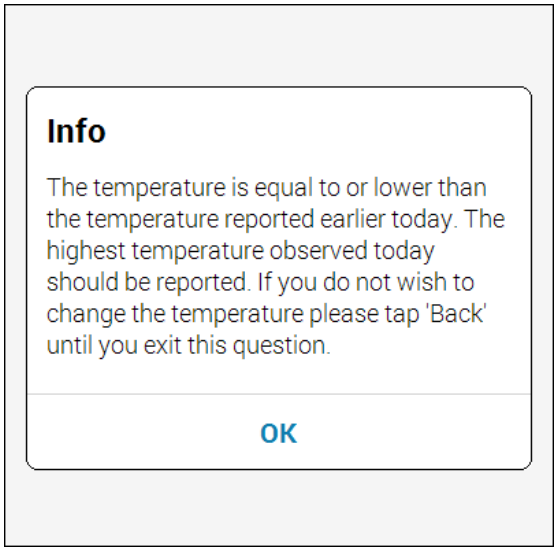
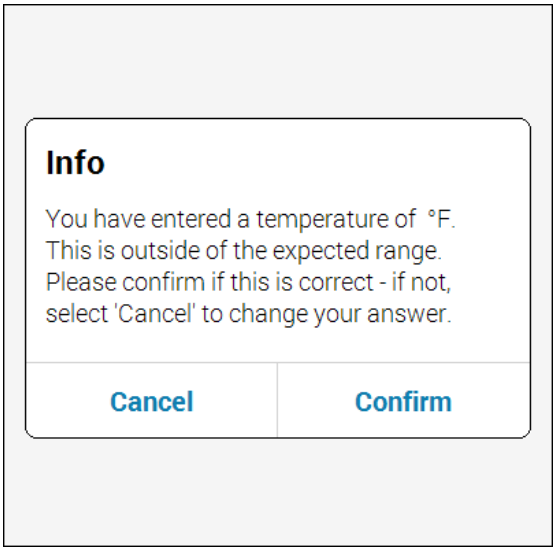


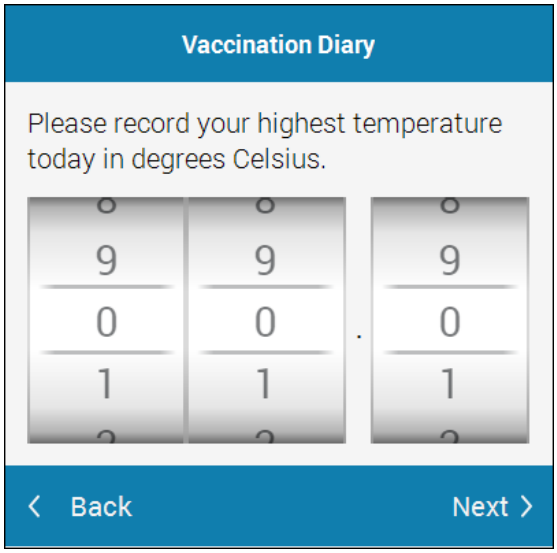
Message 1



Message 2

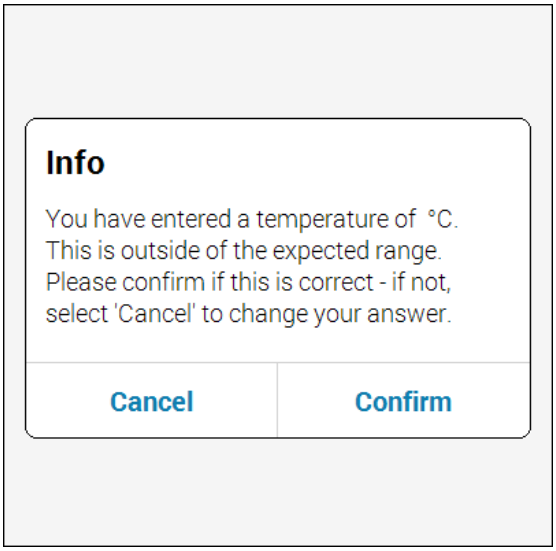


Message 3

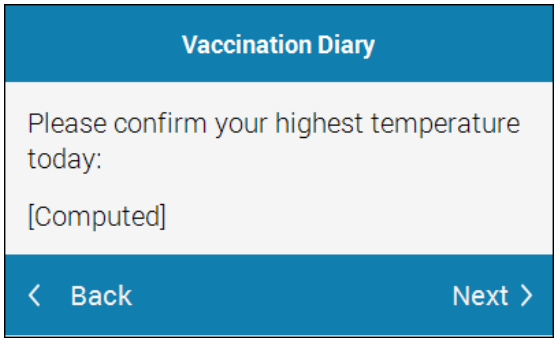


Screen 4

090177e195746b2f\Approved\Approved On: 06-Nov-2020 14:14 (GMT)

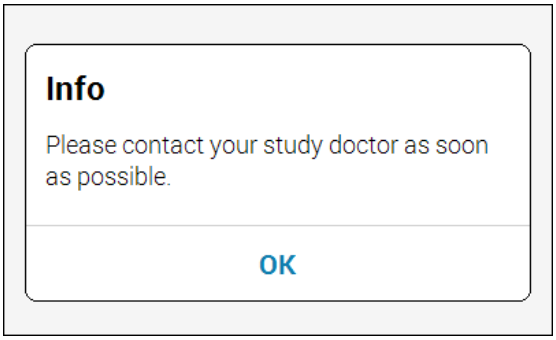


Message 3

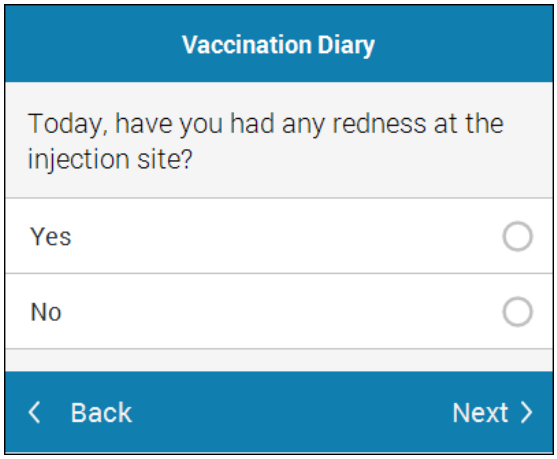


Screen 5

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



Message 1



Screen 6

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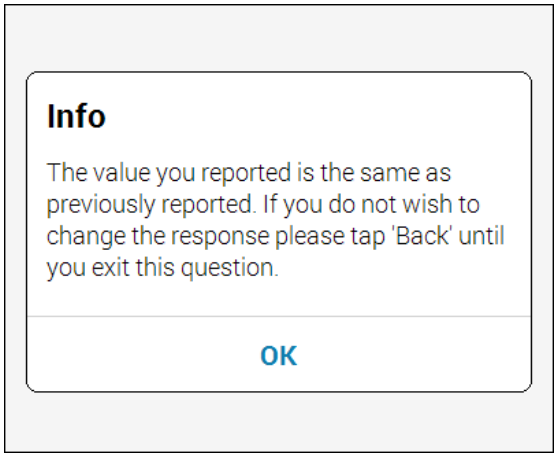
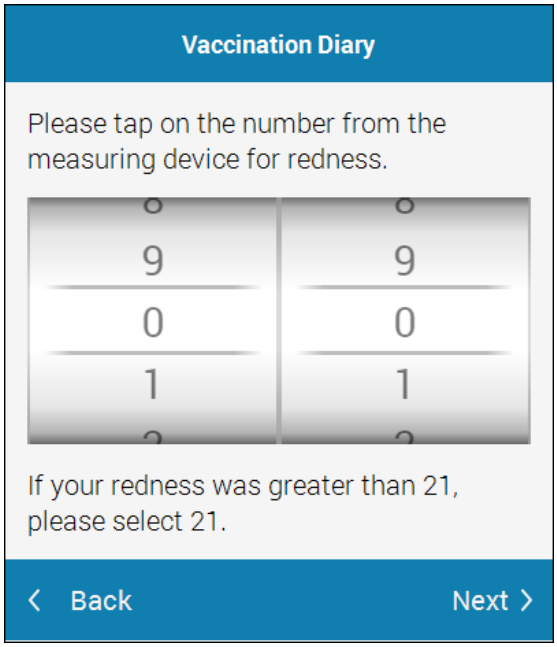
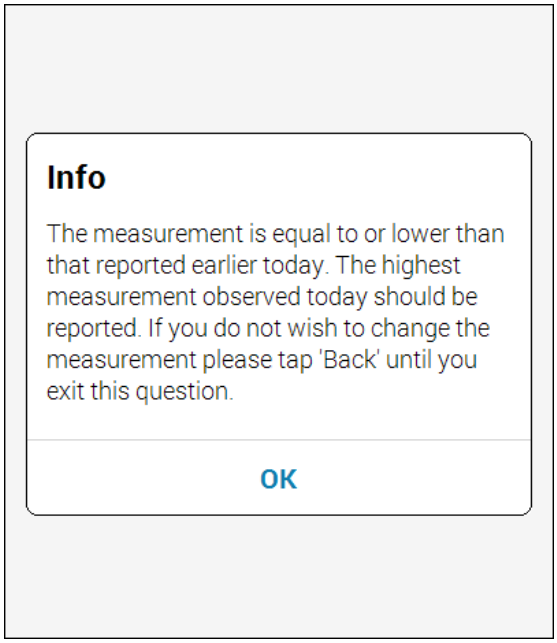


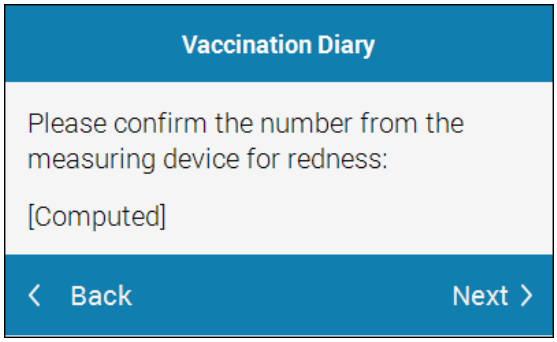
Message 2



Screen 7



Message 2



Screen 8

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

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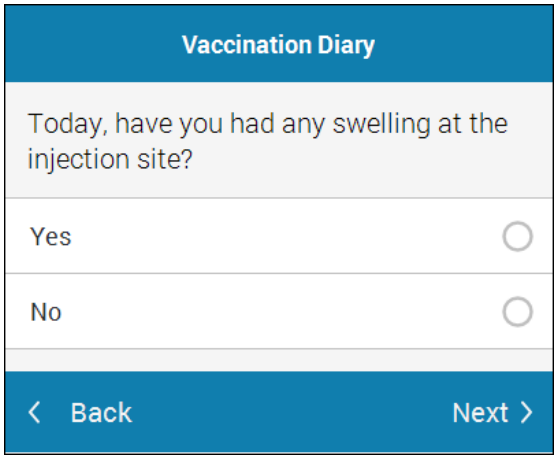
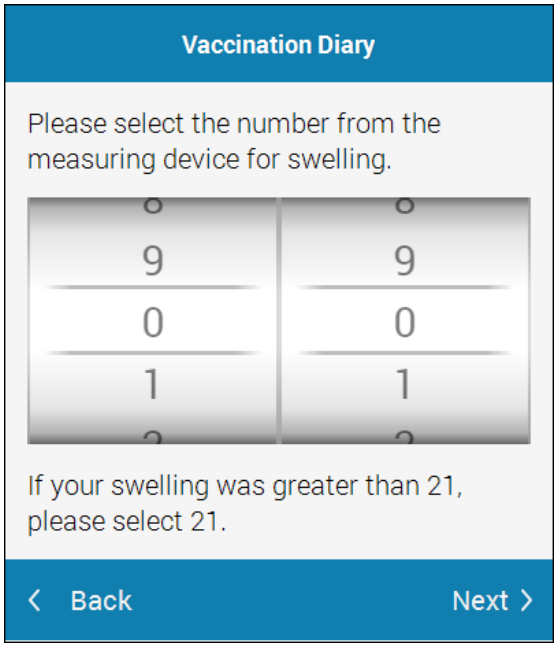
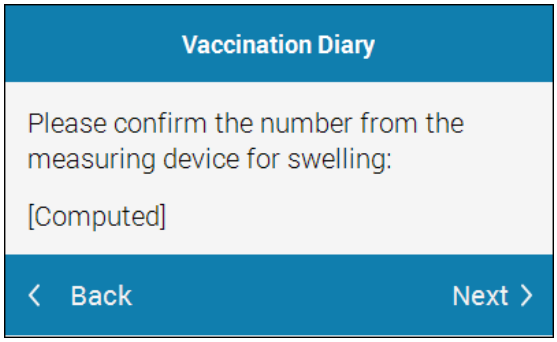


Screen 9

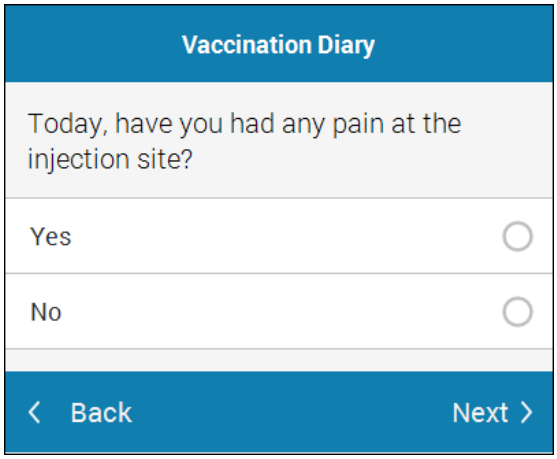


Screen 10



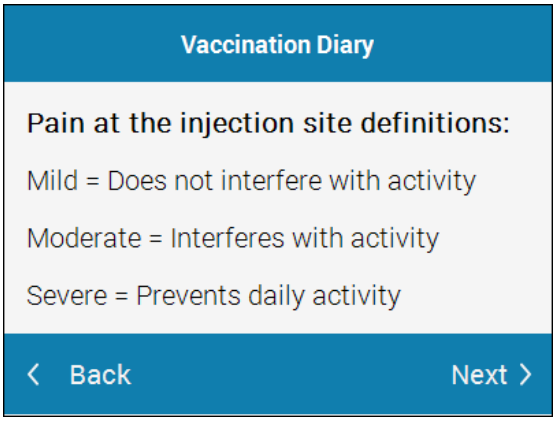
Screen 11

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

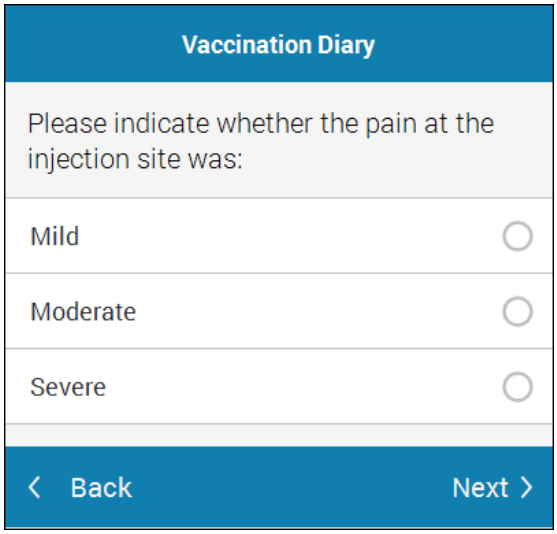


Screen 12

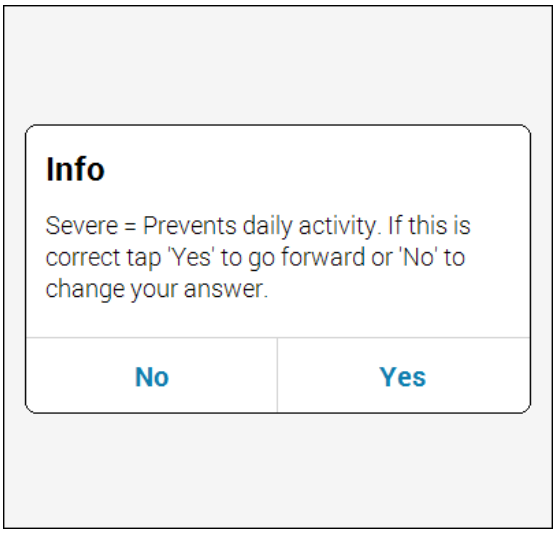
090177e195746b2f\Approved\Approved On: 06-Nov-2020 14:14 (GMT)



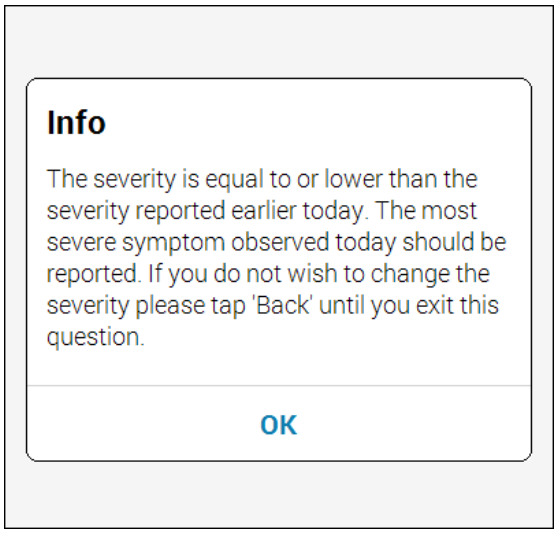
Screen 13



Screen 14



Message 2



Message 4

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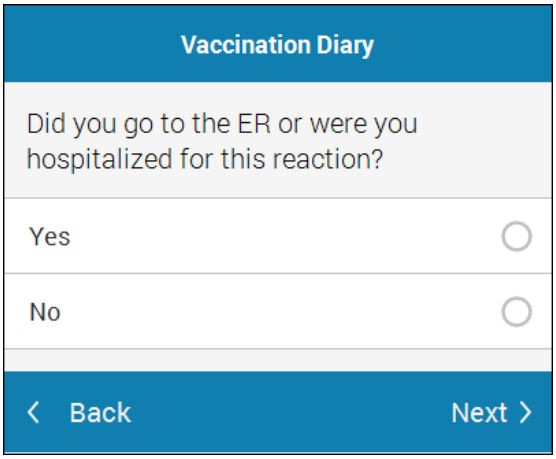
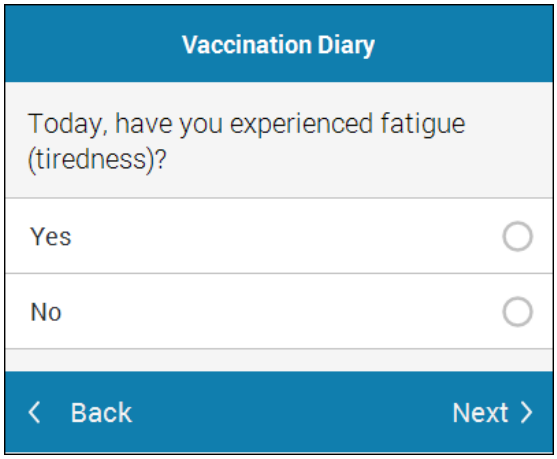
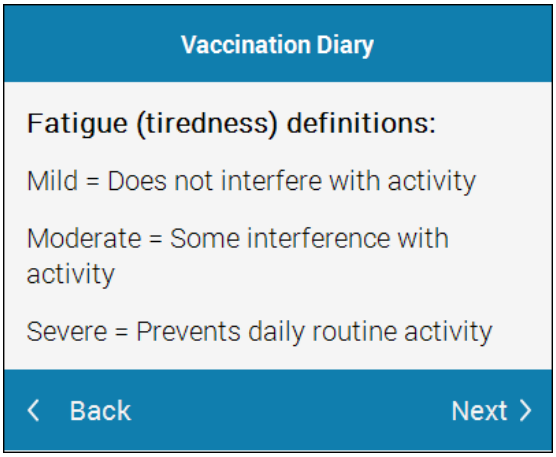


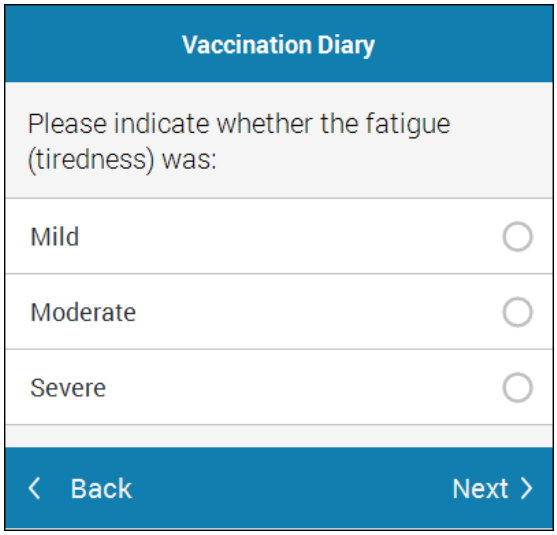
Screen 15



Screen 16

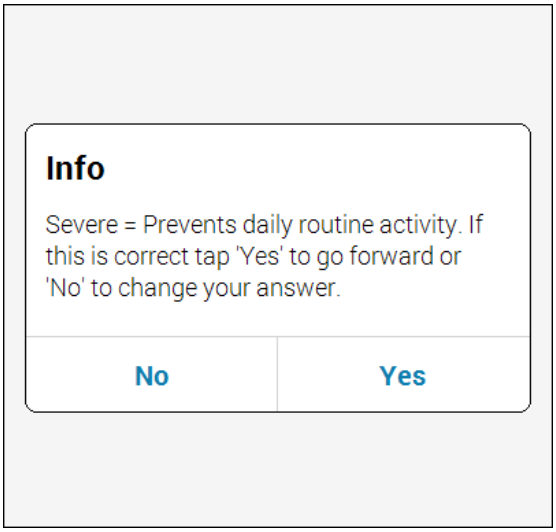


Screen 17

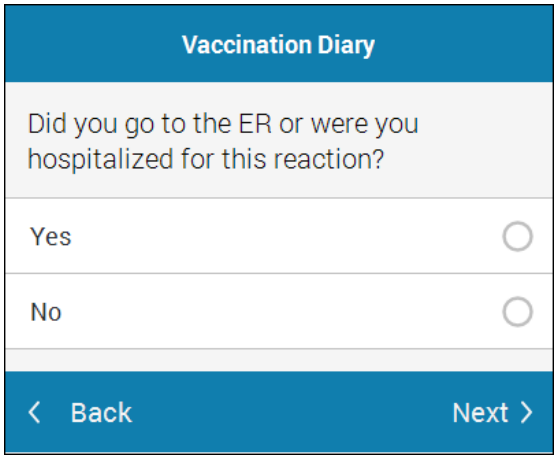


Screen 18

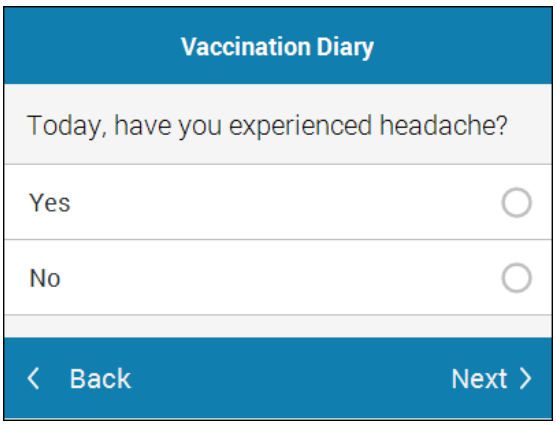
090177e195746b2f\Approved\Approved On: 06-Nov-2020 14:14 (GMT)



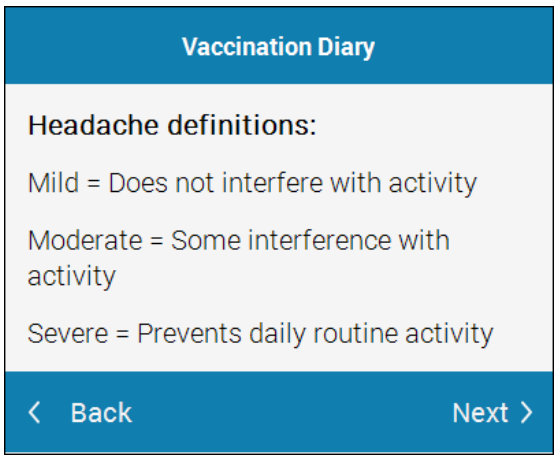
Message 2



Screen 19

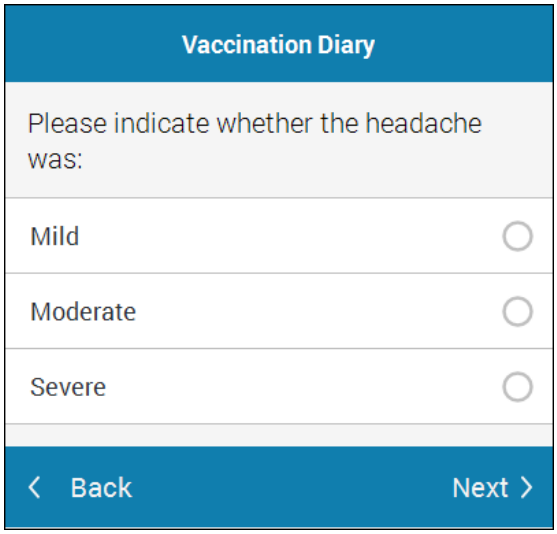


Screen 20

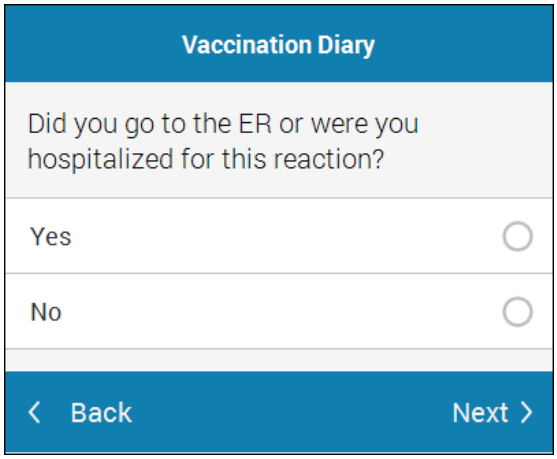


Screen 21

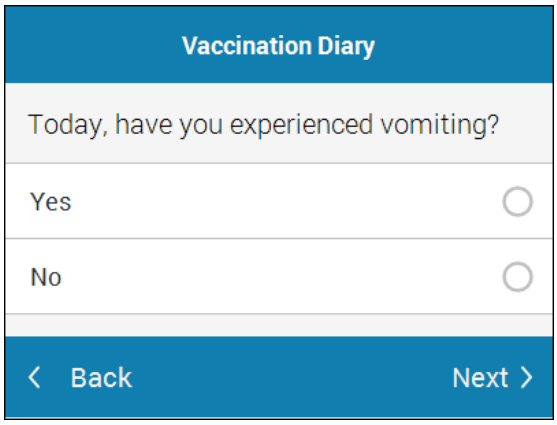
090177e195746b2f\Approved\Approved On: 06-Nov-2020 14:14 (GMT)



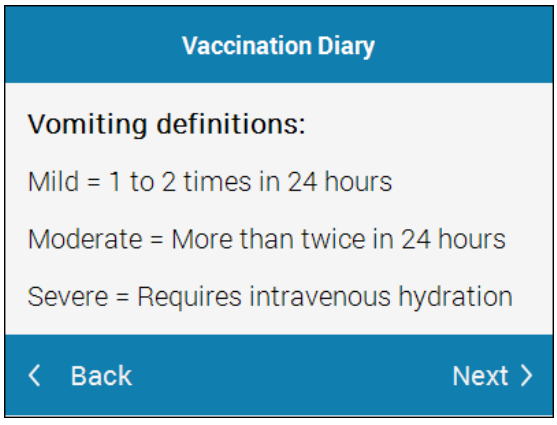
Screen 22



Screen 23

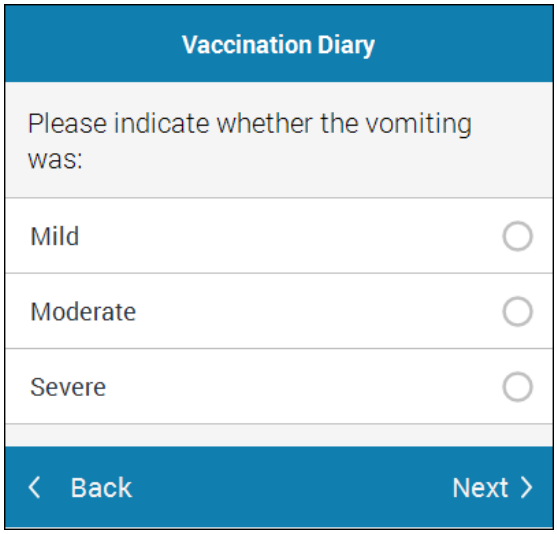


Screen 24

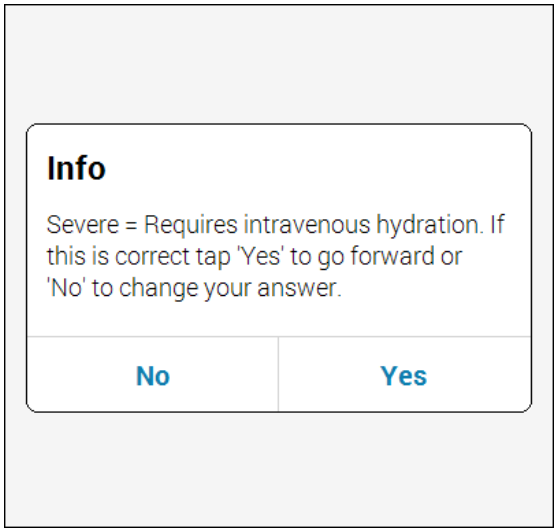


Screen 25

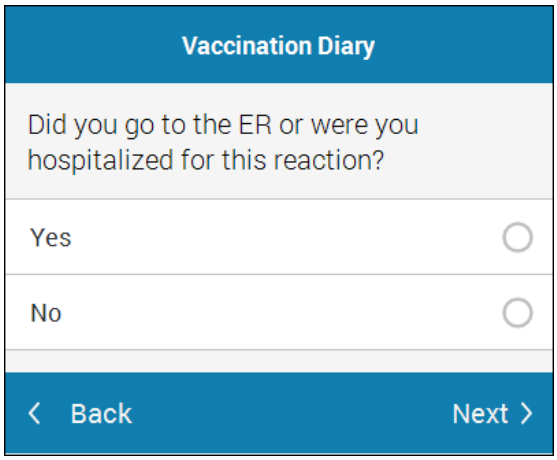
090177e195746b2f\Approved\Approved On: 06-Nov-2020 14:14 (GMT)



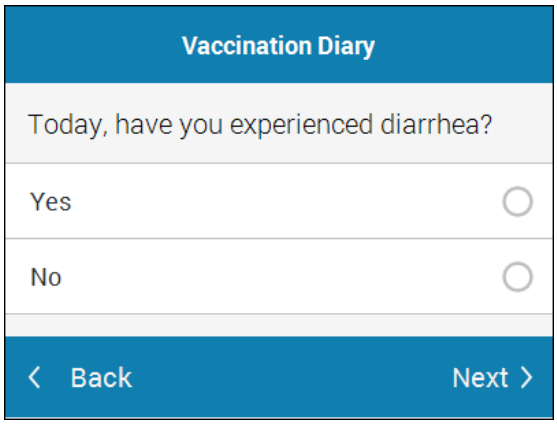
Screen 26



Message 2

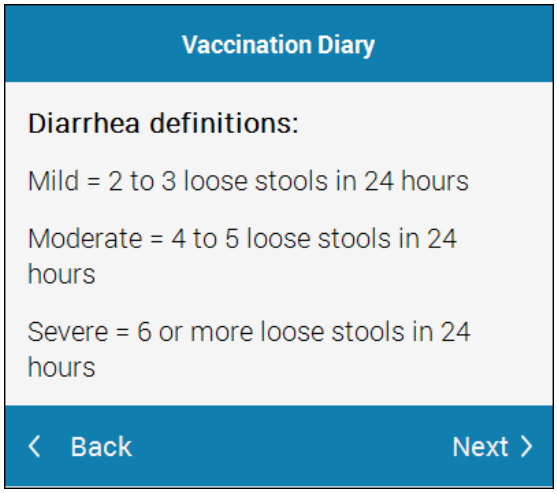


Screen 27

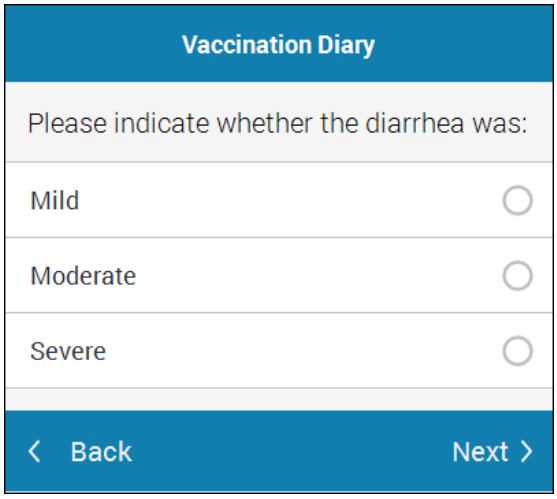


Screen 28

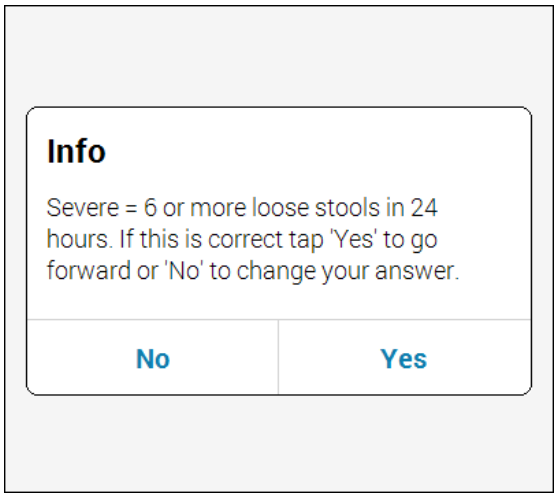
090177e195746b2f\Approved\Approved On: 06-Nov-2020 14:14 (GMT)



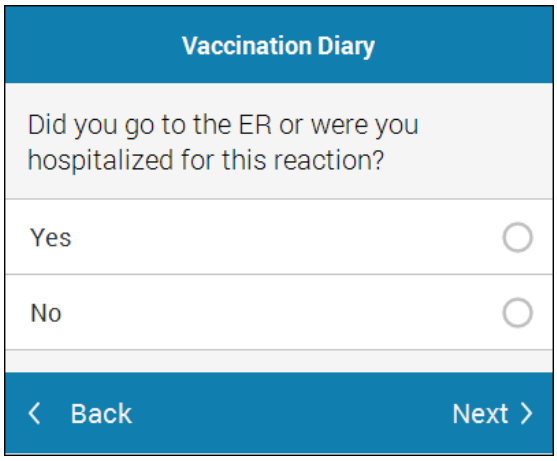
Screen 29



Screen 30

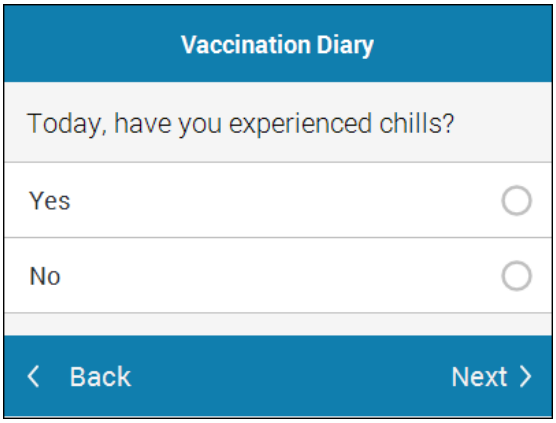


Message 2

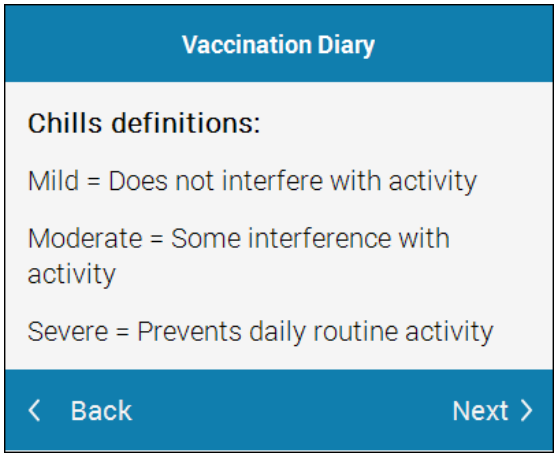


Screen 31

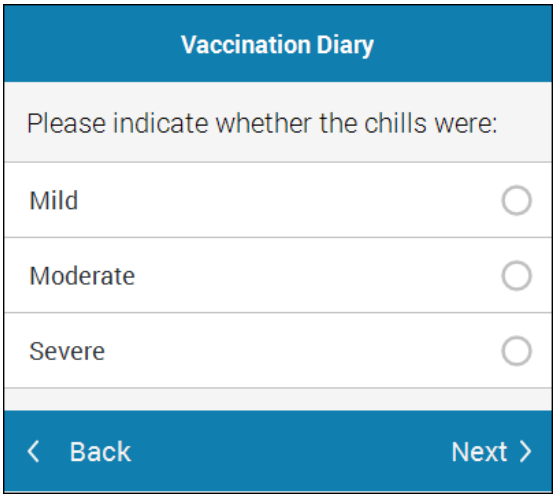
090177e195746b2f\Approved\Approved On: 06-Nov-2020 14:14 (GMT)



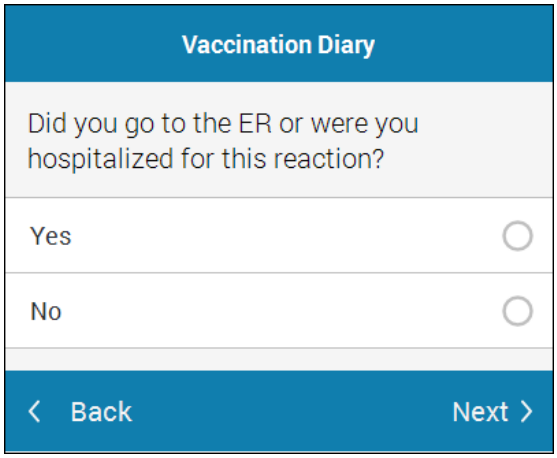
Screen 32



Screen 33

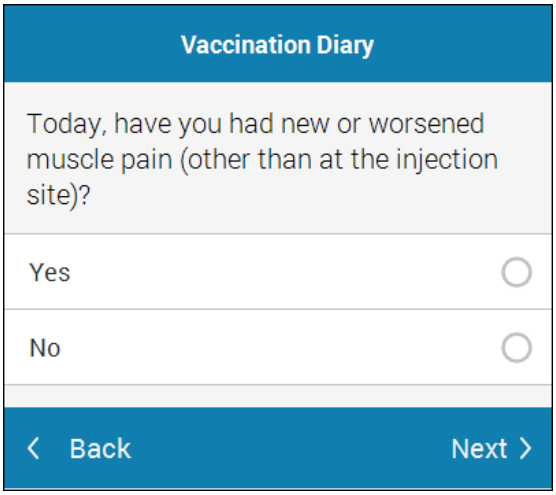


Screen 34

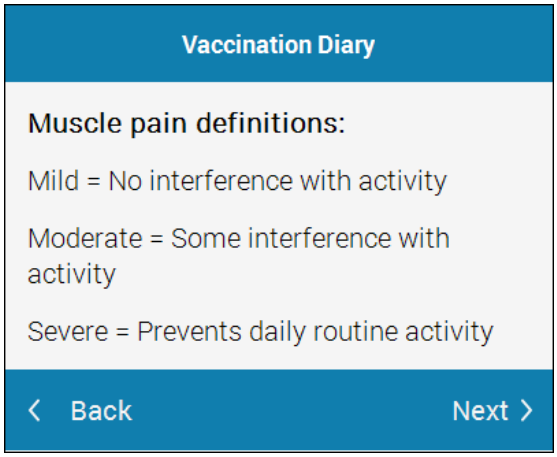


Screen 35

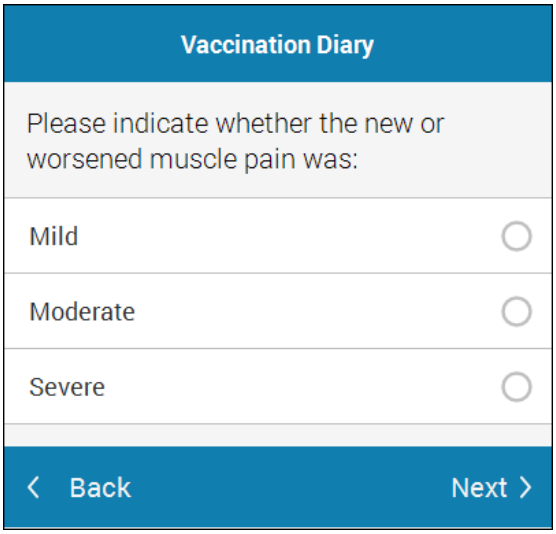
090177e195746b2f\Approved\Approved On: 06-Nov-2020 14:14 (GMT)



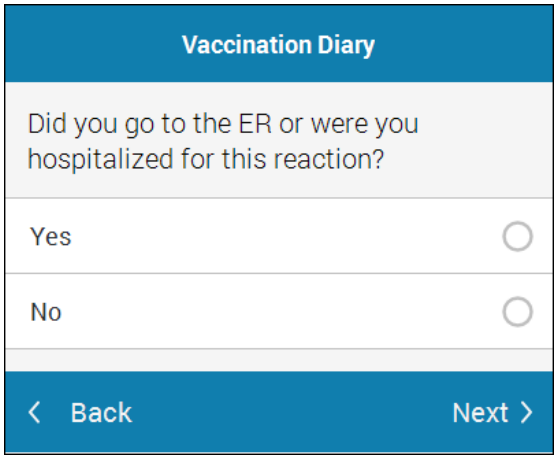
Screen 36



Screen 37

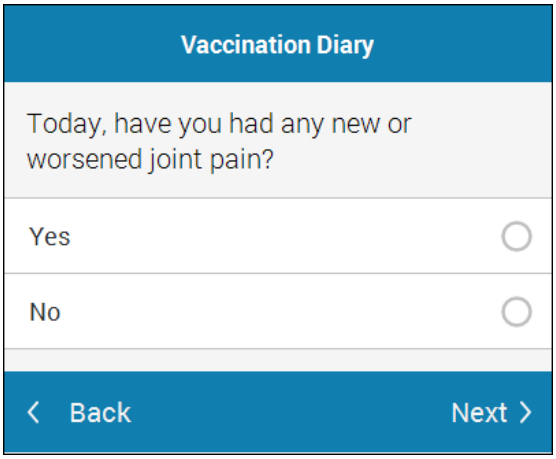


Screen 38

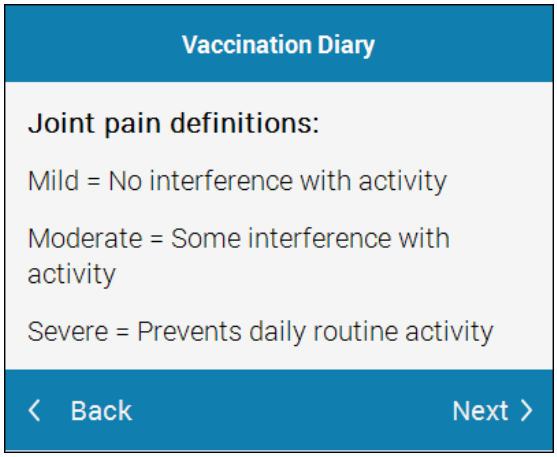


Screen 39

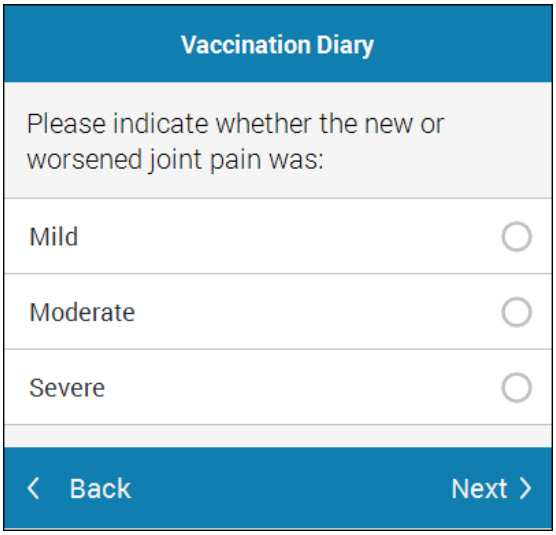
090177e195746b2f\Approved\Approved On: 06-Nov-2020 14:14 (GMT)



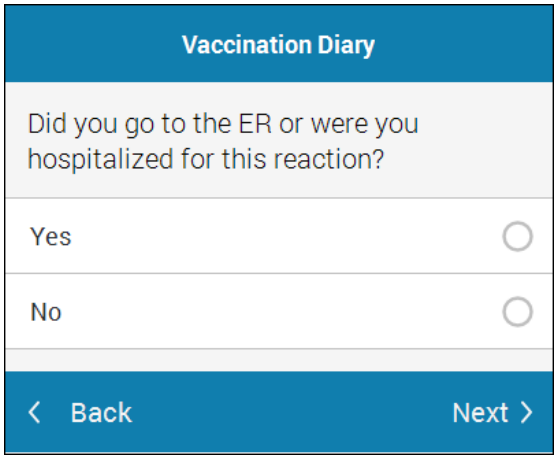
Screen 40



Screen 41



Screen 42



Screen 43

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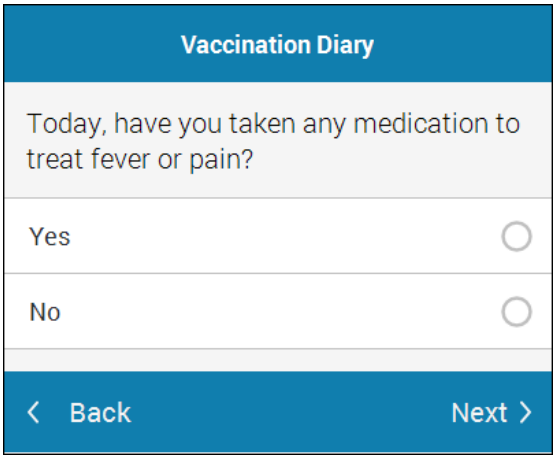
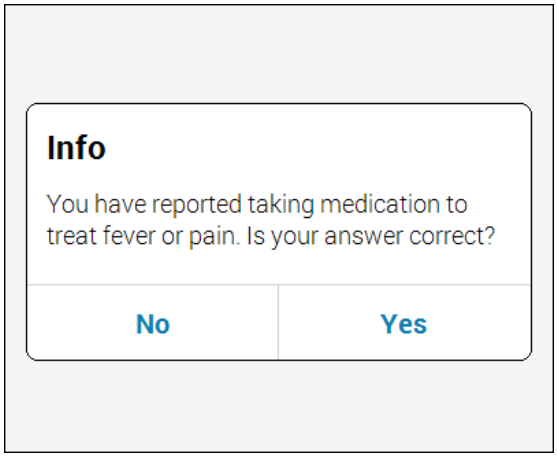
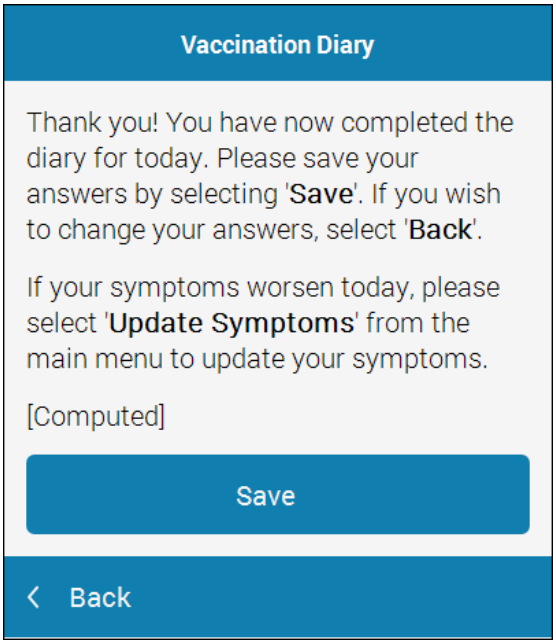


Screen 44



Message 2

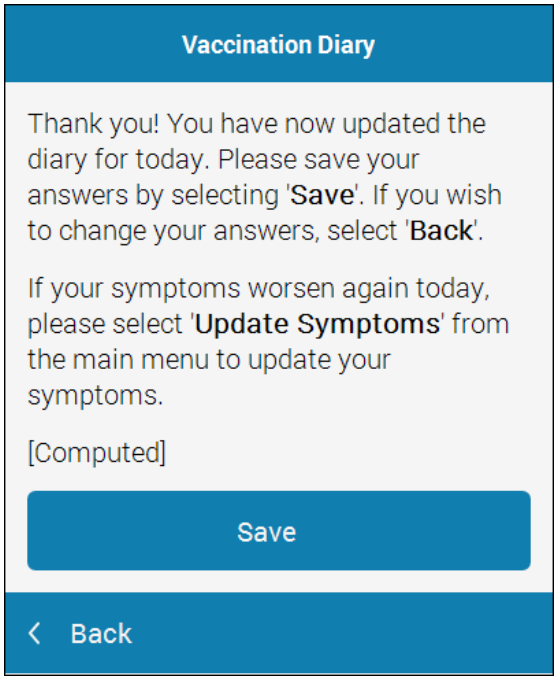


Screen 45

[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).

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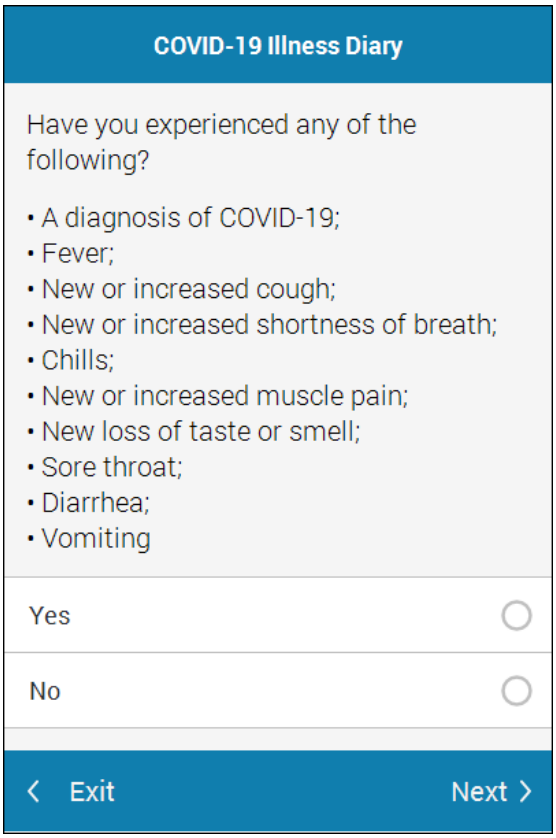
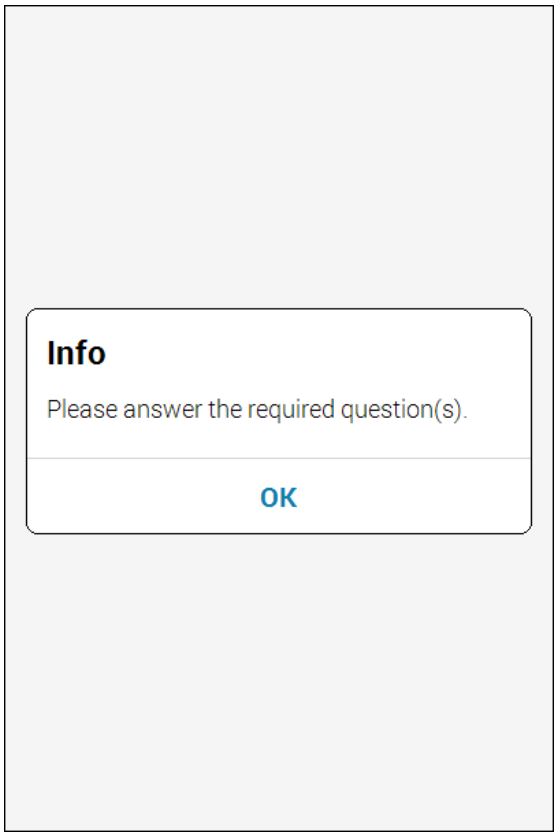
4 Form: COVID-19 Illness Diary



Screen 1



Message 1

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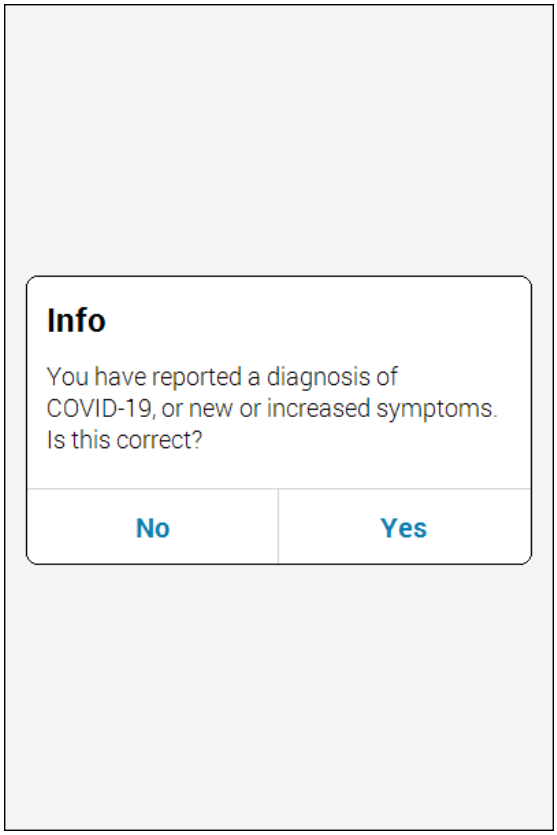
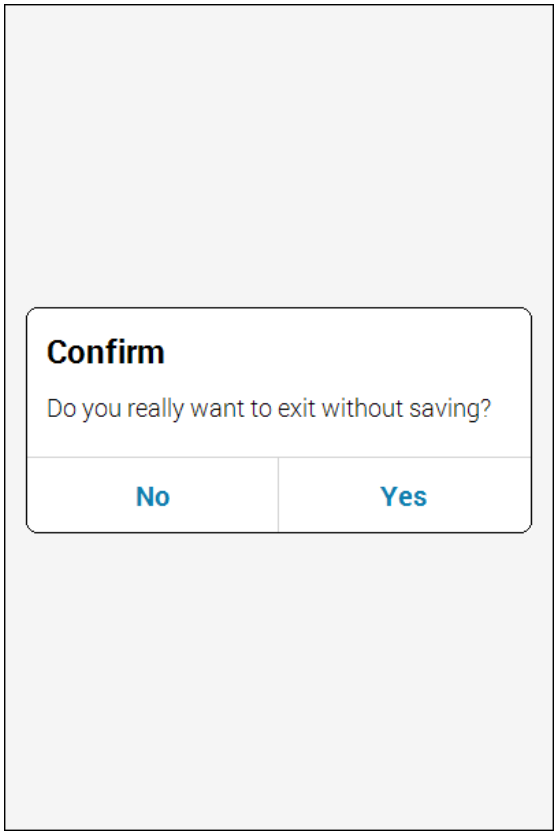
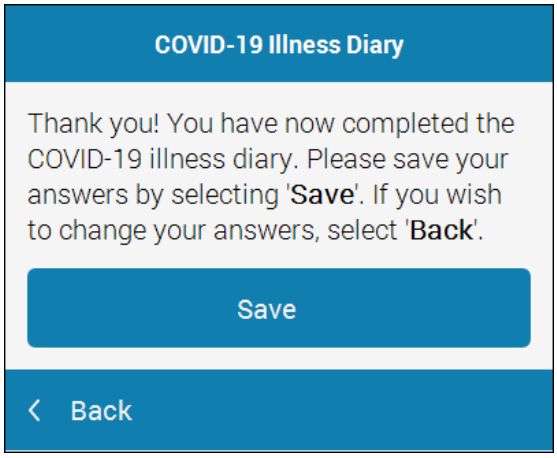


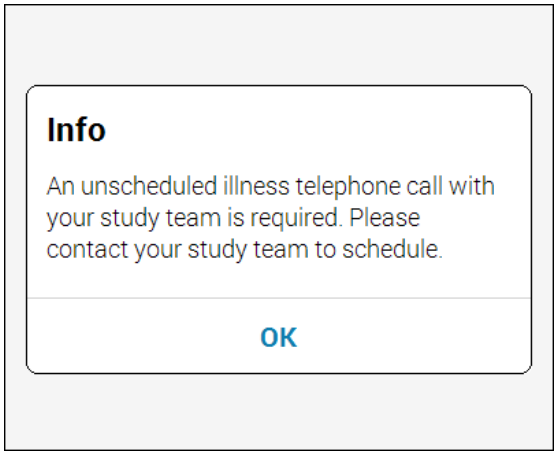
Message 2



Message 3



Screen 2



Message 1

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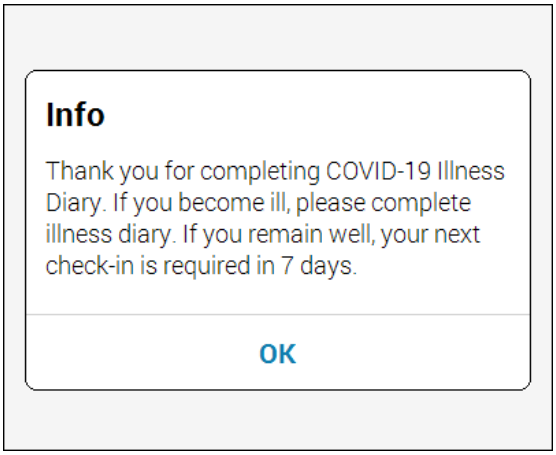

Message 2

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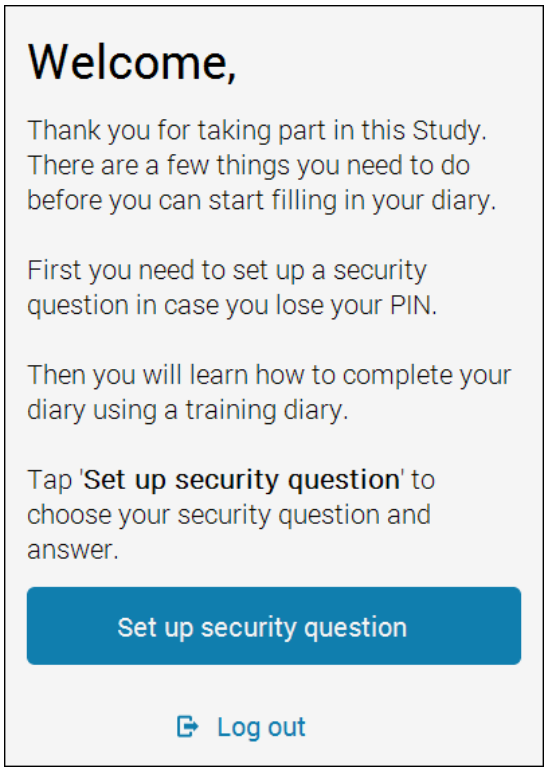
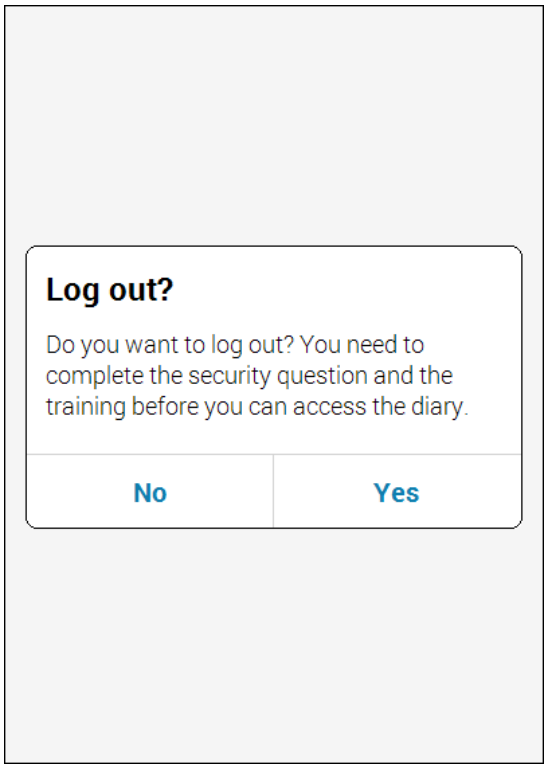
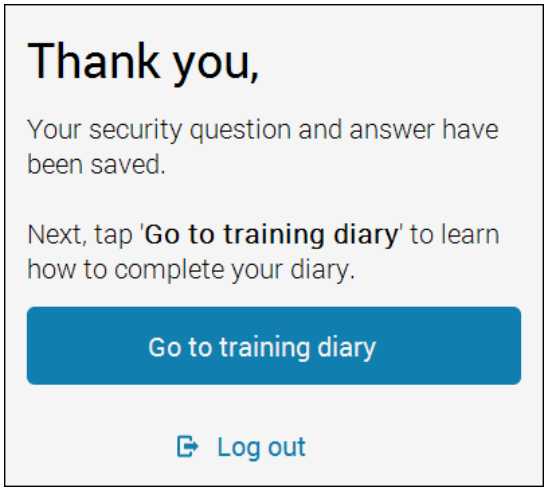
5 Form: Patient main menu



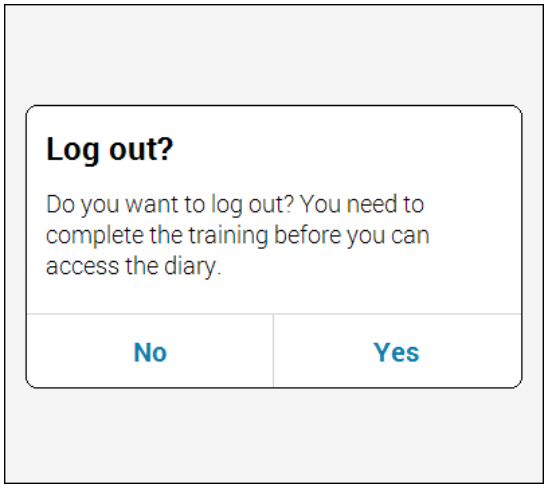
Screen 1



Message 1



Screen 2



Message 1

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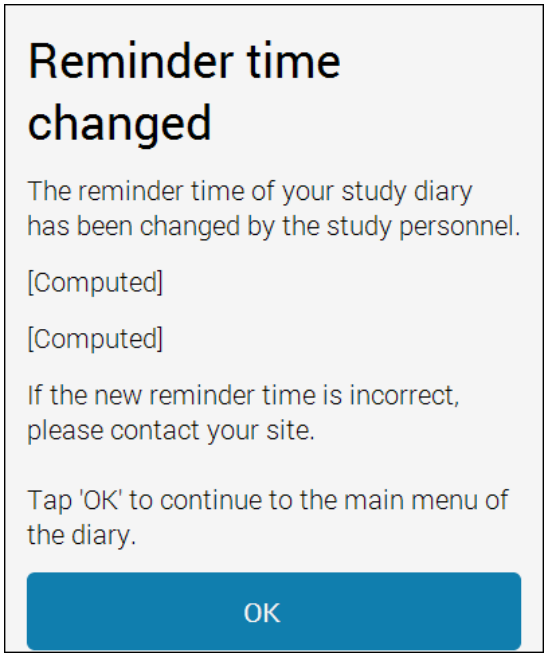
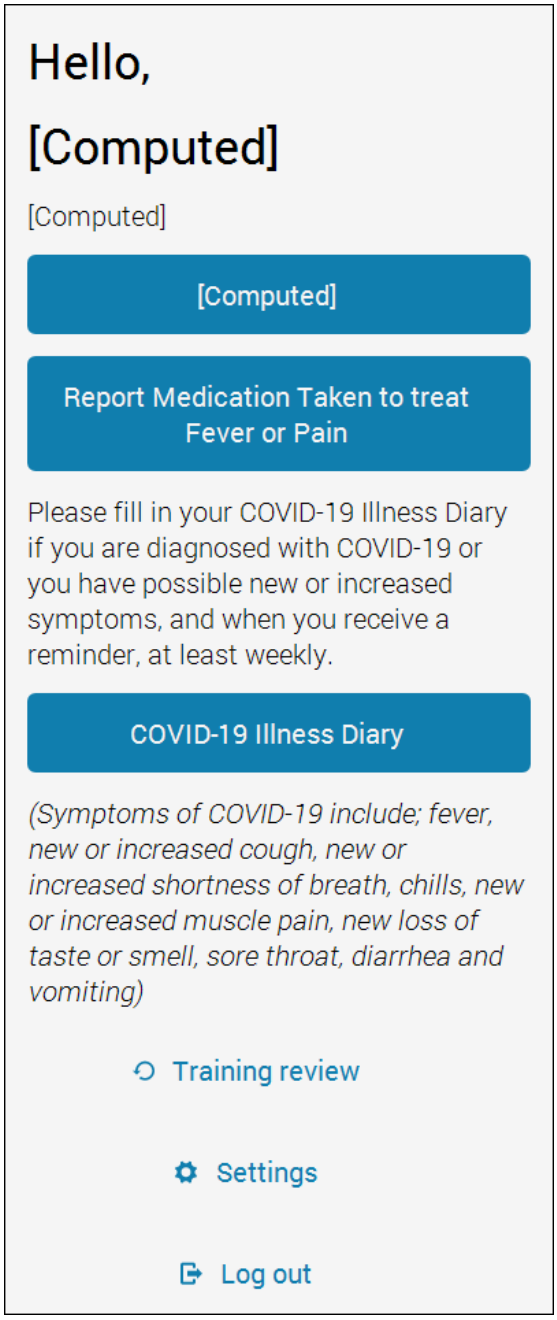


Screen 3

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>."

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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”

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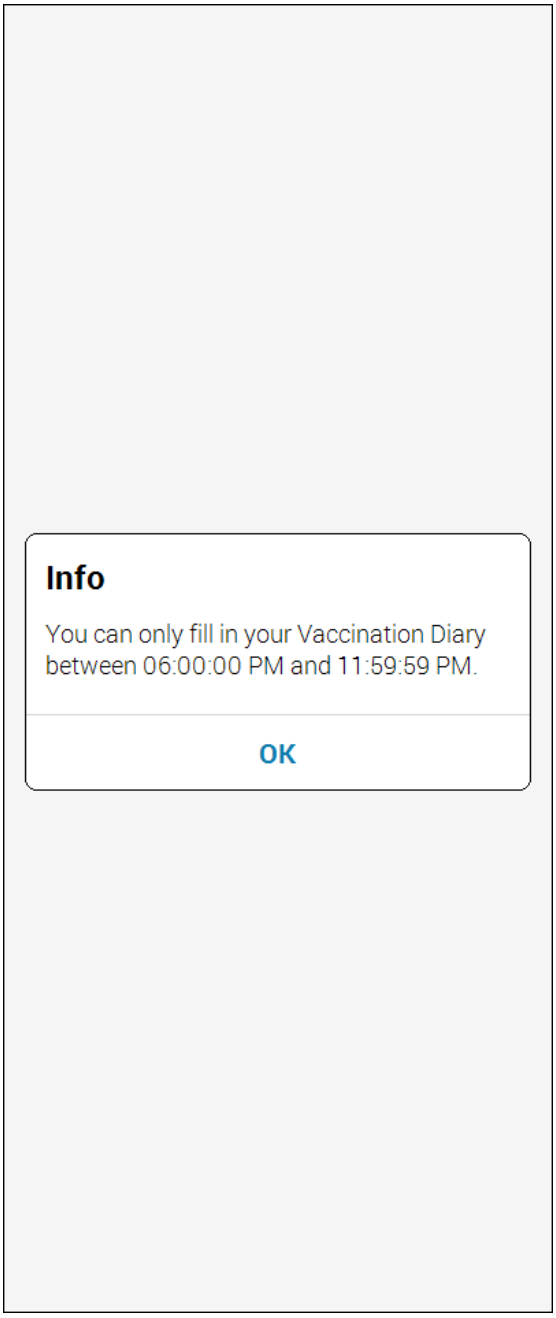
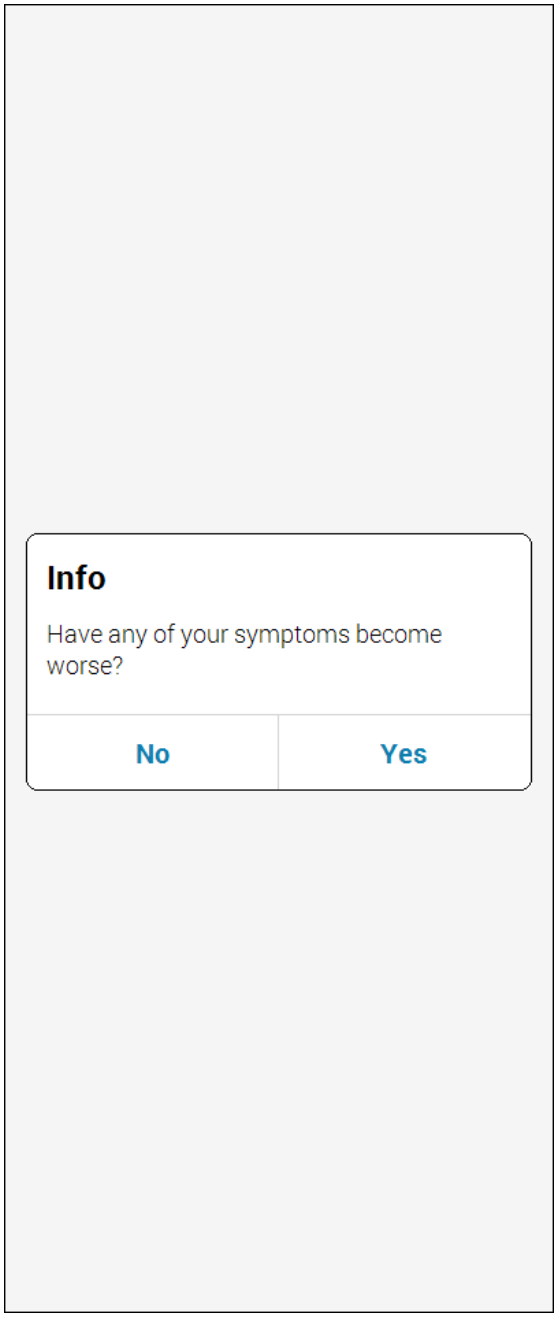


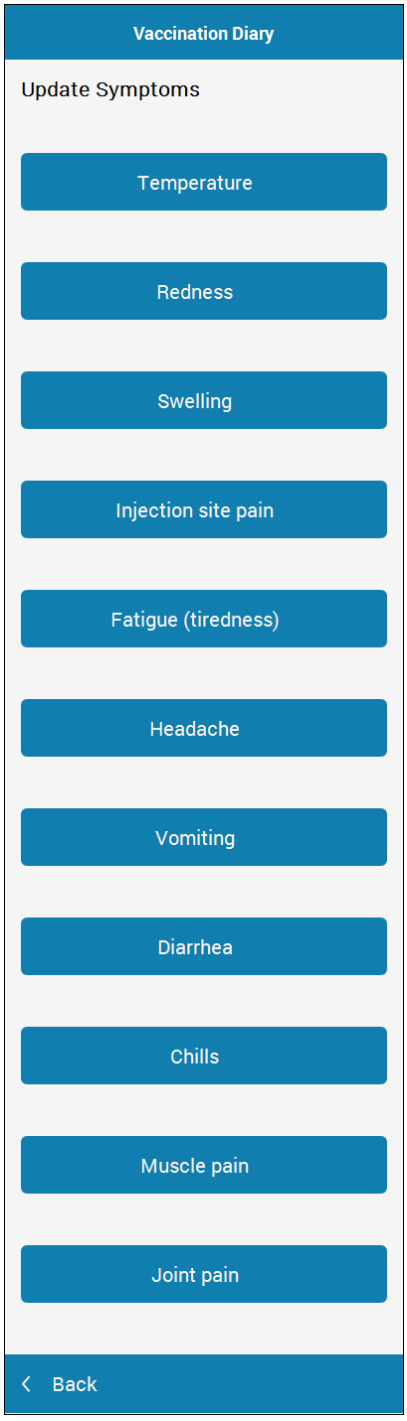
Message 1

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

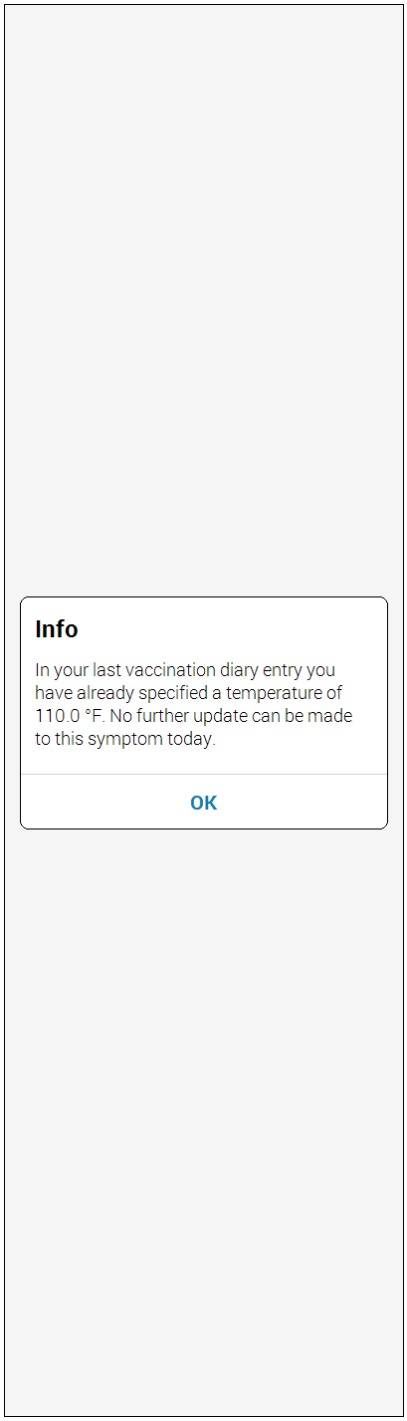


Message 2

090177e195746b2f\Approved\Approved On: 06-Nov-2020 14:14 (GMT)

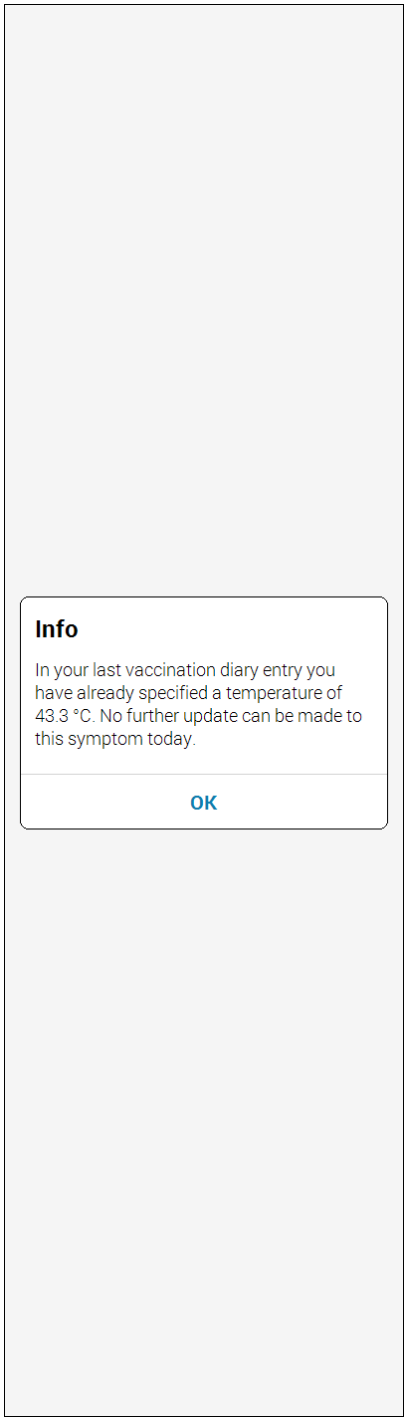


Screen 5

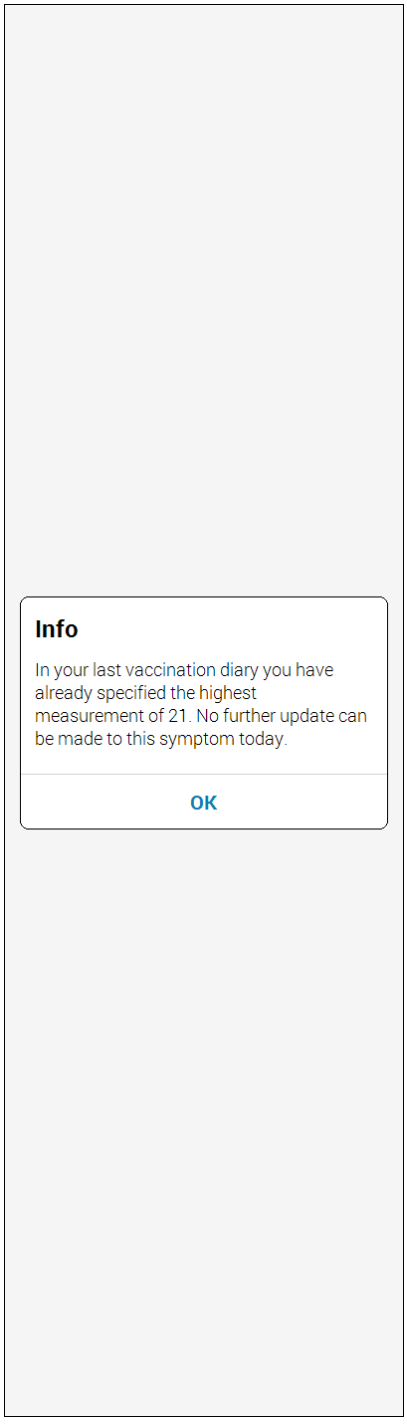


Message 2

090177e195746b2f\Approved\Approved On: 06-Nov-2020 14:14 (GMT)



Message 3



Message 5

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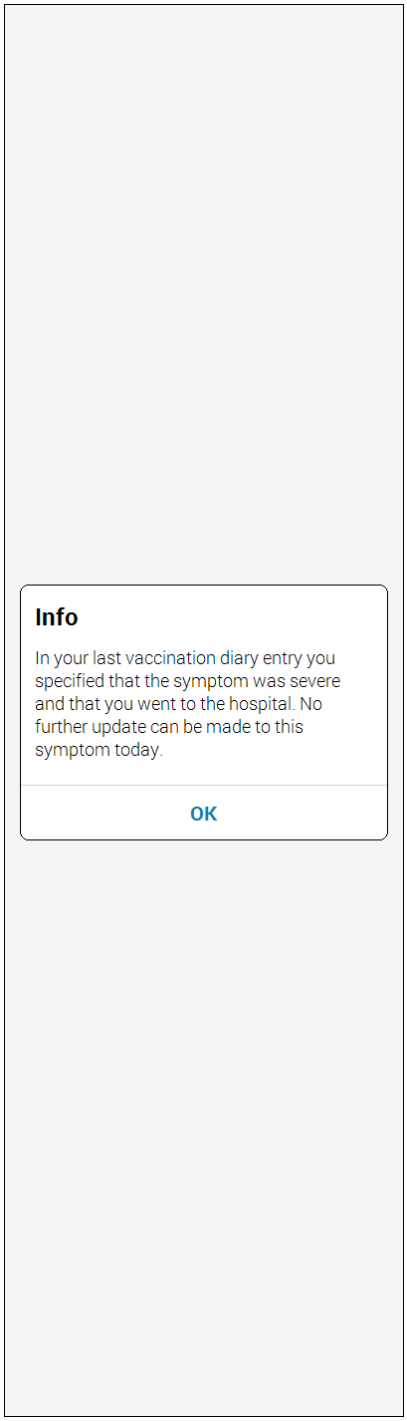

Message 9

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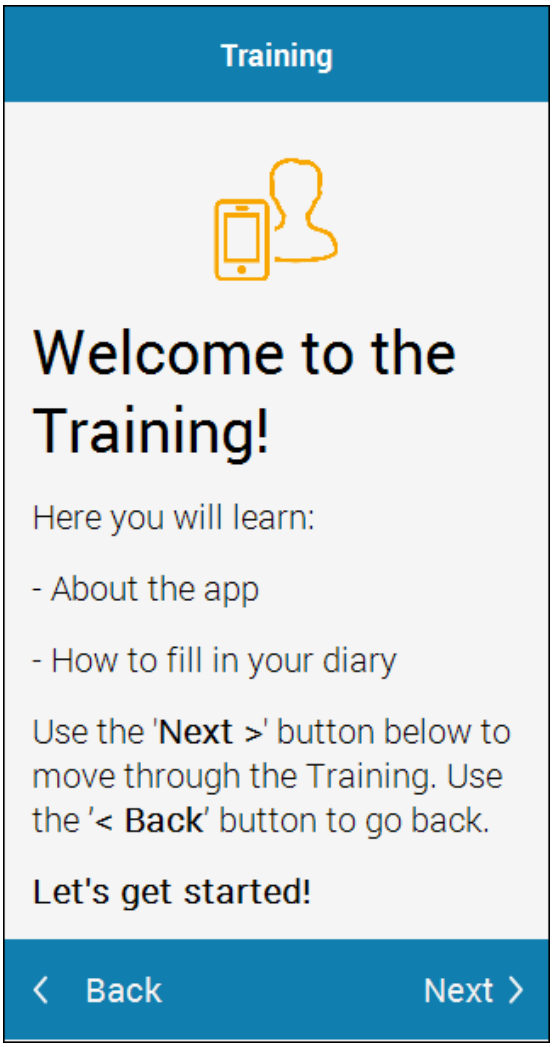
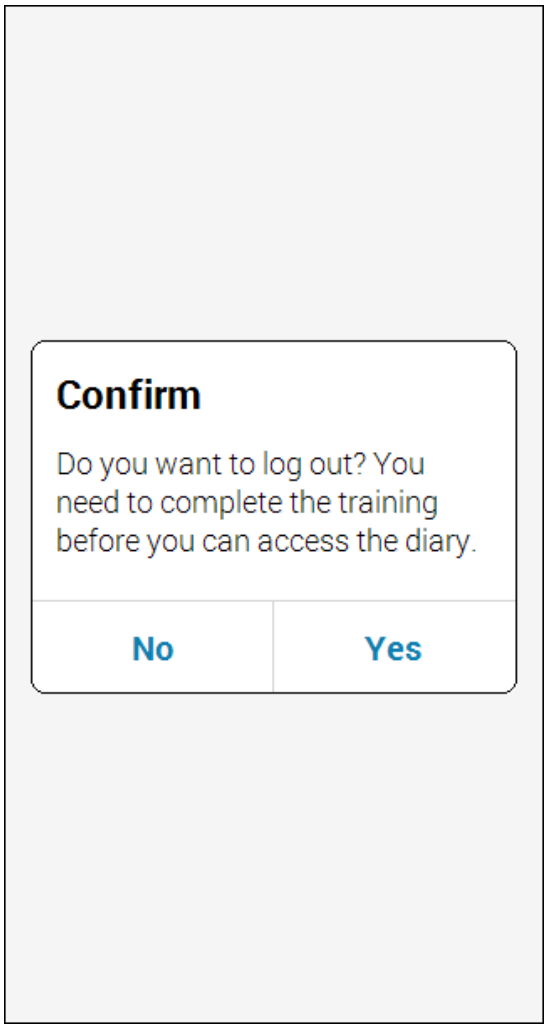
6 Form: Subject training diary

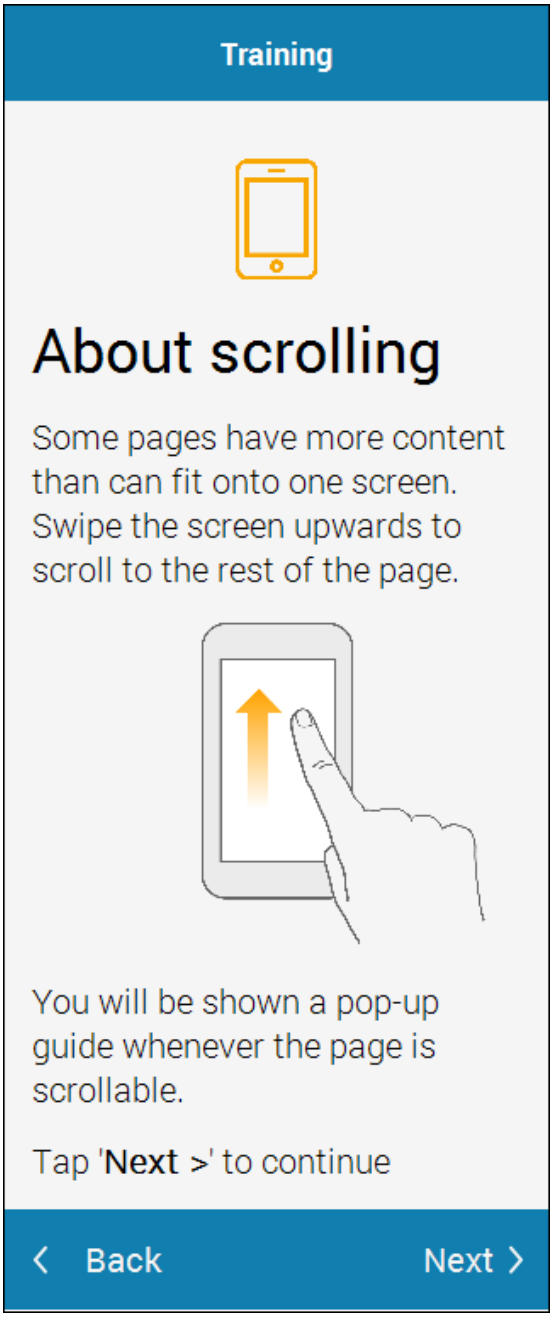


Screen 1

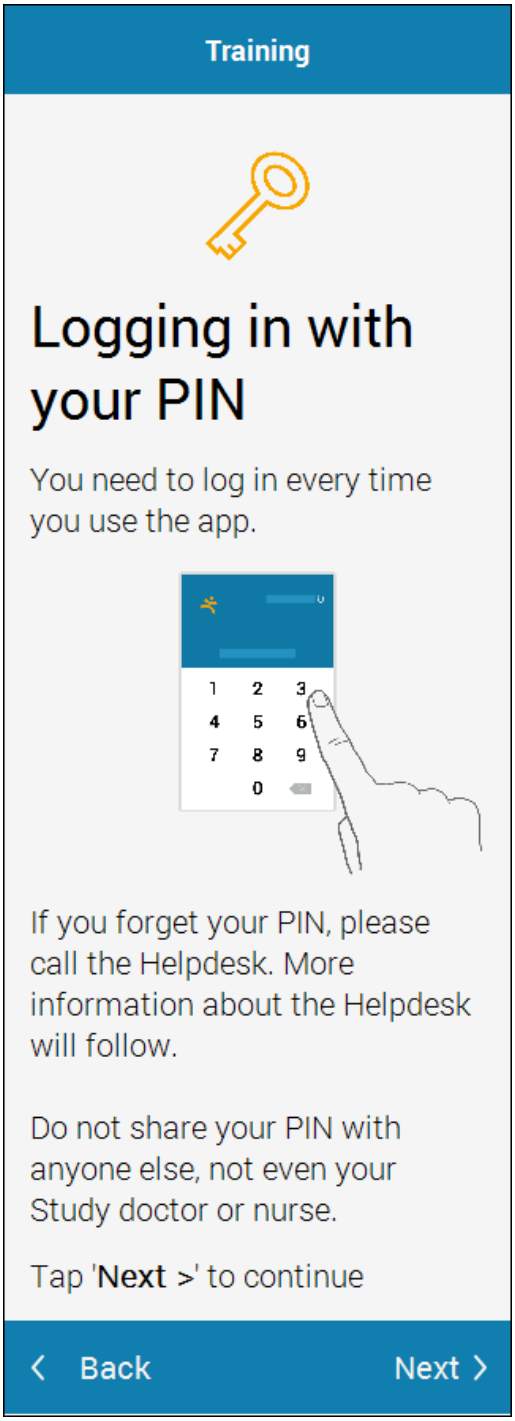


Message 1

090177e195746b2f\Approved\Approved On: 06-Nov-2020 14:14 (GMT)

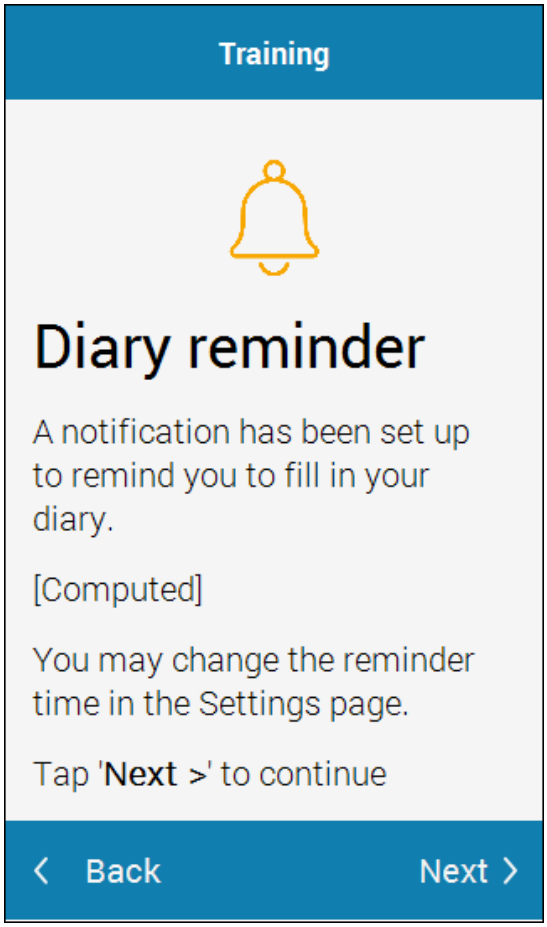


Screen 2



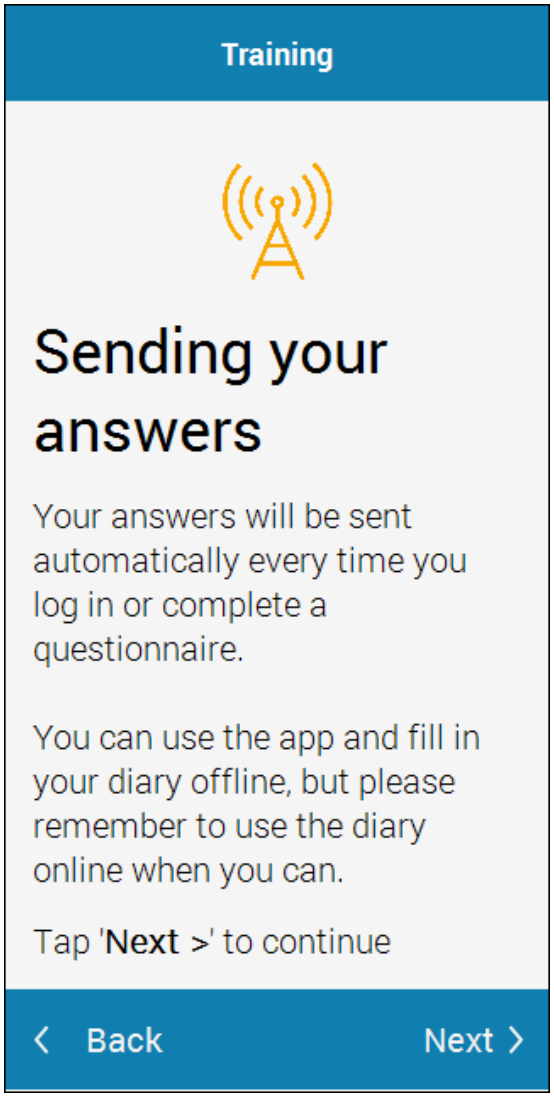
Screen 3

090177e195746b2f\Approved\Approved On: 06-Nov-2020 14:14 (GMT)



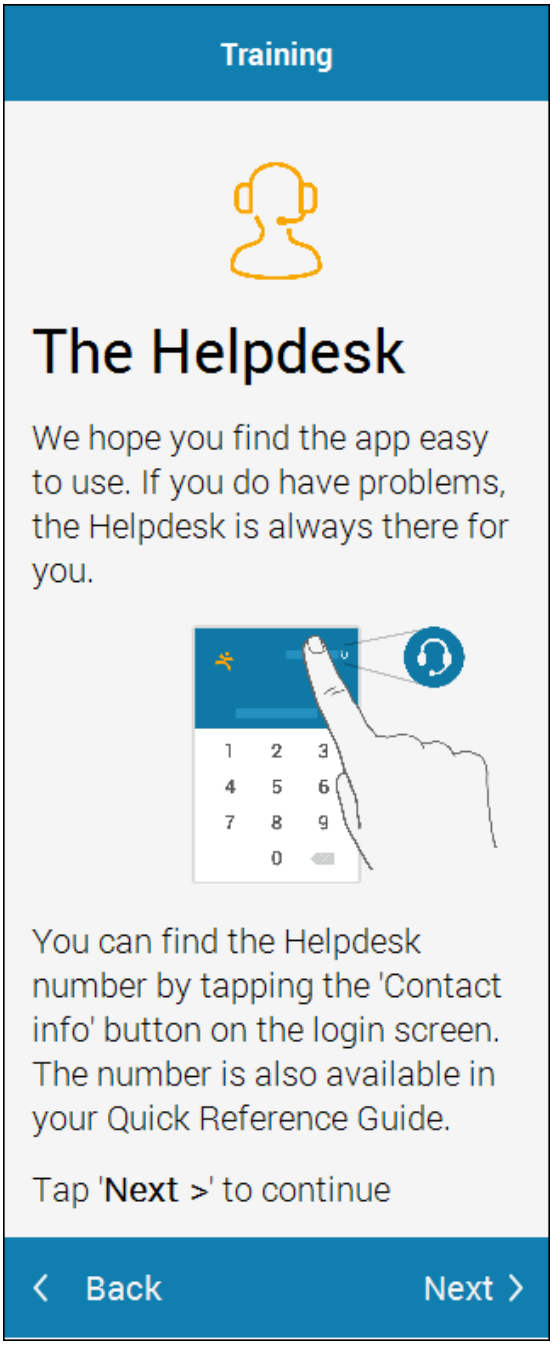
Screen 4

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

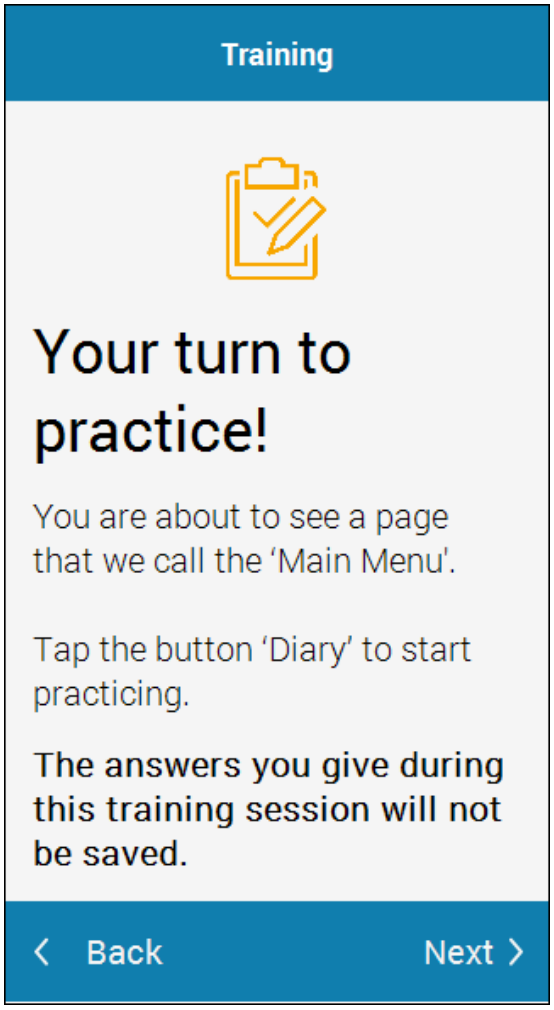


Screen 5

090177e195746b2f\Approved\Approved On: 06-Nov-2020 14:14 (GMT)

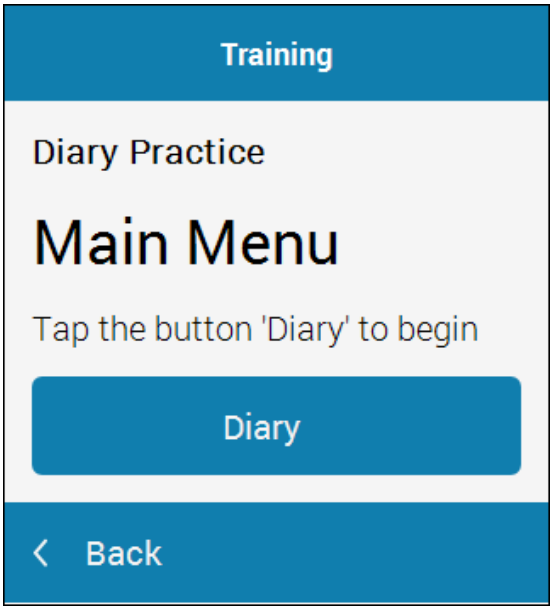


Screen 6

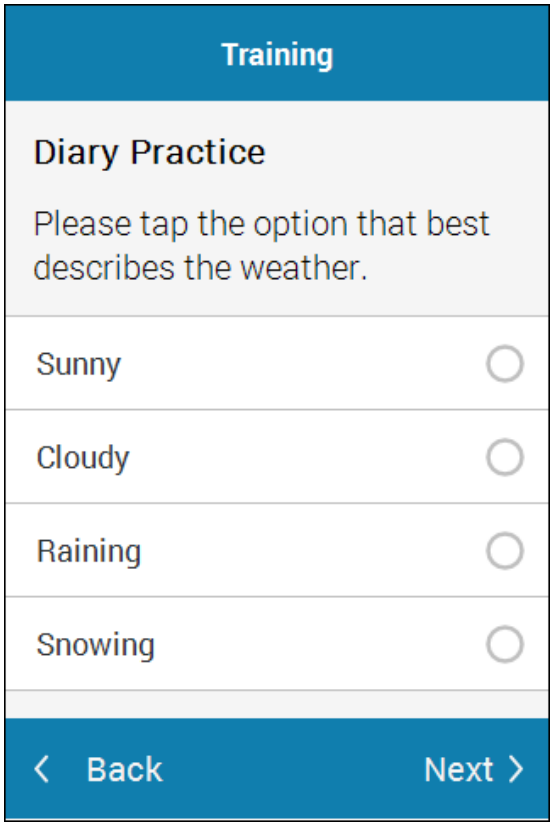


Screen 7

090177e195746b2f\Approved\Approved On: 06-Nov-2020 14:14 (GMT)

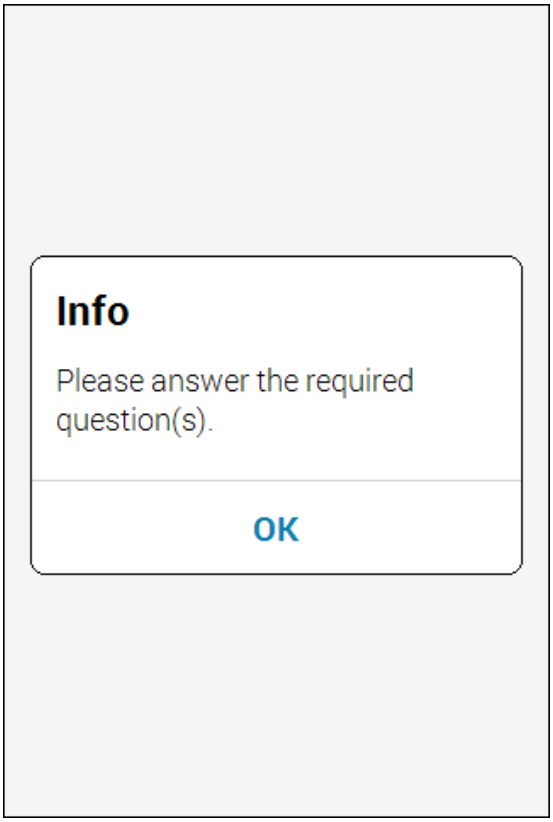


Screen 8

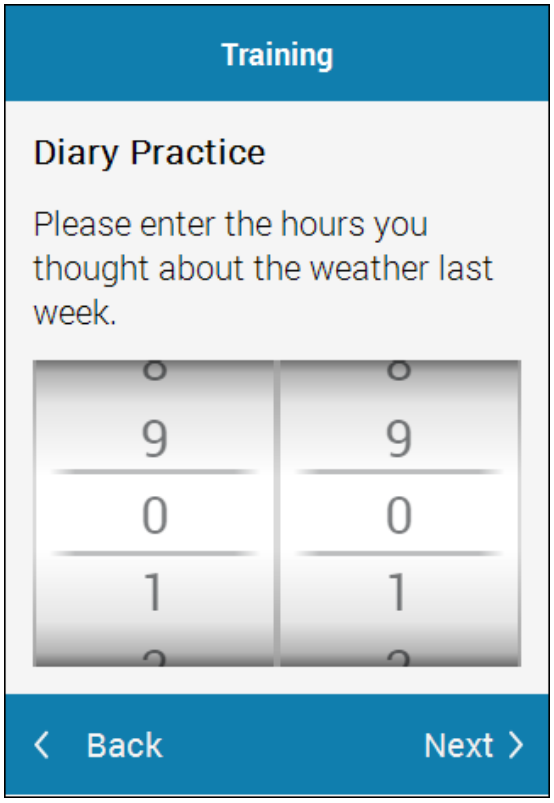


Screen 9

090177e195746b2f\Approved\Approved On: 06-Nov-2020 14:14 (GMT)

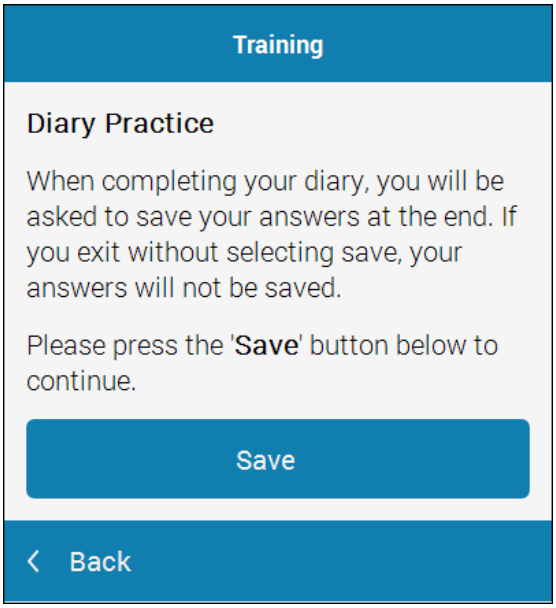


Message 1

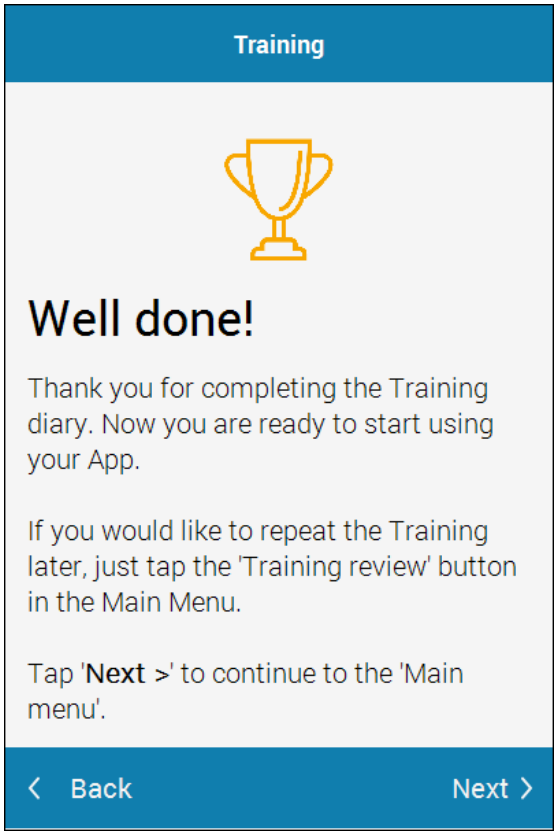


Screen 10

090177e195746b2f\Approved\Approved On: 06-Nov-2020 14:14 (GMT)



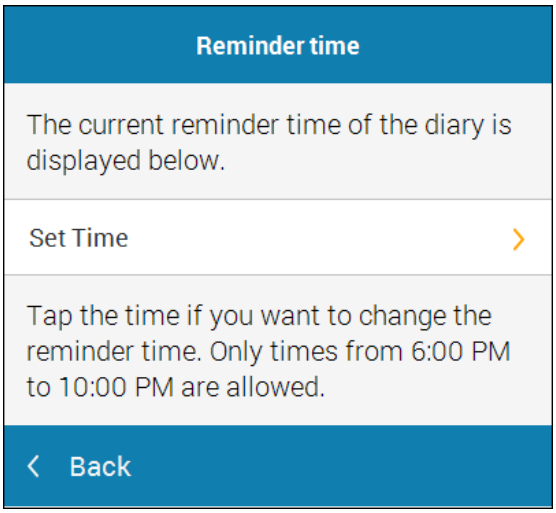
Screen 11



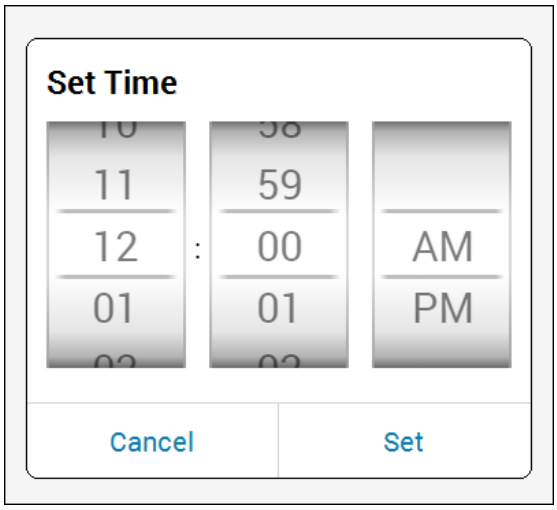
Screen 12

090177e195746b2f\Approved\Approved On: 06-Nov-2020 14:14 (GMT)

7 Form: Settings



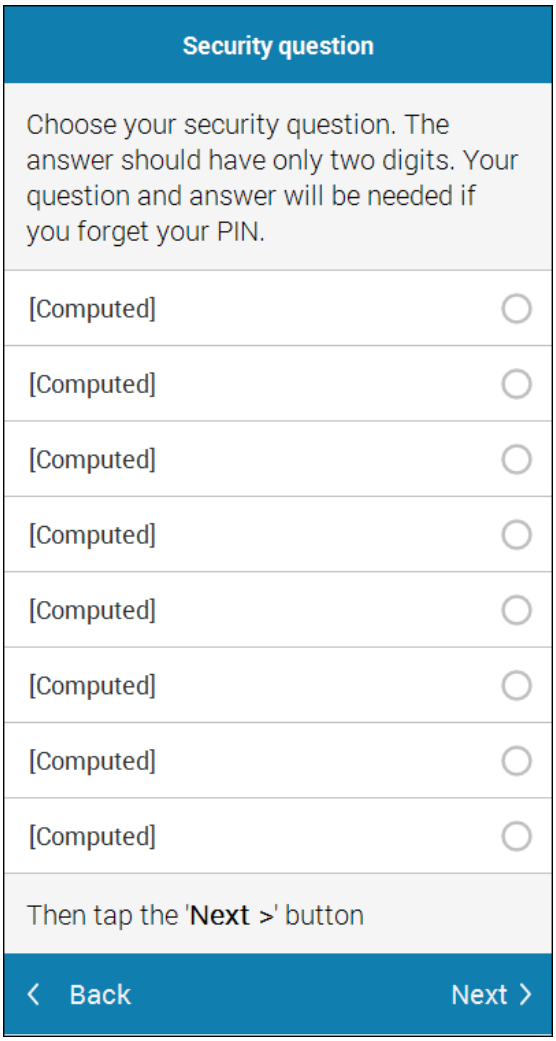
Screen 1



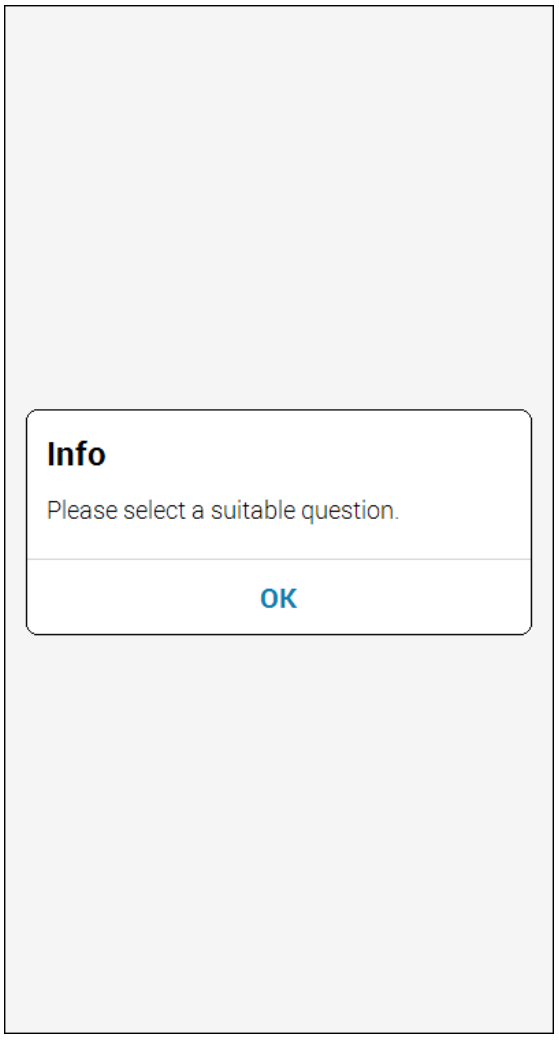
Popup input 1

090177e195746b2f\Approved\Approved On: 06-Nov-2020 14:14 (GMT)

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)'

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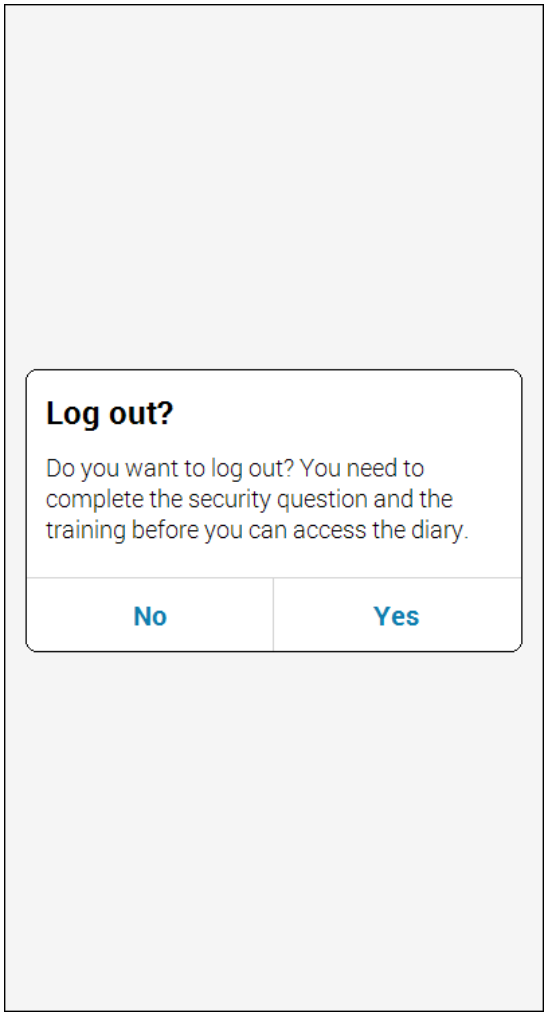
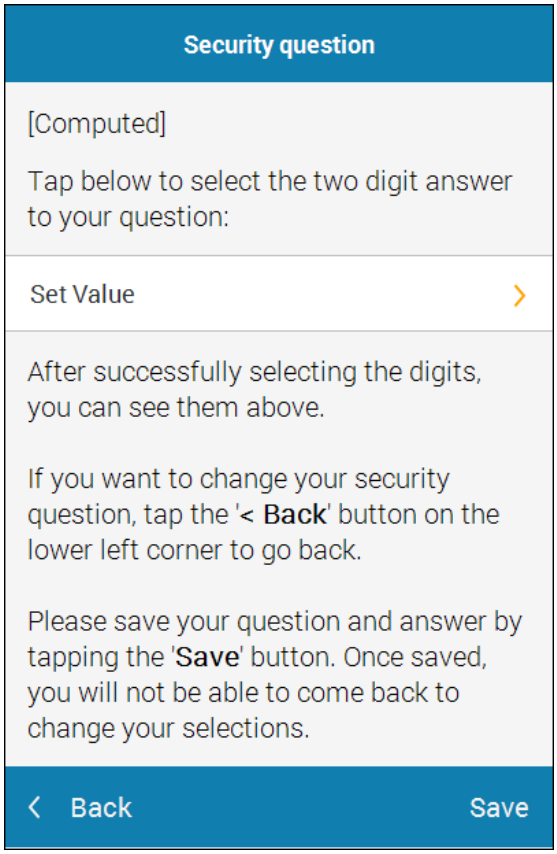


Message 2



Screen 2

[Computed] will display

'Your question:

{1}'

{1} will show the question selected on Screen 1

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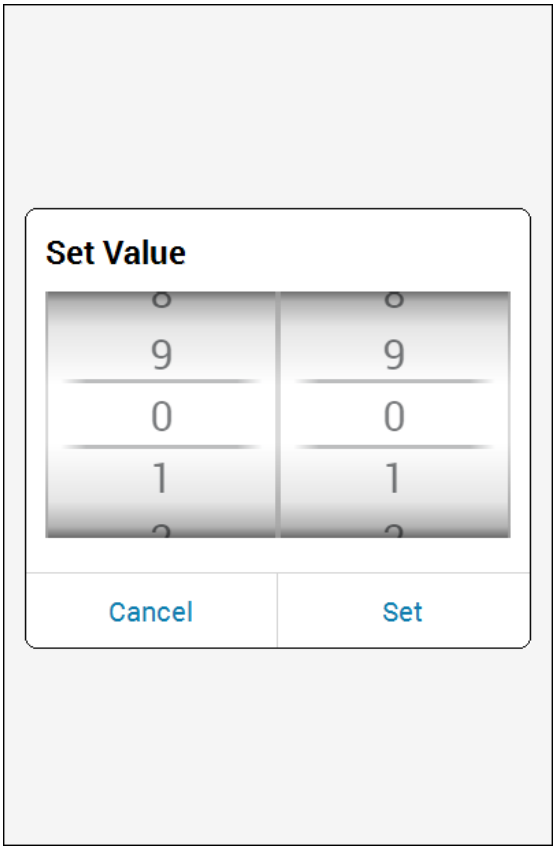
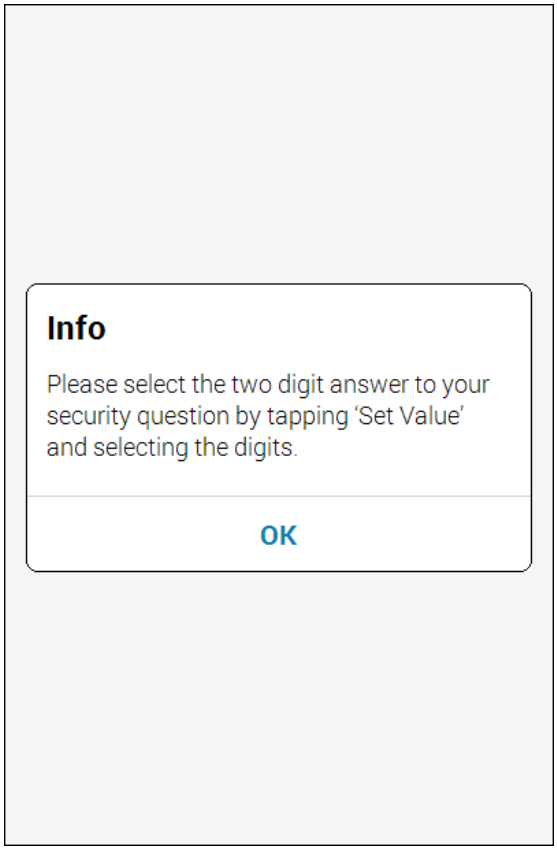


Popup input 1



Message 1

090177e195746b2f\Approved\Approved On: 06-Nov-2020 14:14 (GMT)

SCREEN REPORT APPROVAL

Content for Approval					
Language	English for United States				
Subject screen report	A-1426-0086-5270SR_enUS	**Version**	3	**Date**	02-Oct-2020

CUSTOMER

Approval		
Name and Title: Kimberly Rarrick		Signature:
Company: Pfizer	Role: Study Manager	Date: DocuSigned by: Kimberly Rarrick D1BD069CC2B34D9... 02-Oct-2020 | 13:16 EDT

SIGNANT HEALTH

Approval	
Name: Brittany Hayes	Signature:
Title: Project Manager III	Date: DocuSigned by: Brittany Hayes C4D491375B6548E... 02-Oct-2020 | 13:15 EDT

090177e19533c1ac\Approved\Approved On: 12-Oct-2020 12:43 (GMT)

A-1426-0082 / C4591001
App Subject Facing Screen Report

Localized texts are displayed in English (US).

Contents

1 Notifications / Subject card 2
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3 Form: Vaccination Diary 22
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5 Form: Subject training diary 42
6 Form: Settings 49
7 Form: Security question 50

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

090177e194d02327\Approved\Approved On: 02-Sep-2020 17:58 (GMT)

FDA-CBER-2021-5683-0024441

1 Notifications / Subject card

Email notification/Subject card to provisioned device subjects:

Welcome to the C4591001 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

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 Study! Activate the TrialMax App with code:
[Activation Code]

090177e194d02327\Approved\Approved On: 02-Sep-2020 17:58 (GMT)

FDA-CBER-2021-5683-0024442

Email notification/Subject card to BYOD subjects:

Welcome to the C4591001 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

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. **]**

090177e194d02327\Approved\Approved On: 02-Sep-2020 17:58 (GMT)

FDA-CBER-2021-5683-0024443

SMS Body for BYOD subjects:

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

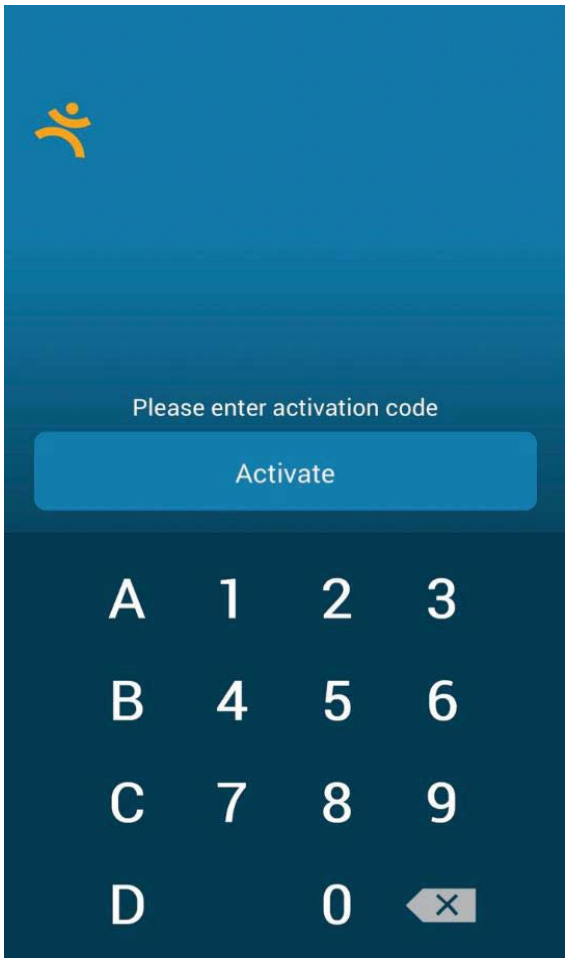
App notification:

Please fill in your vaccination diary!

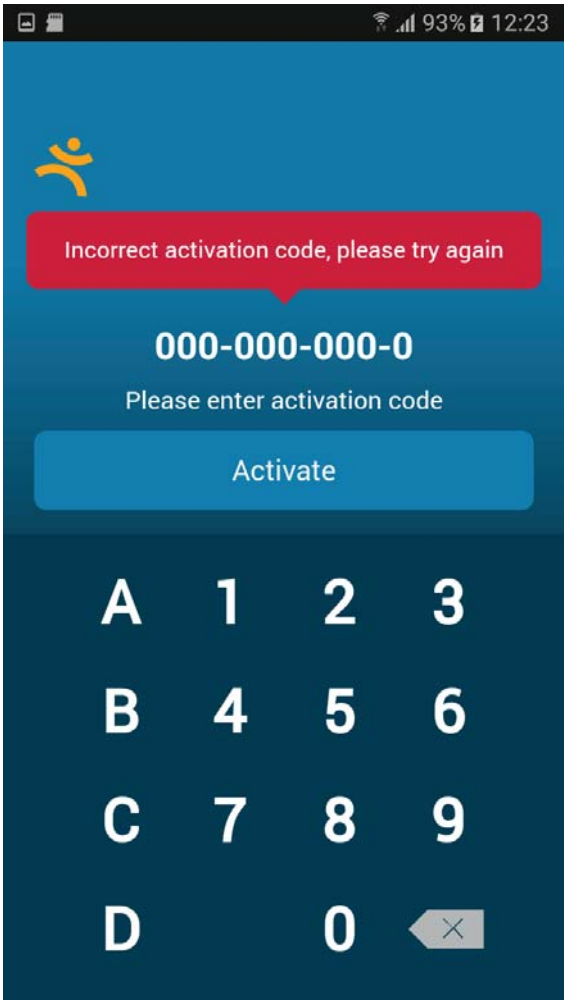
090177e194d02327\Approved\Approved On: 02-Sep-2020 17:58 (GMT)

FDA-CBER-2021-5683-0024444

2 Common



Screen 1

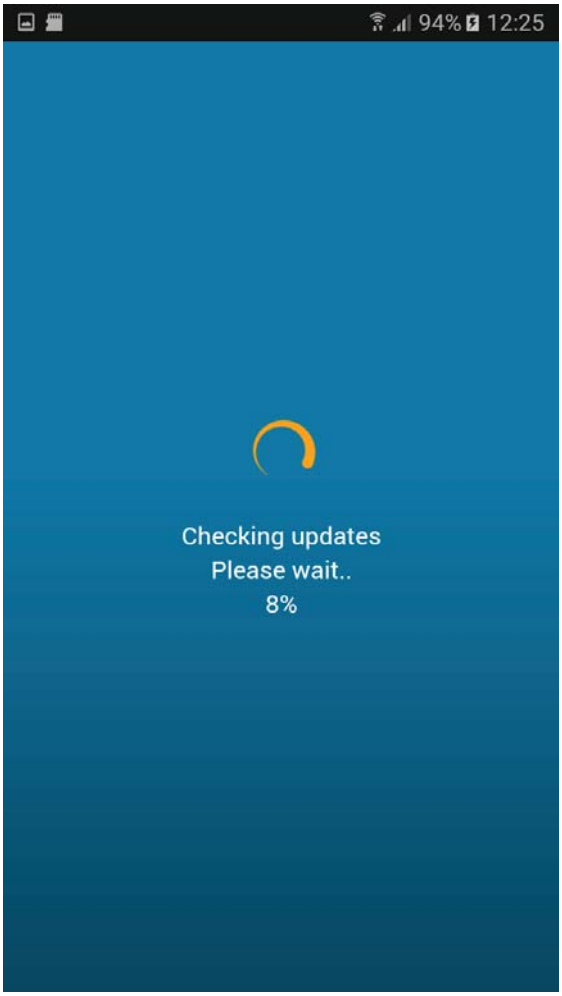


Screen 2

090177e194d02327\Approved\Approved On: 02-Sep-2020 17:58 (GMT)

FDA-CBER-2021-5683-0024445

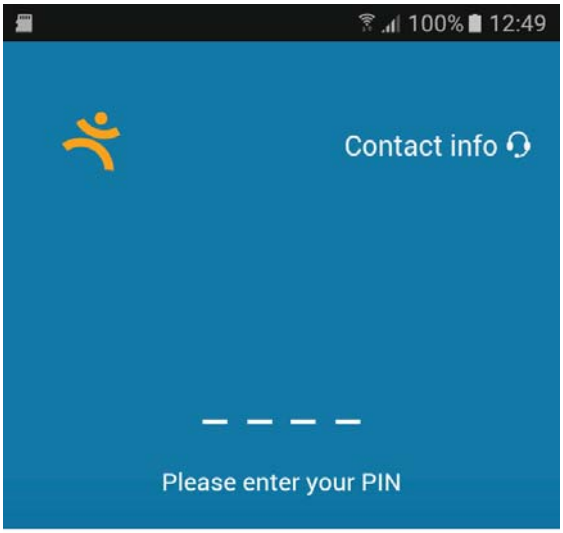
Screen 3



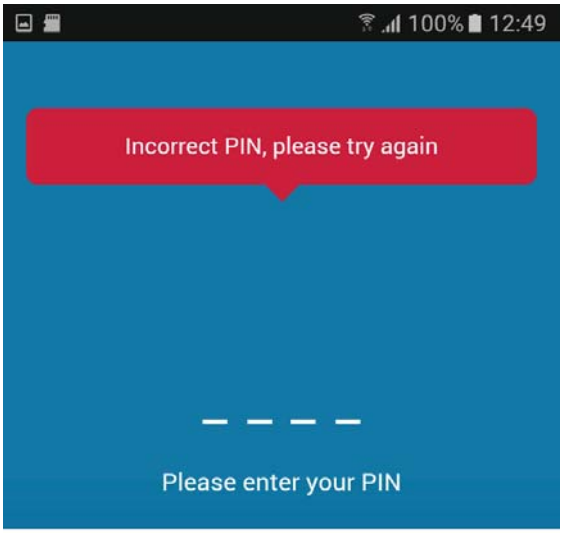
Screen 4

090177e194d02327\Approved\Approved On: 02-Sep-2020 17:58 (GMT)

FDA-CBER-2021-5683-0024446

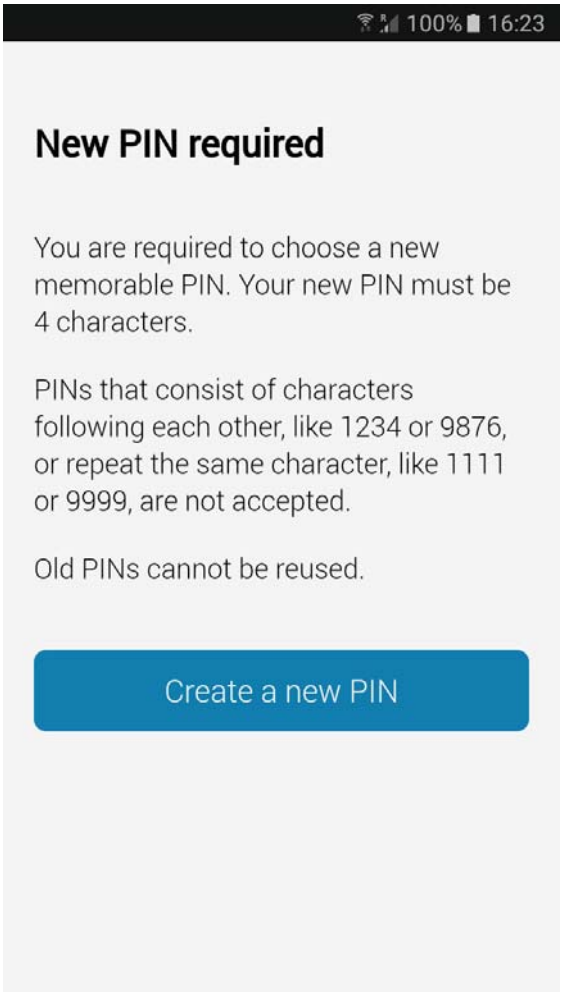


Screen 5



Screen 6

090177e194d02327\Approved\Approved On: 02-Sep-2020 17:58 (GMT)

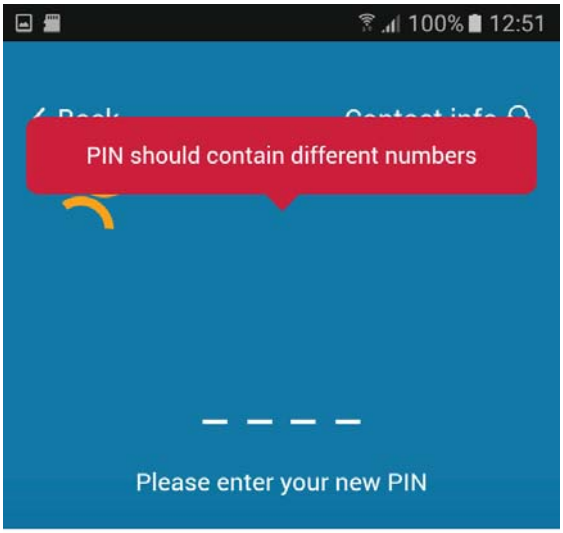


Screen 7

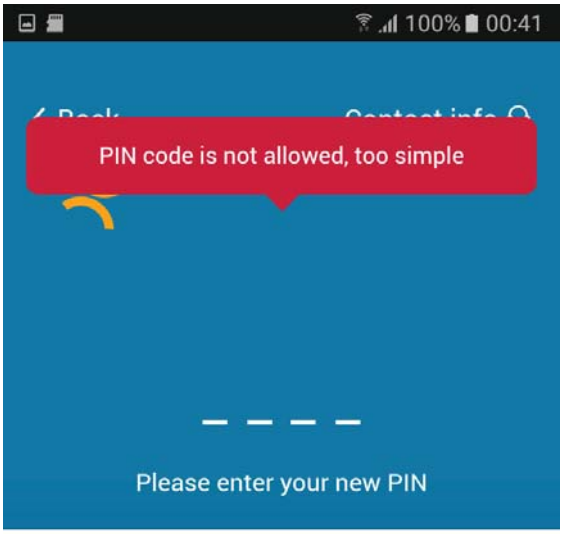
Screen 8

090177e194d02327\Approved\Approved On: 02-Sep-2020 17:58 (GMT)

FDA-CBER-2021-5683-0024448

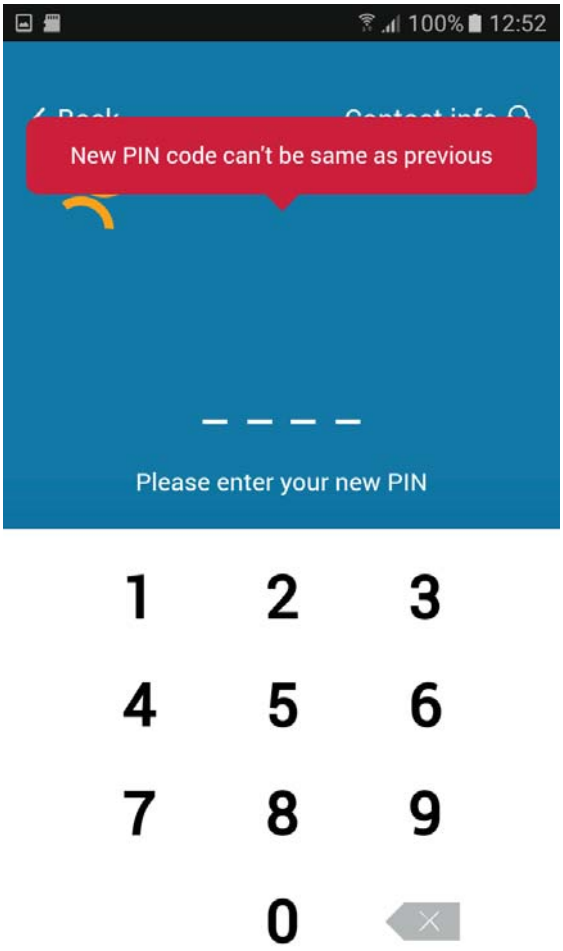


Screen 9

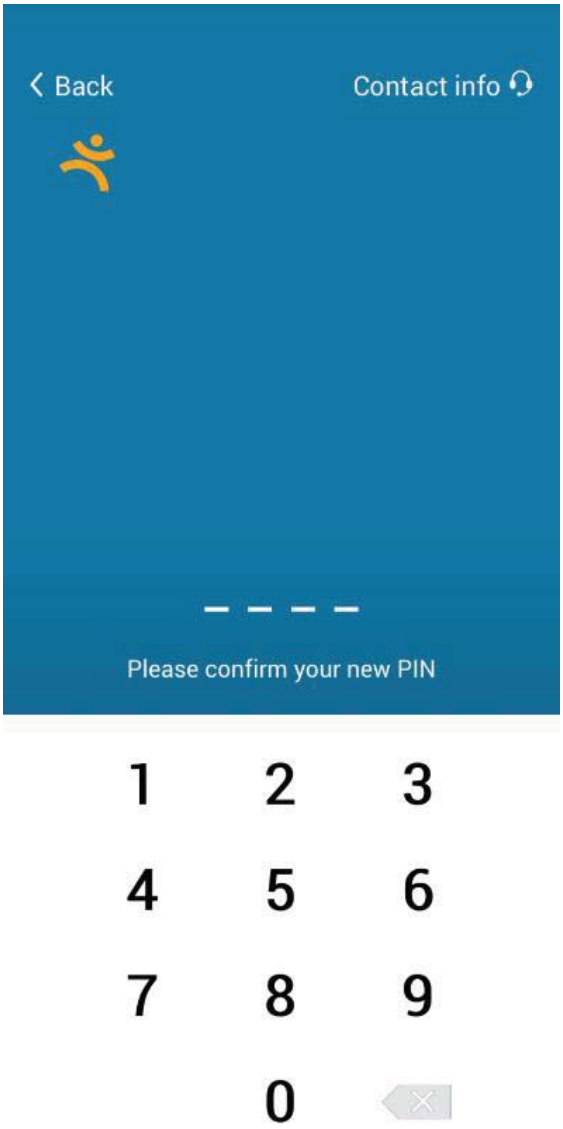


Screen 10

090177e194d02327\Approved\Approved On: 02-Sep-2020 17:58 (GMT)



Screen 11



Screen 12

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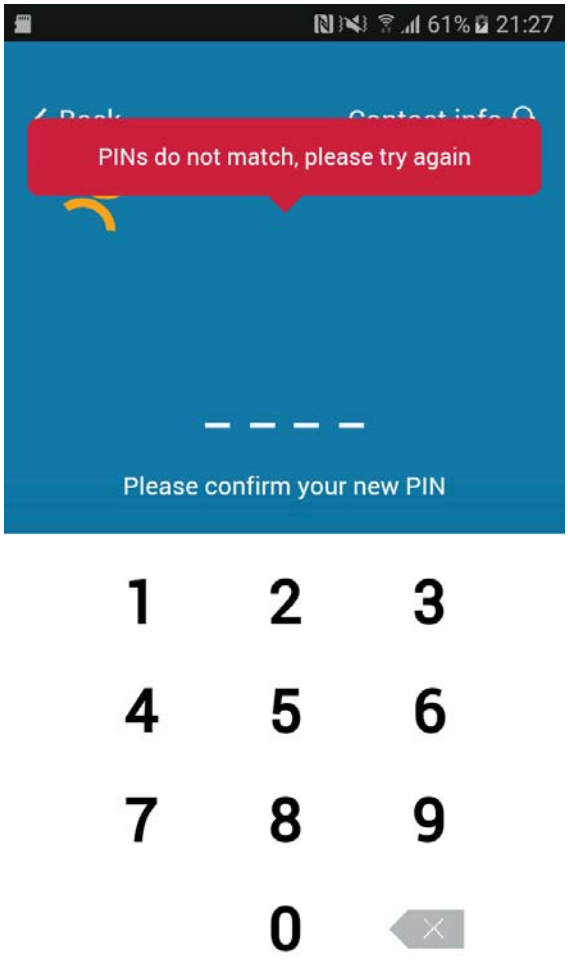
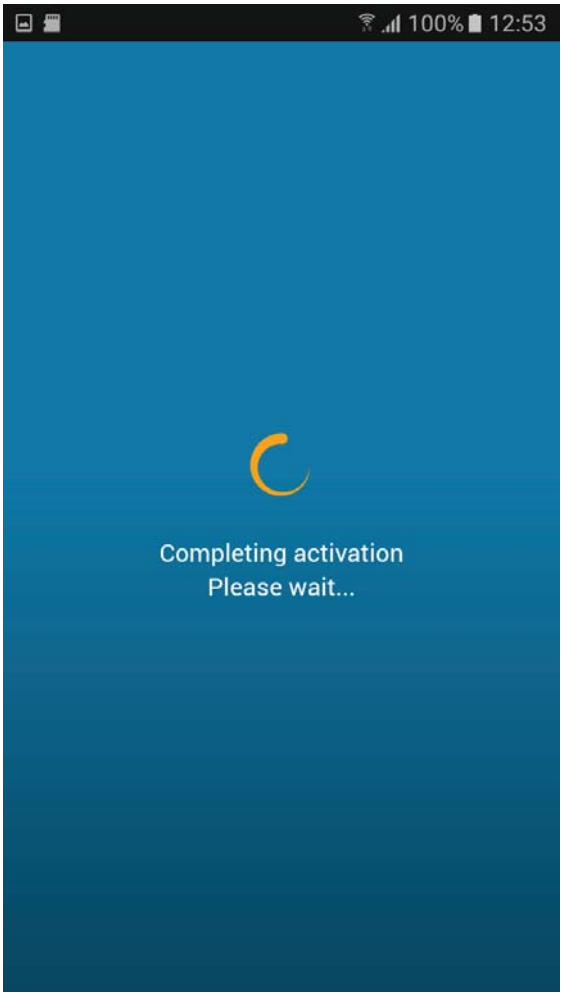
FDA-CBER-2021-5683-0024450



Screen 13



Screen 14

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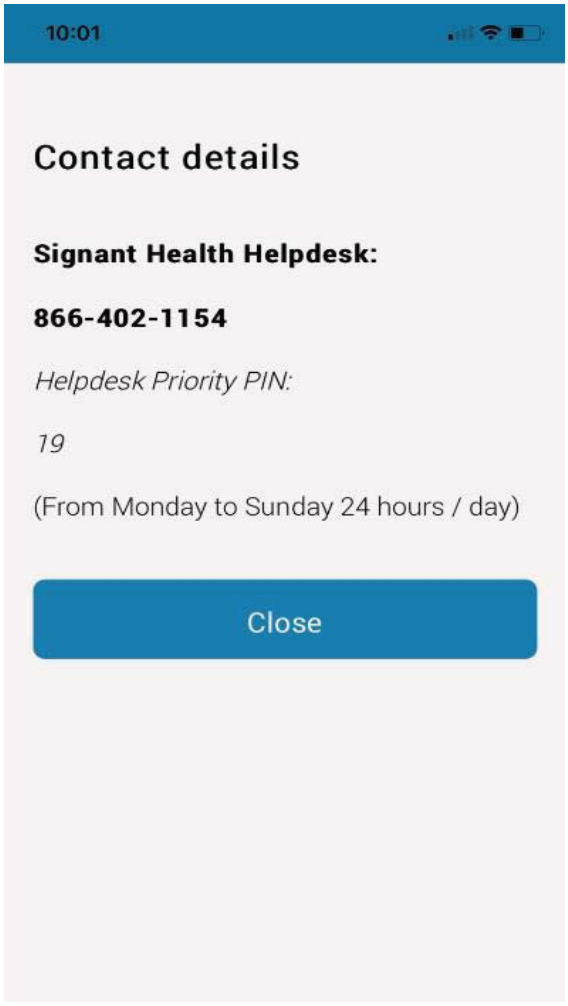
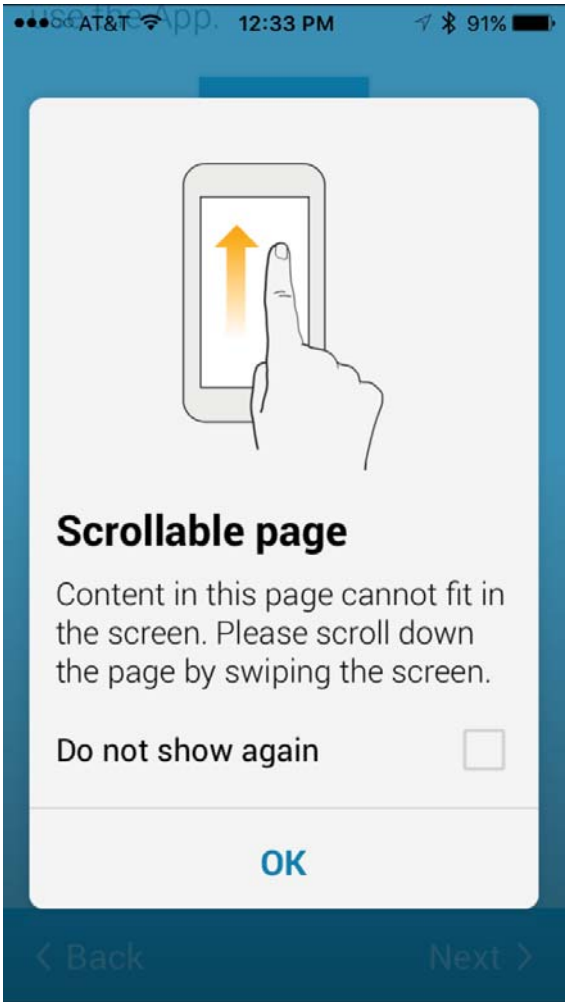


Screen 15



Screen 16

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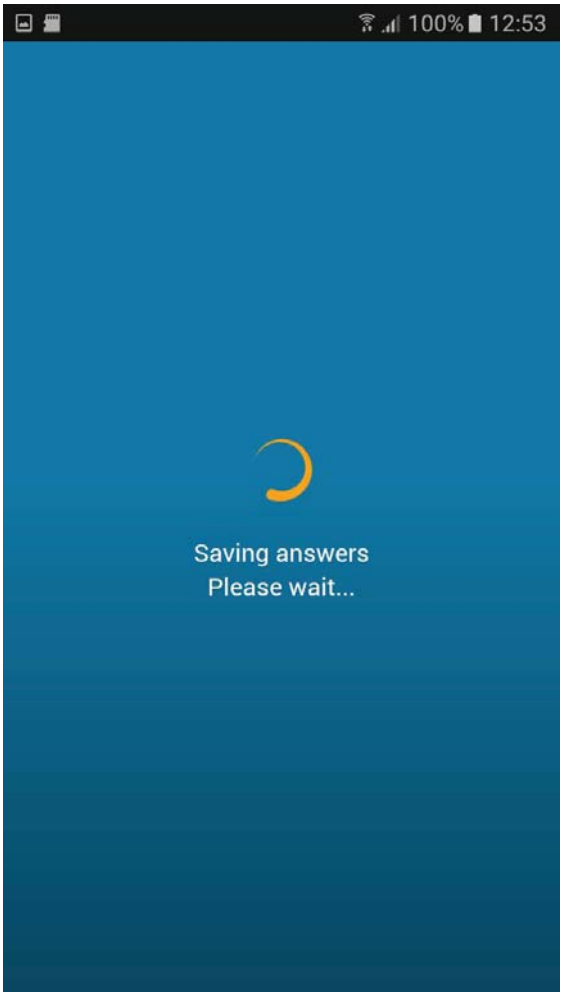
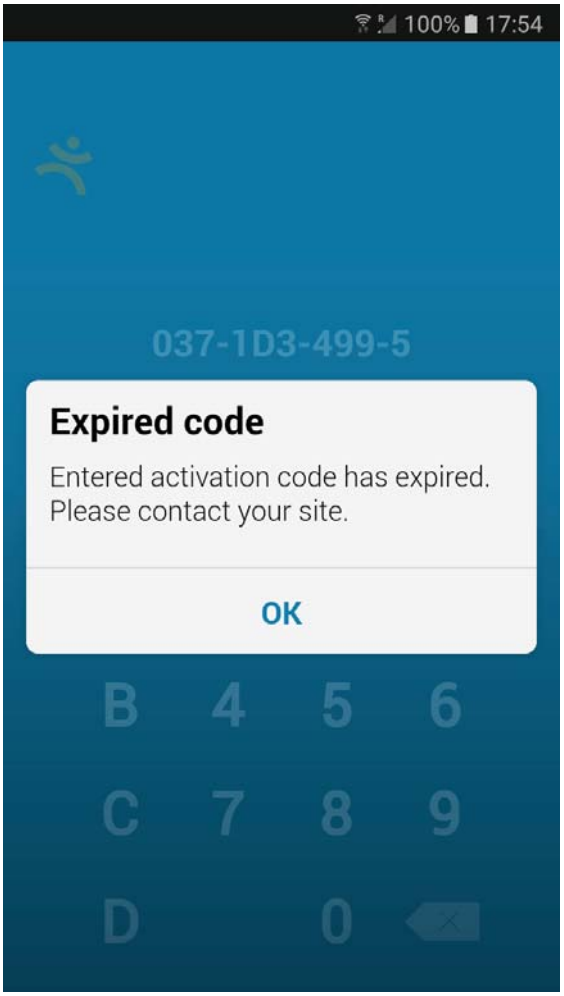
FDA-CBER-2021-5683-0024452



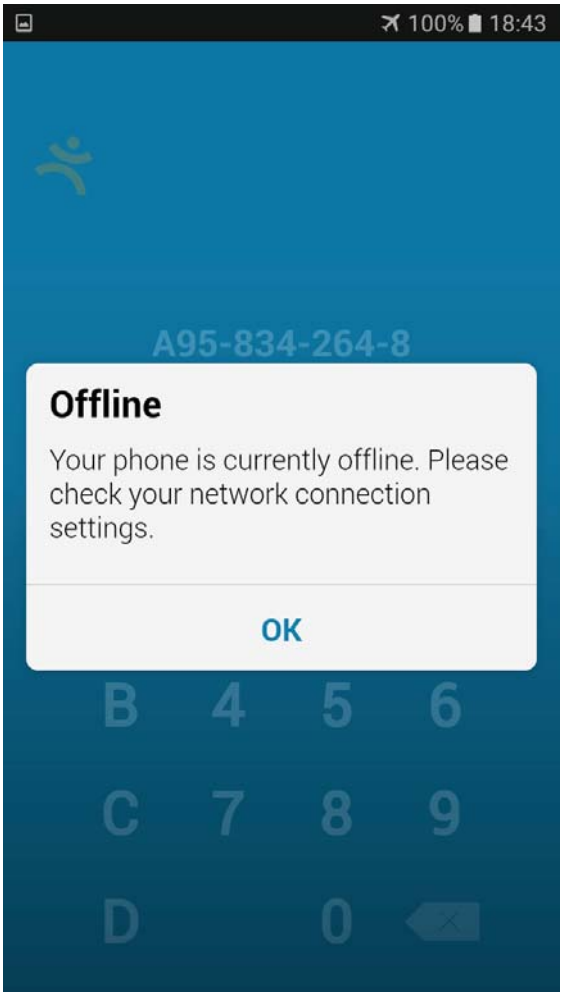
Screen 17



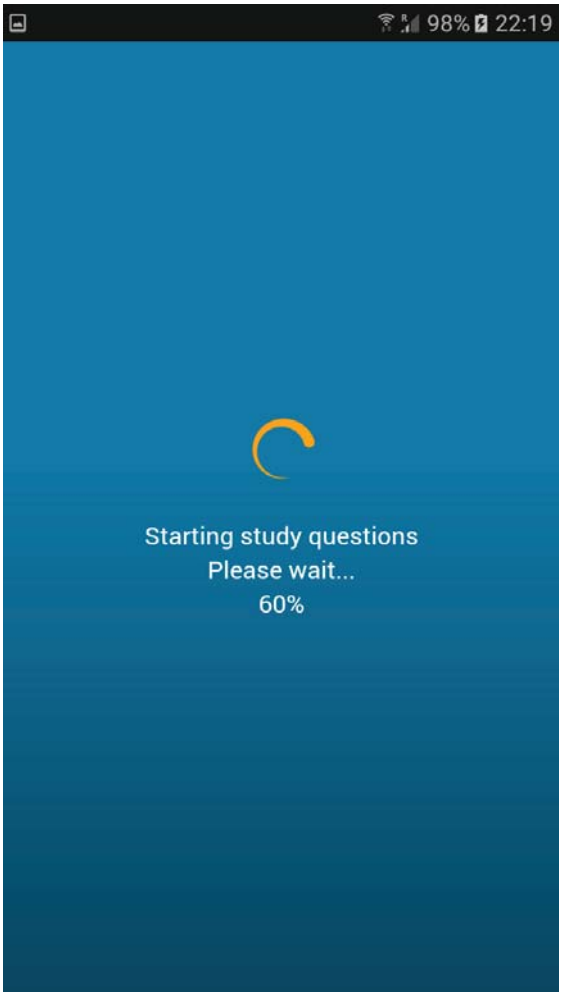
Screen 18

090177e194d02327\Approved\Approved On: 02-Sep-2020 17:58 (GMT)

FDA-CBER-2021-5683-0024453



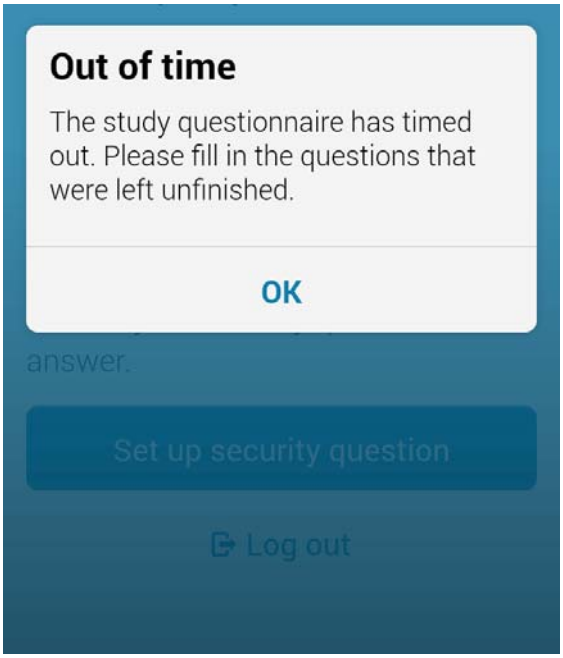
Screen 19



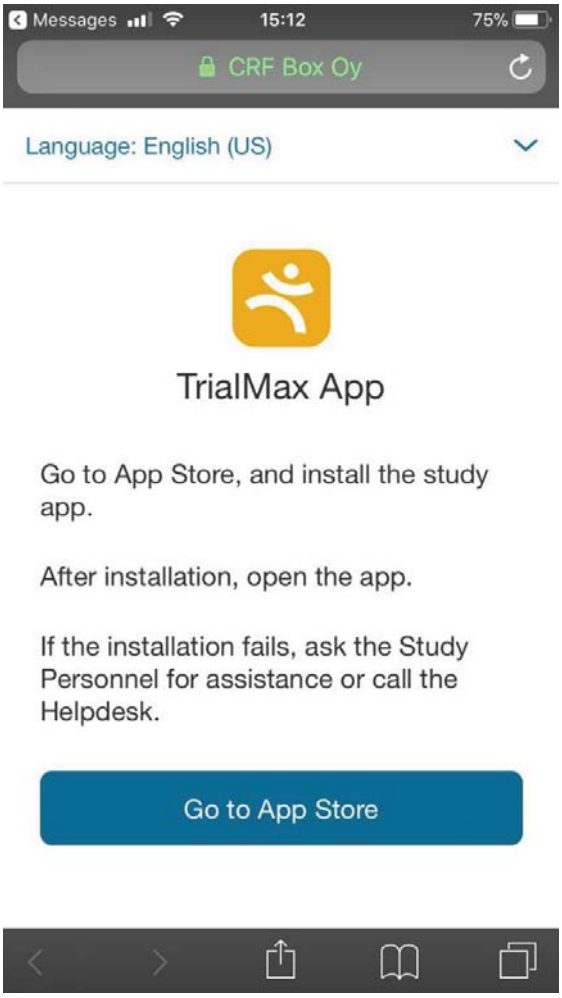
Screen 20

090177e194d02327\Approved\Approved On: 02-Sep-2020 17:58 (GMT)

FDA-CBER-2021-5683-0024454



Screen 21



Screen 22

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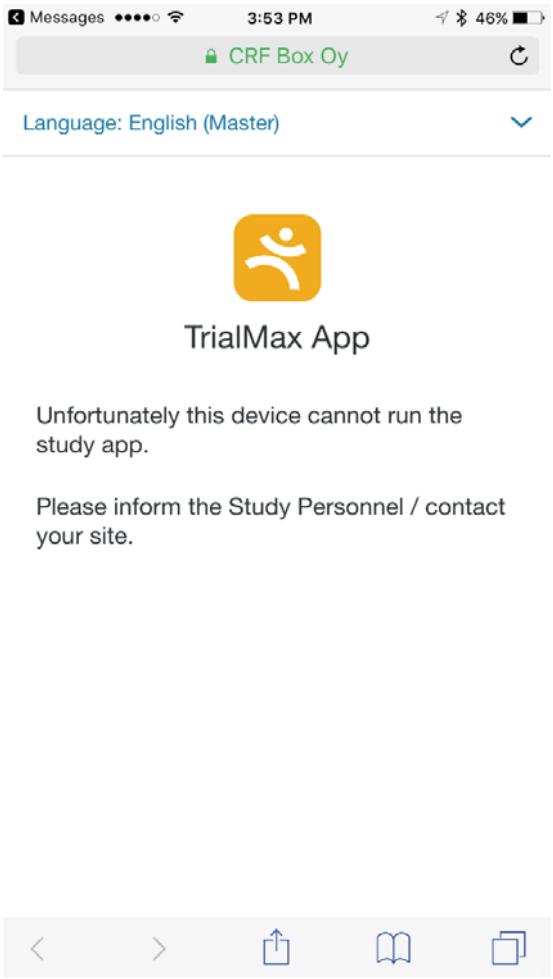
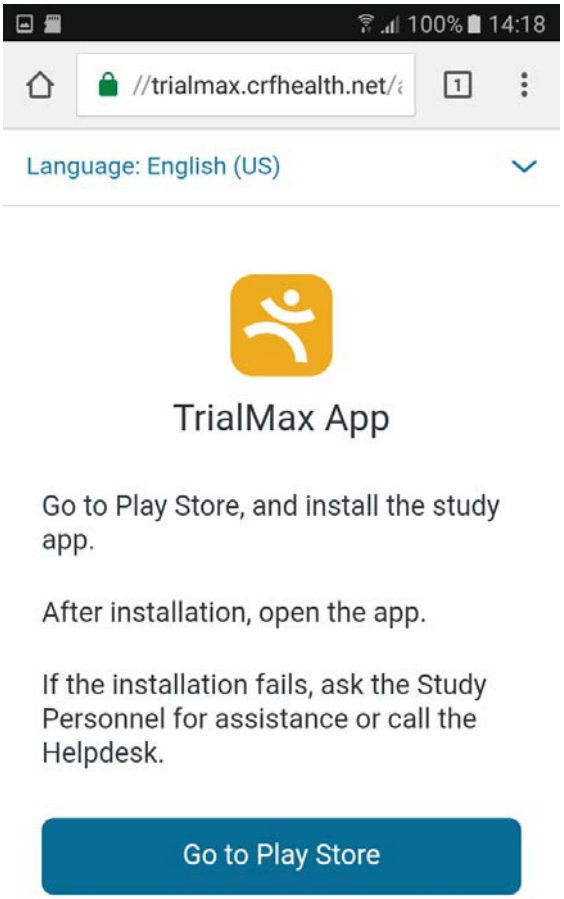
FDA-CBER-2021-5683-0024455



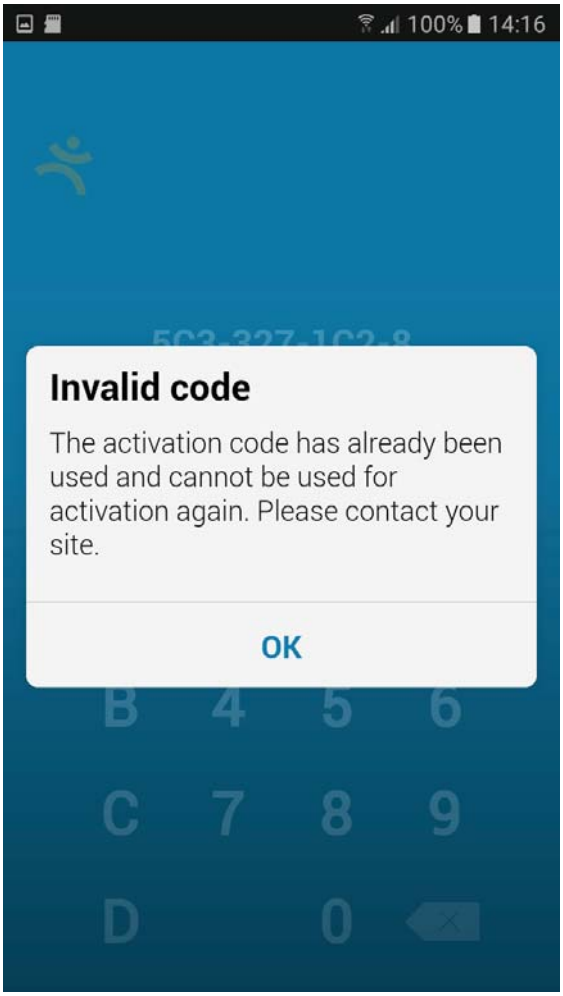
Screen 23



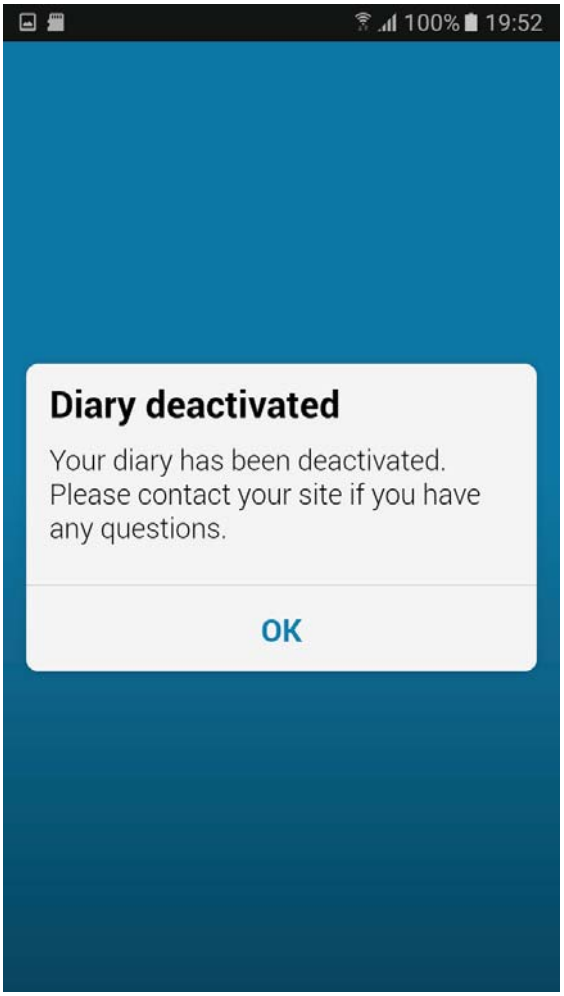
Screen 24

090177e194d02327\Approved\Approved On: 02-Sep-2020 17:58 (GMT)

FDA-CBER-2021-5683-0024456



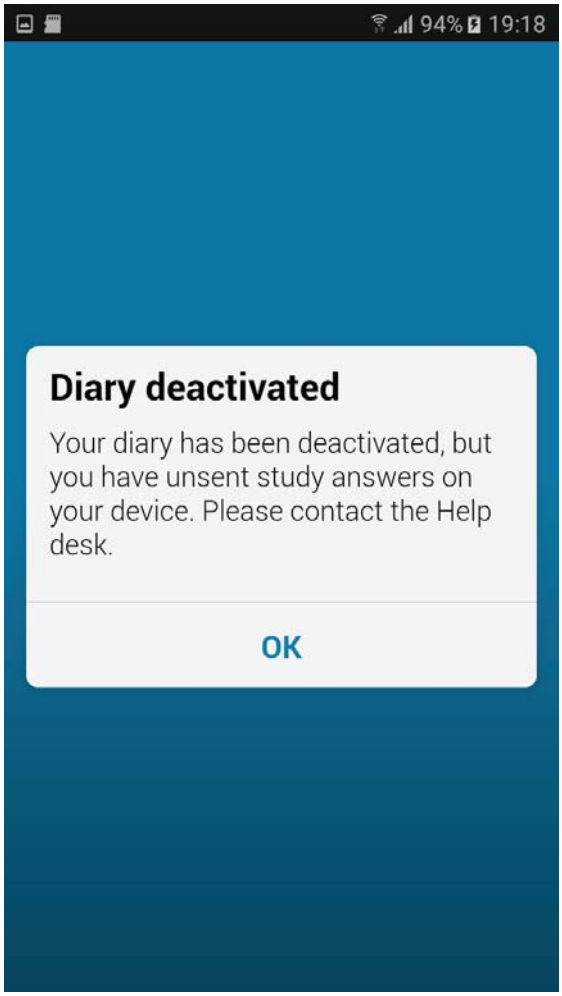
Screen 25



Screen 26

090177e194d02327\Approved\Approved On: 02-Sep-2020 17:58 (GMT)

FDA-CBER-2021-5683-0024457

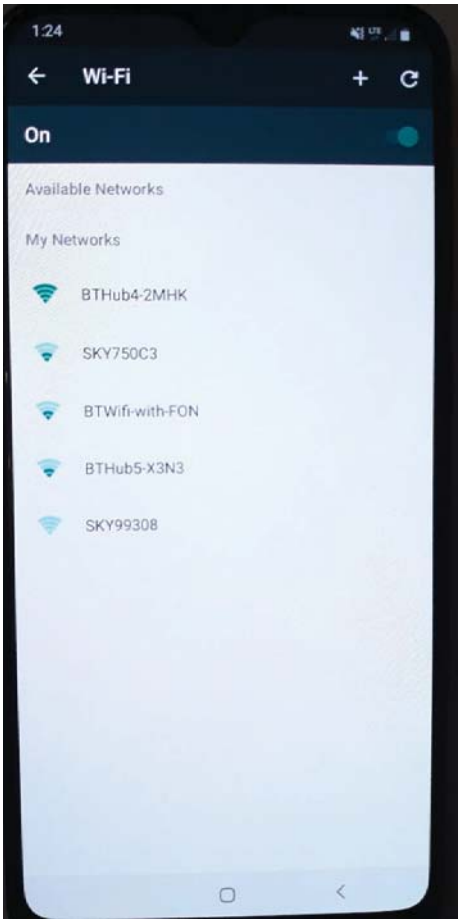


Screen 27

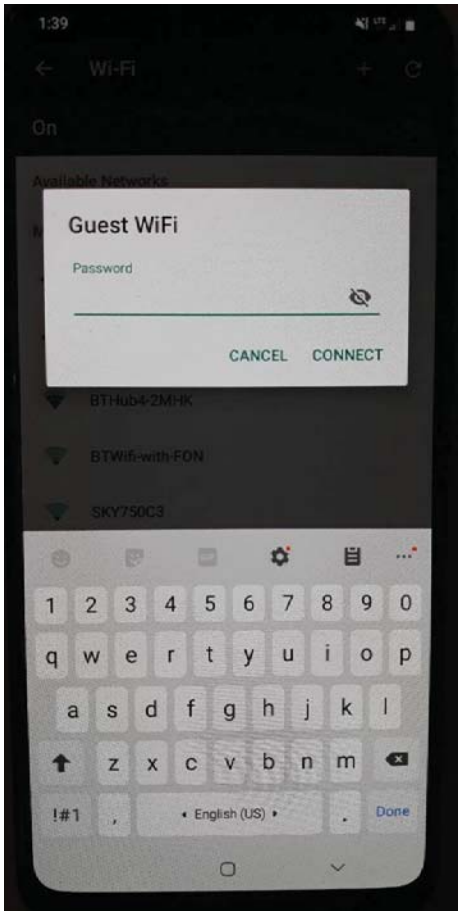
Screen 28

090177e194d02327\Approved\Approved On: 02-Sep-2020 17:58 (GMT)

FDA-CBER-2021-5683-0024458



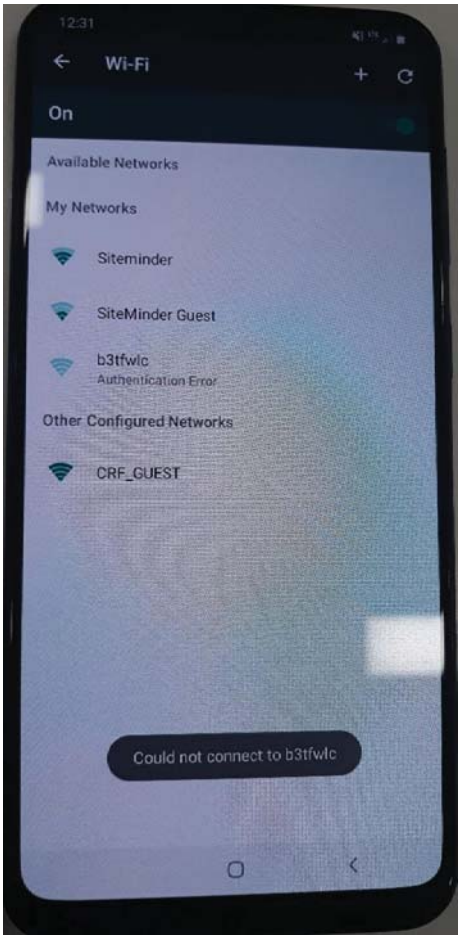
Screen 29



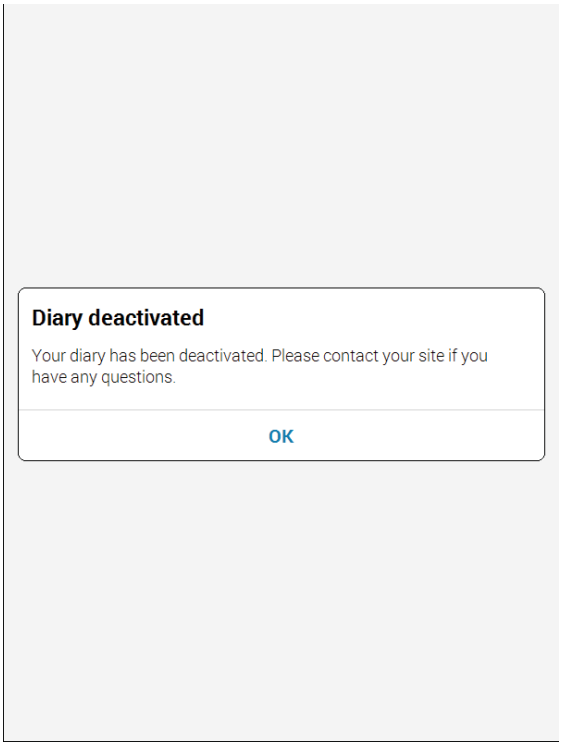
Screen 30

090177e194d02327\Approved\Approved On: 02-Sep-2020 17:58 (GMT)

FDA-CBER-2021-5683-0024459



Screen 31



Message 1

090177e194d02327\Approved\Approved On: 02-Sep-2020 17:58 (GMT)

FDA-CBER-2021-5683-0024460

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.'

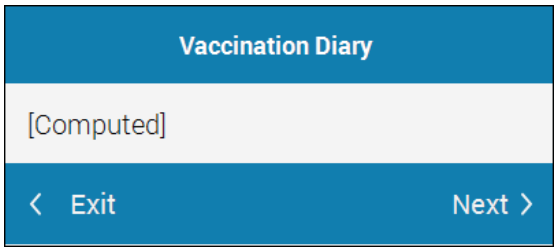
'Error'

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

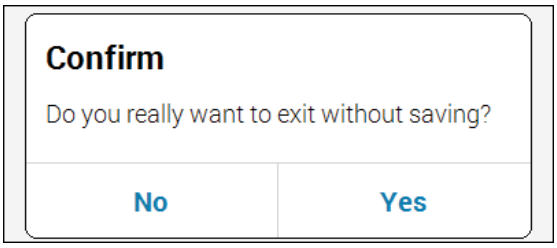
090177e194d02327\Approved\Approved On: 02-Sep-2020 17:58 (GMT)

FDA-CBER-2021-5683-0024461

3 Form: Vaccination Diary



Screen 1



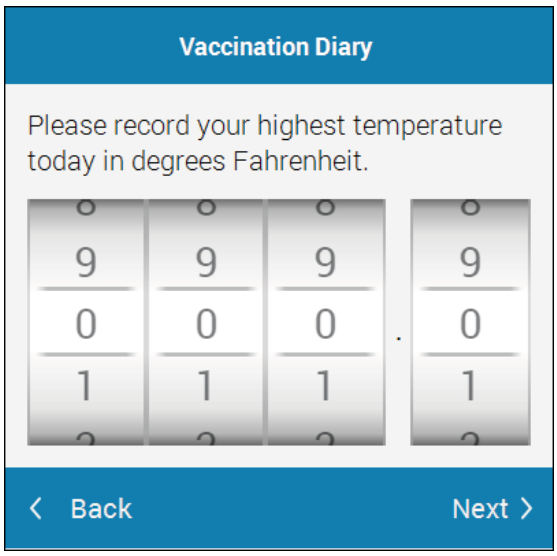
Message 1

[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} more 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 more day(s).

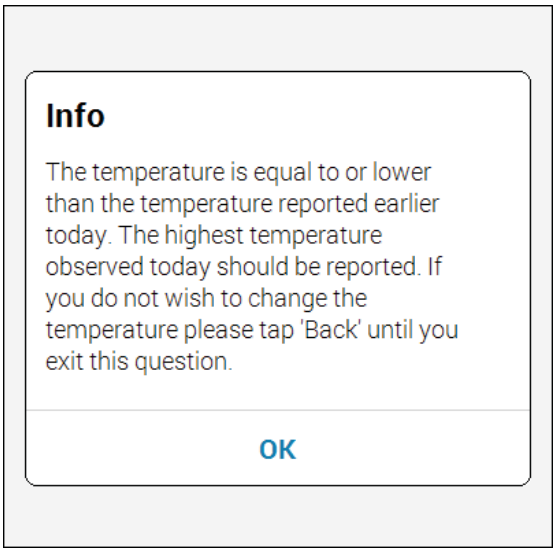


Screen 2

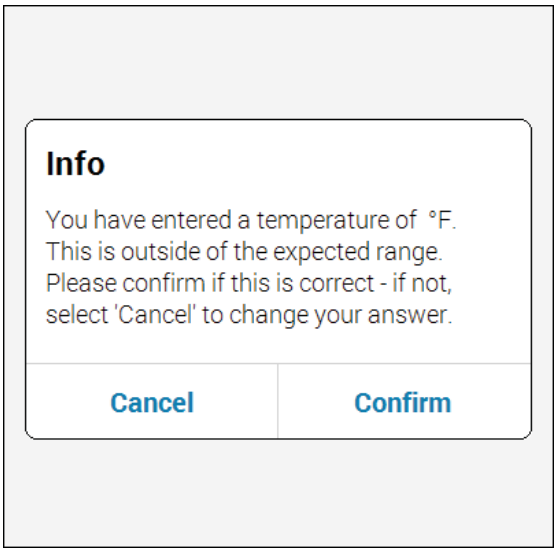
Message 1

090177e194d02327\Approved\Approved On: 02-Sep-2020 17:58 (GMT)

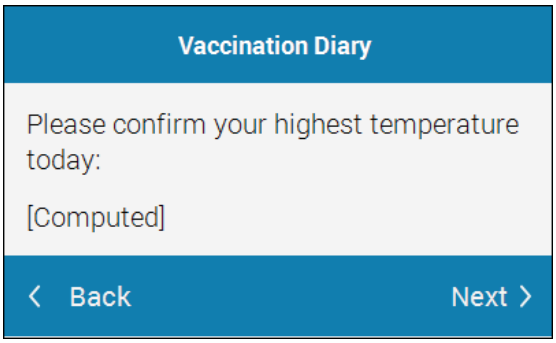
FDA-CBER-2021-5683-0024462



Message 2

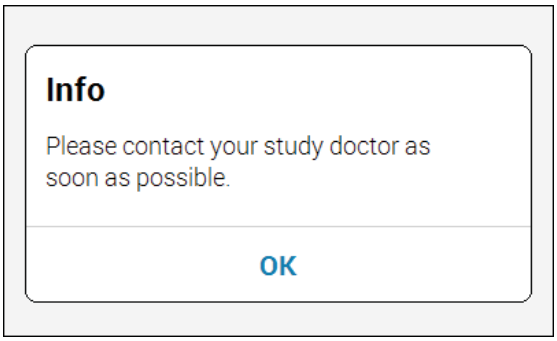


Message 3



Screen 3

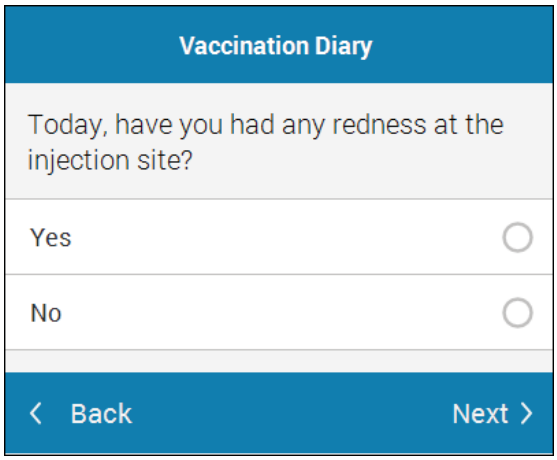
[Computed] will display the temperature selected on Screen 2.



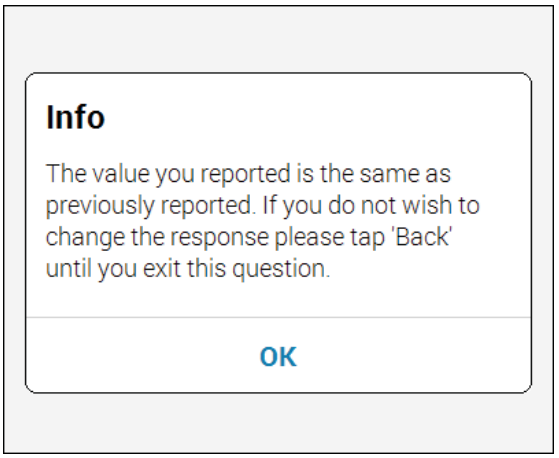
Message 1

090177e194d02327\Approved\Approved On: 02-Sep-2020 17:58 (GMT)

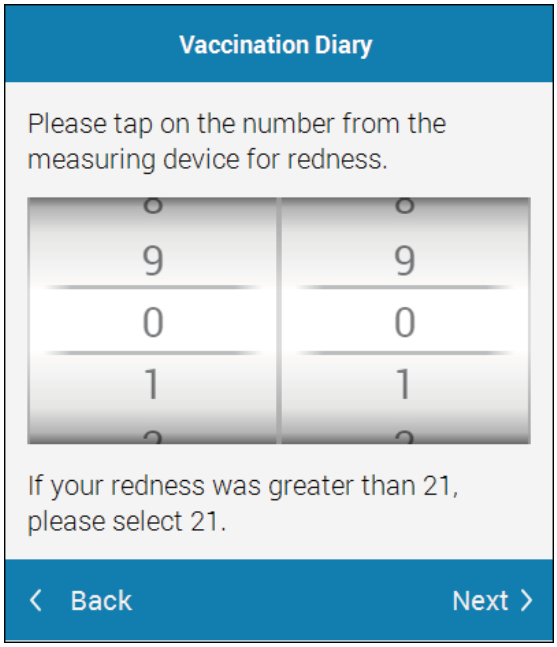
FDA-CBER-2021-5683-0024463



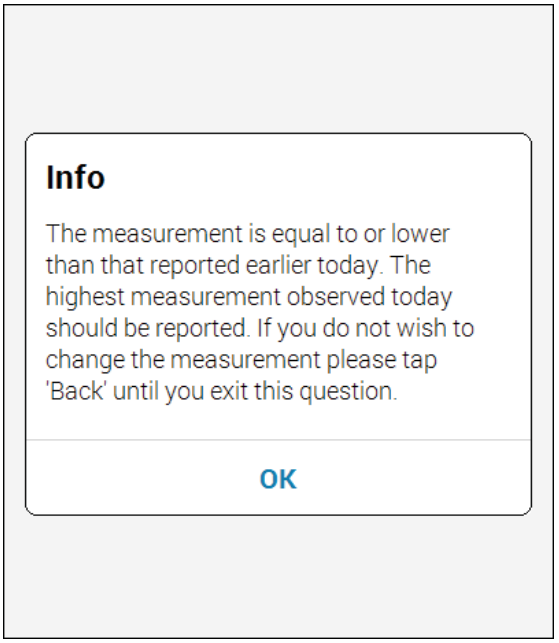
Screen 4



Message 2



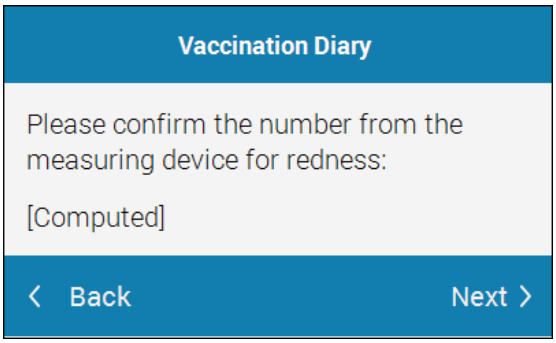
Screen 5



Message 2

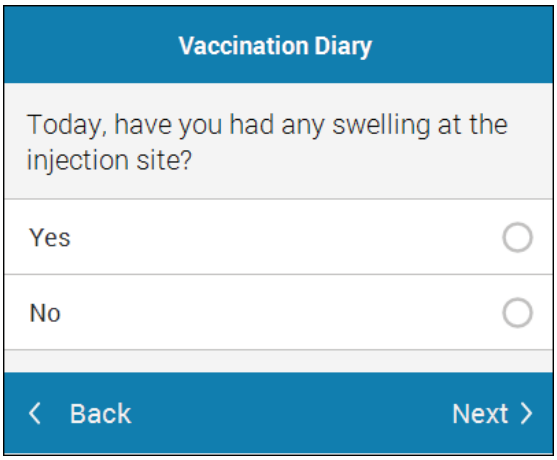
090177e194d02327\Approved\Approved On: 02-Sep-2020 17:58 (GMT)

FDA-CBER-2021-5683-0024464

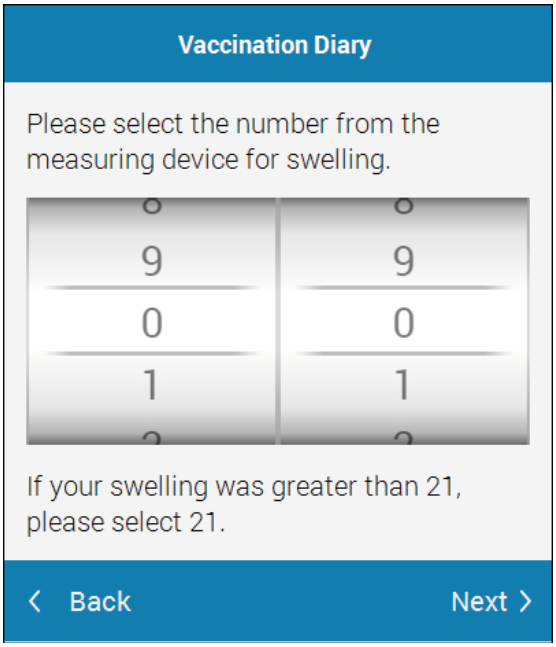


Screen 6

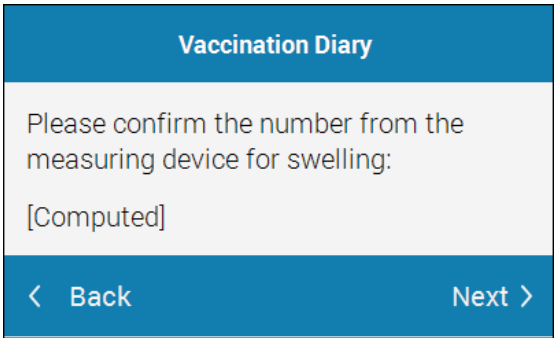
[Computed] will display the number selected on Screen 5.



Screen 7



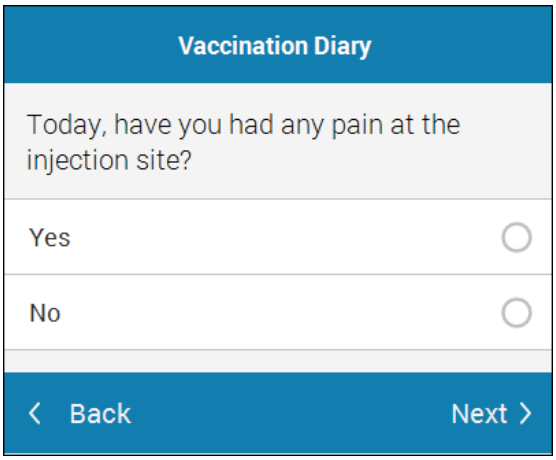
Screen 8



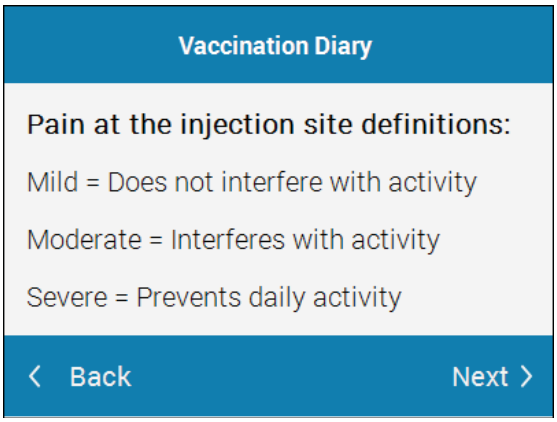
Screen 9

090177e194d02327\Approved\Approved On: 02-Sep-2020 17:58 (GMT)

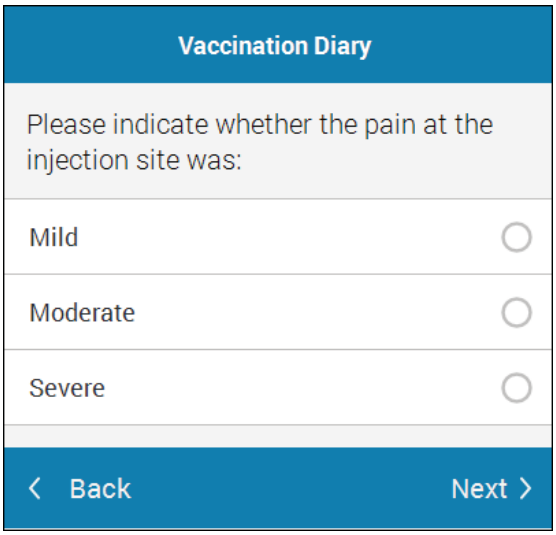
FDA-CBER-2021-5683-0024465



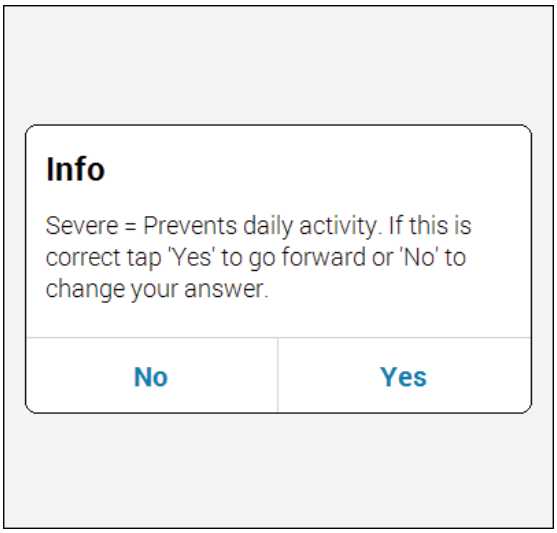
Screen 10



Screen 11



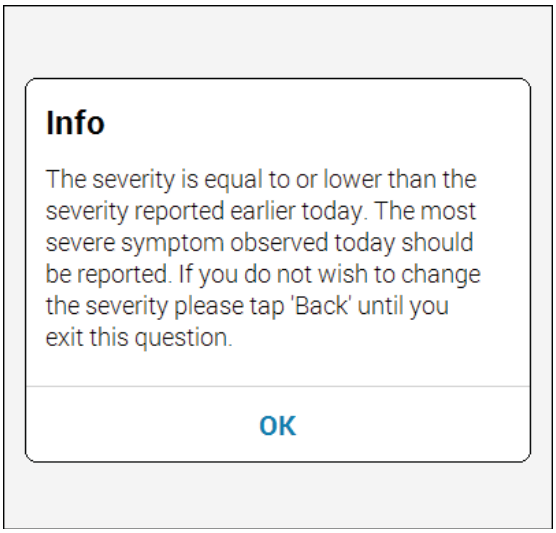
Screen 12



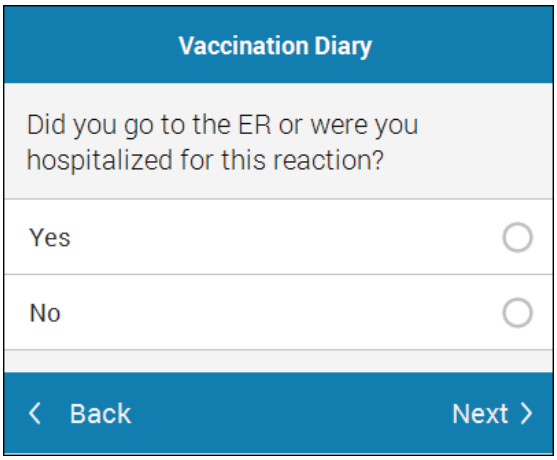
Message 2

090177e194d02327\Approved\Approved On: 02-Sep-2020 17:58 (GMT)

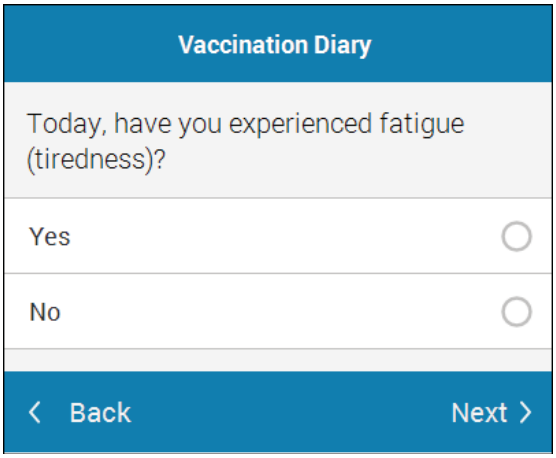
FDA-CBER-2021-5683-0024466



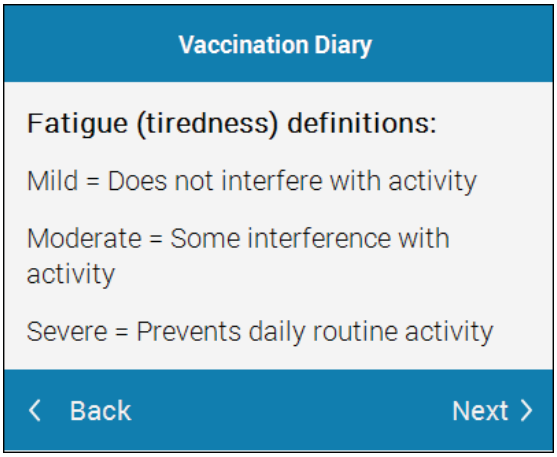
Message 4



Screen 13



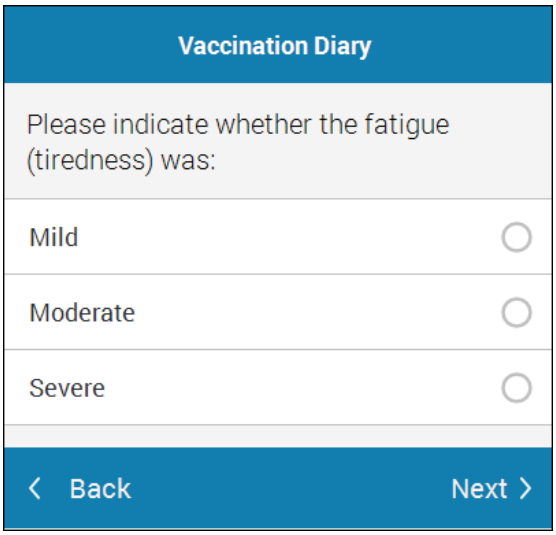
Screen 14



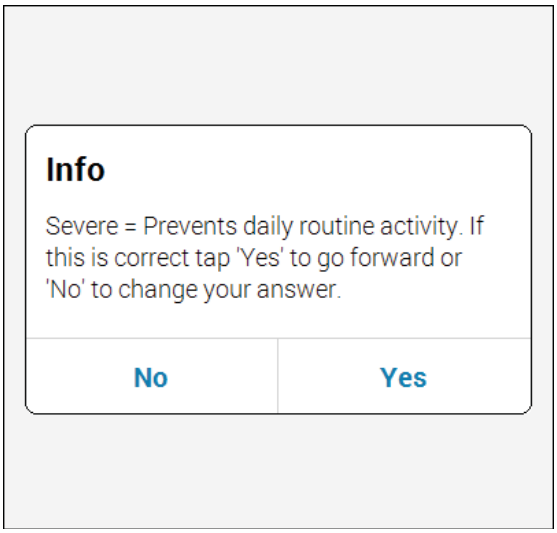
Screen 15

090177e194d02327\Approved\Approved On: 02-Sep-2020 17:58 (GMT)

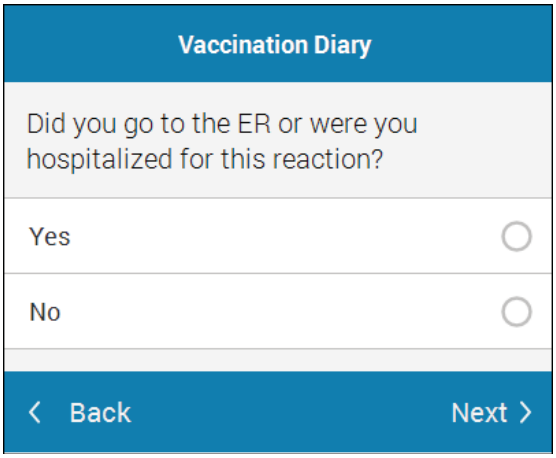
FDA-CBER-2021-5683-0024467



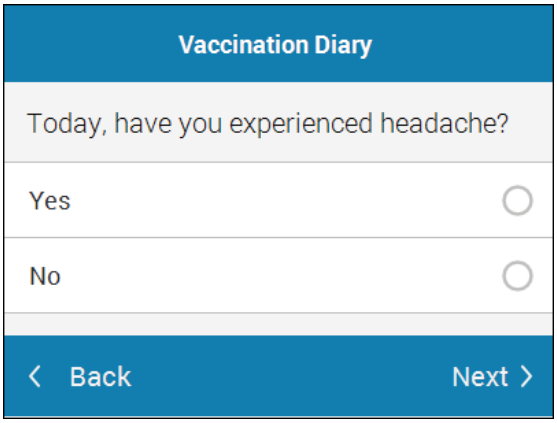
Screen 16



Message 2



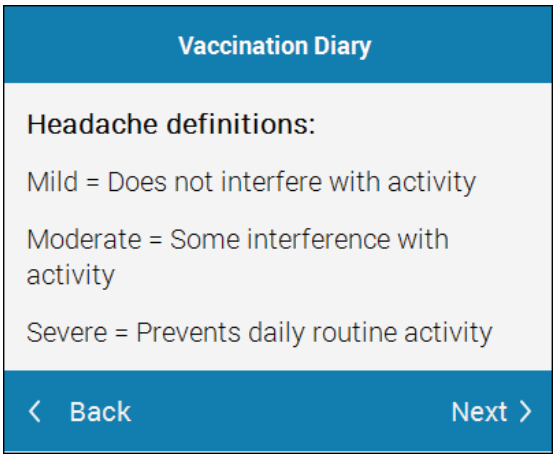
Screen 17



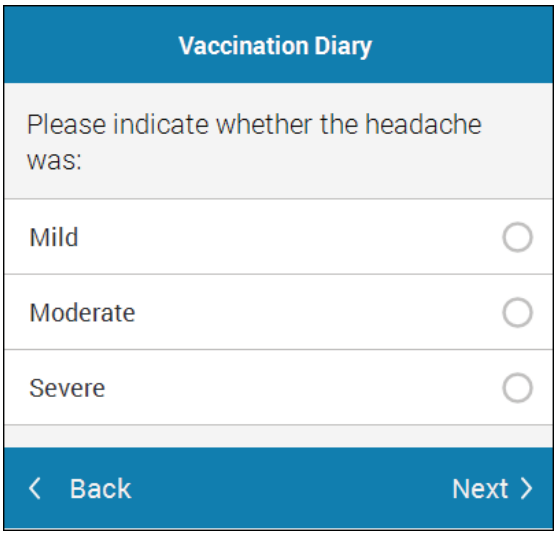
Screen 18

090177e194d02327\Approved\Approved On: 02-Sep-2020 17:58 (GMT)

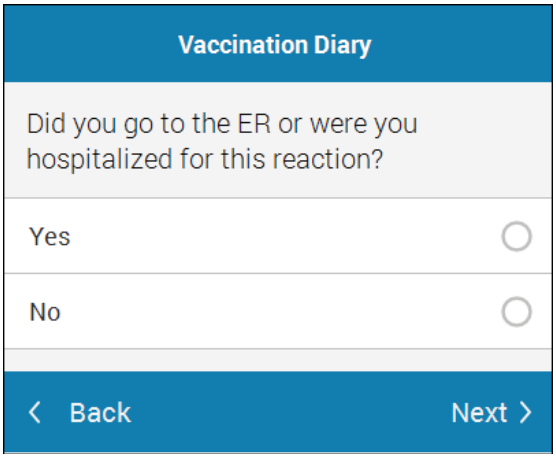
FDA-CBER-2021-5683-0024468



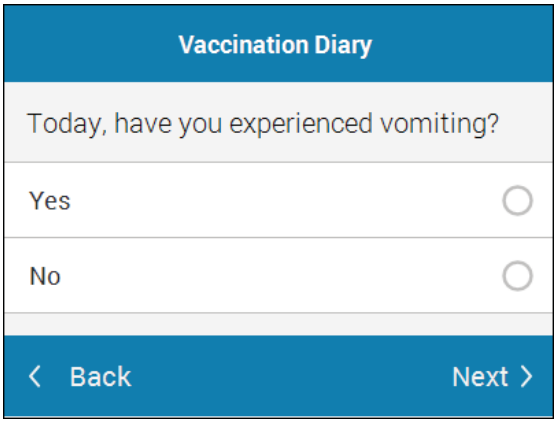
Screen 19



Screen 20



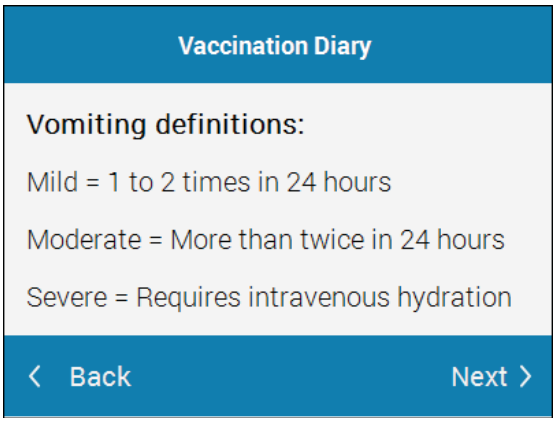
Screen 21



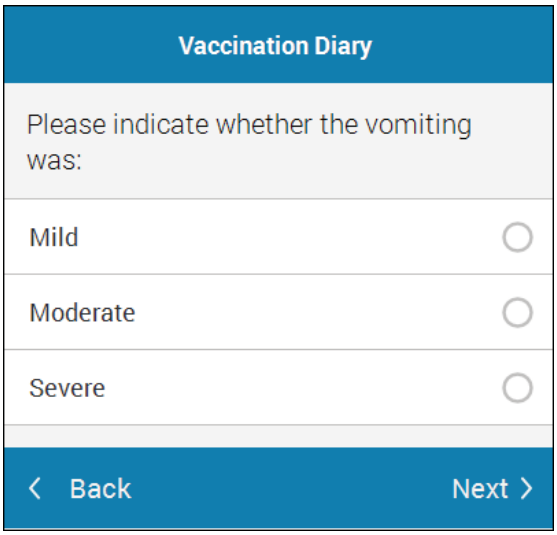
Screen 23

090177e194d02327\Approved\Approved On: 02-Sep-2020 17:58 (GMT)

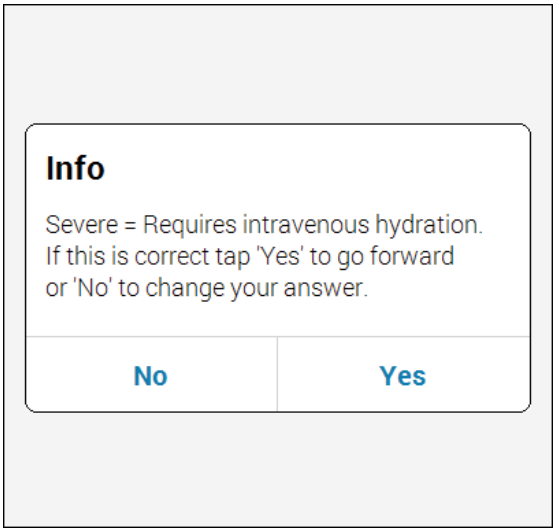
FDA-CBER-2021-5683-0024469



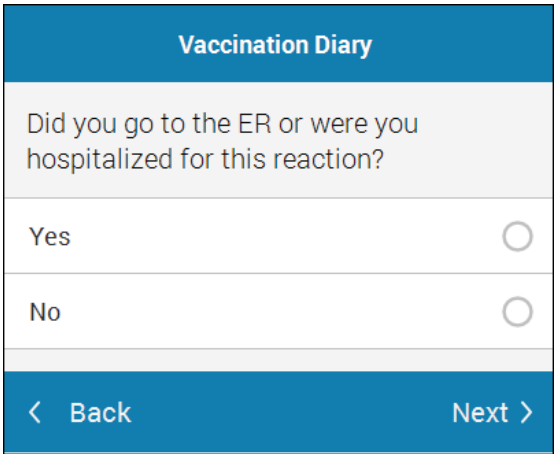
Screen 23



Screen 24



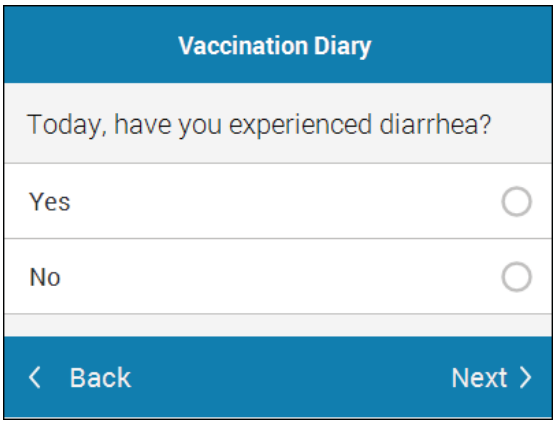
Message 2



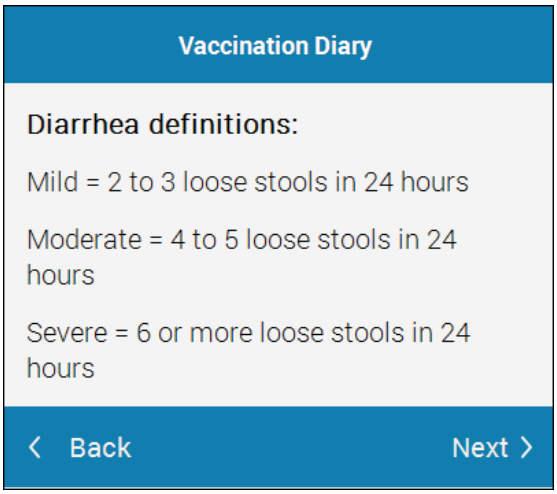
Screen 25

090177e194d02327\Approved\Approved On: 02-Sep-2020 17:58 (GMT)

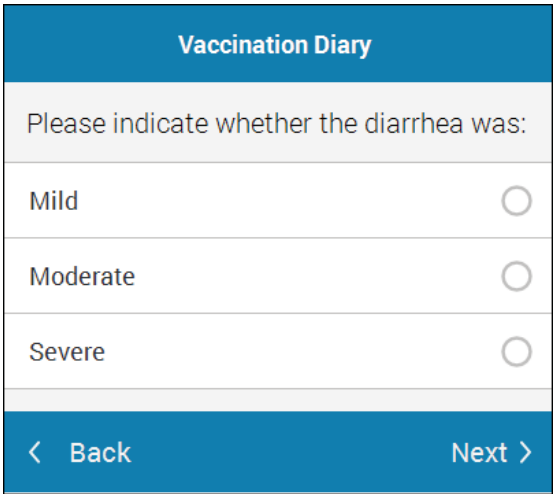
FDA-CBER-2021-5683-0024470



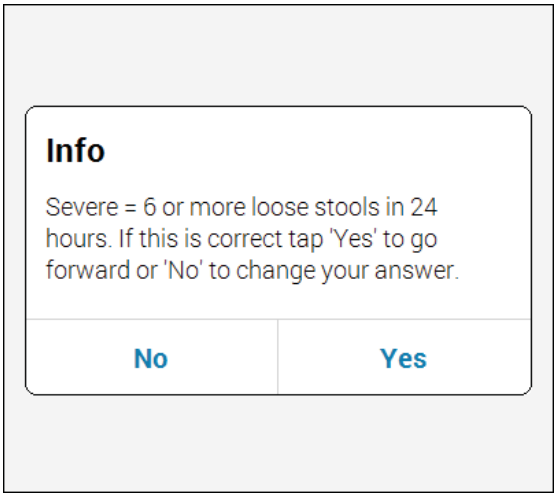
Screen 26



Screen 27



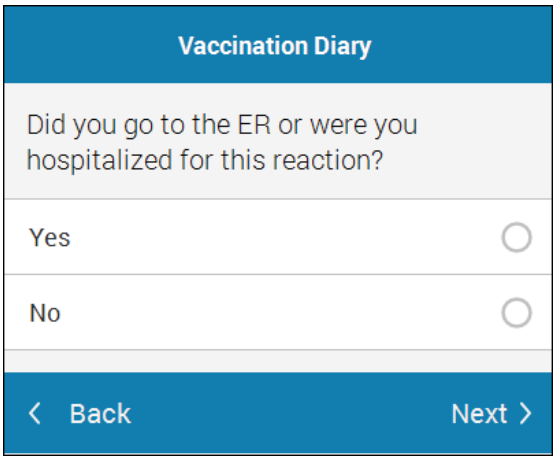
Screen 28



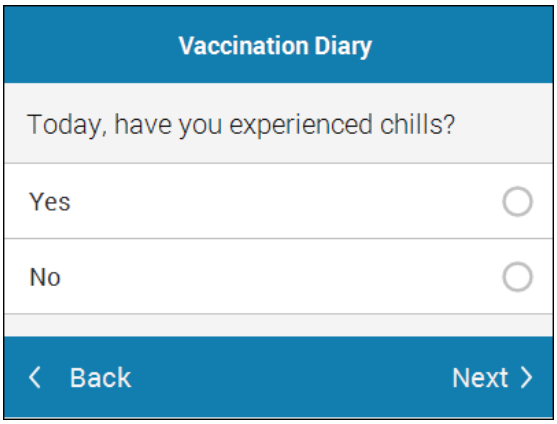
Message 2

090177e194d02327\Approved\Approved On: 02-Sep-2020 17:58 (GMT)

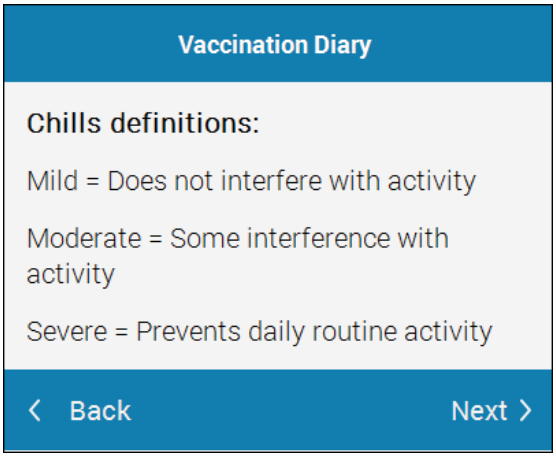
FDA-CBER-2021-5683-0024471



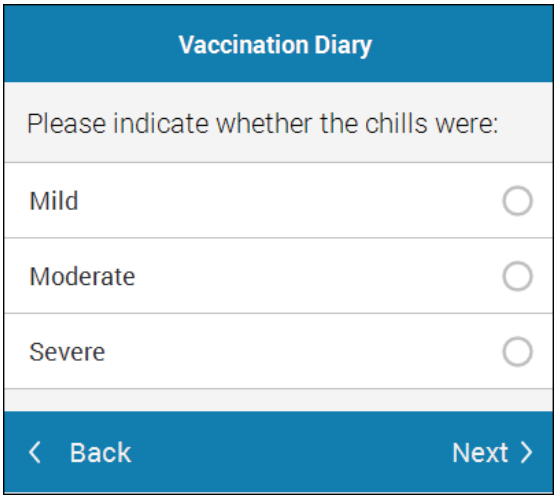
Screen 29



Screen 30



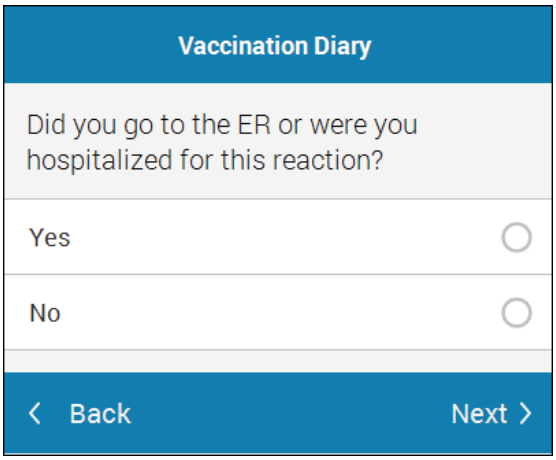
Screen 31



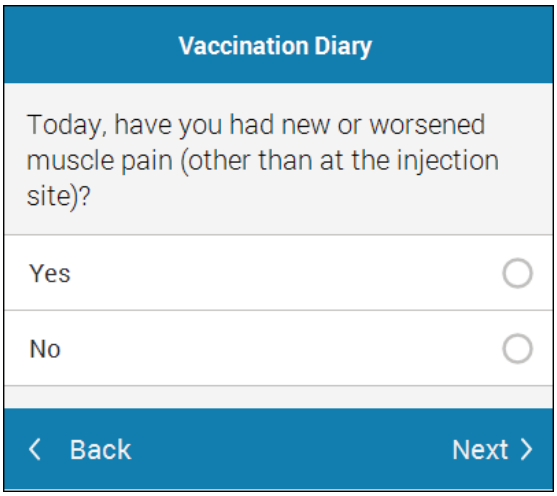
Screen 32

090177e194d02327\Approved\Approved On: 02-Sep-2020 17:58 (GMT)

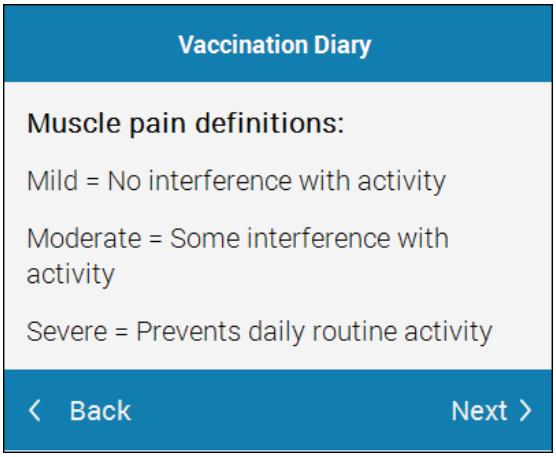
FDA-CBER-2021-5683-0024472



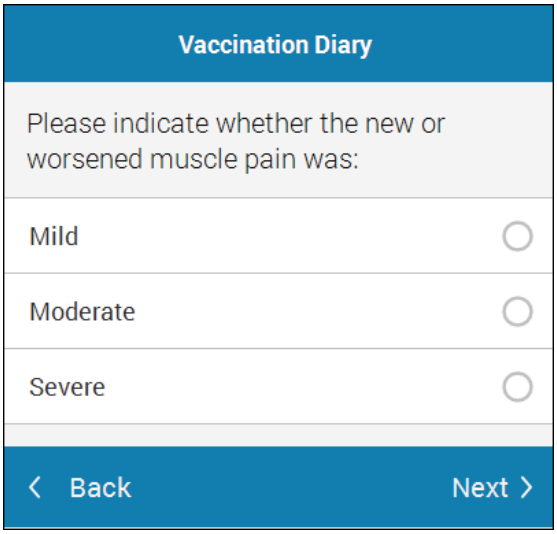
Screen 33



Screen 34



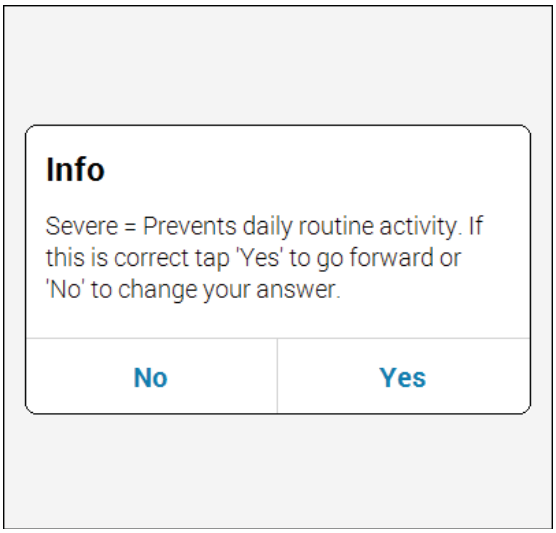
Screen 35



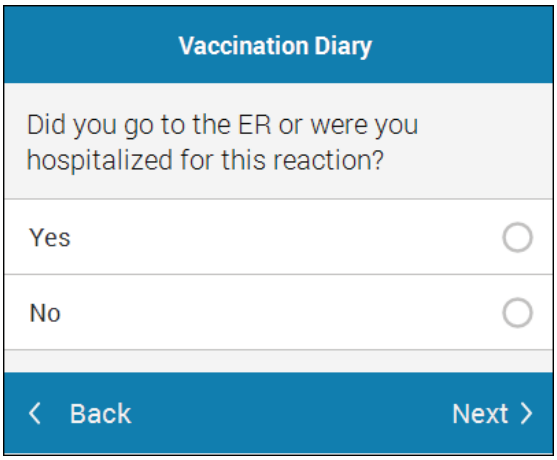
Screen 36

090177e194d02327\Approved\Approved On: 02-Sep-2020 17:58 (GMT)

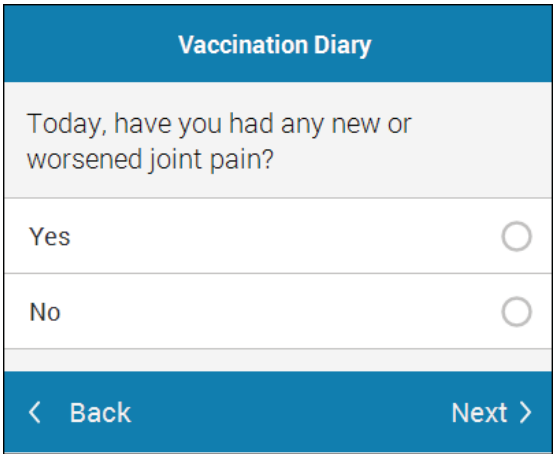
FDA-CBER-2021-5683-0024473



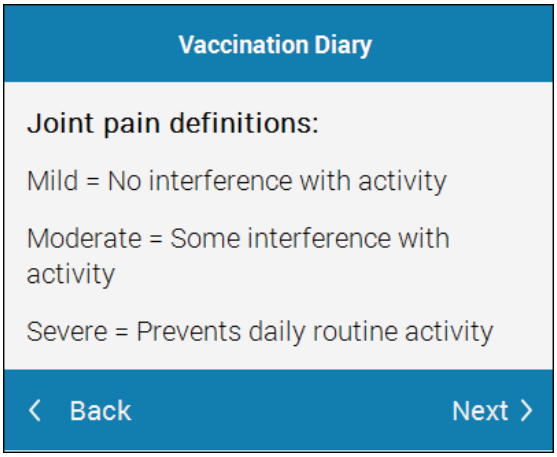
Message 2



Screen 37



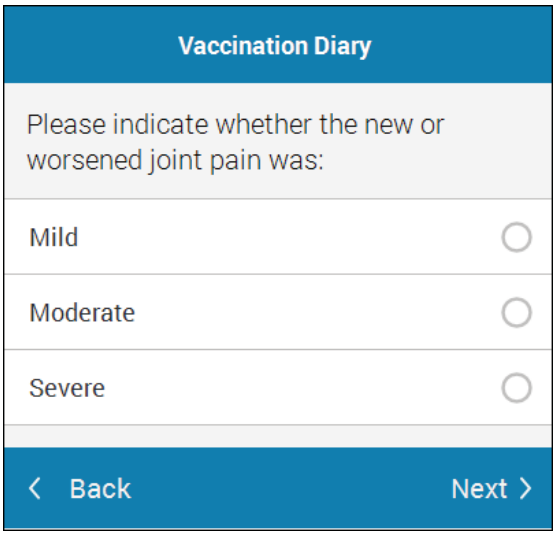
Screen 38



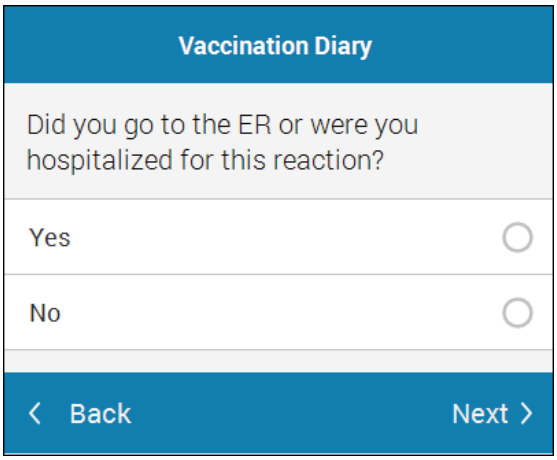
Screen 39

090177e194d02327\Approved\Approved On: 02-Sep-2020 17:58 (GMT)

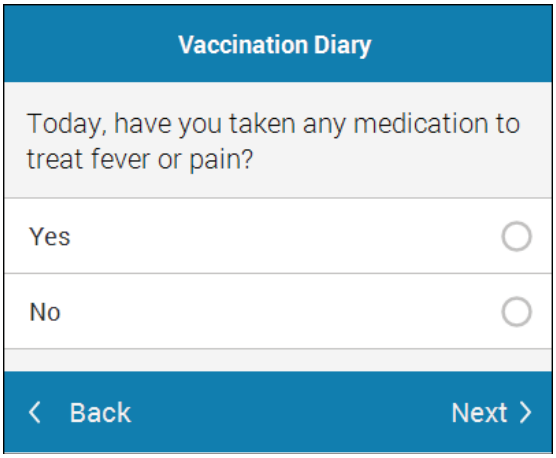
FDA-CBER-2021-5683-0024474



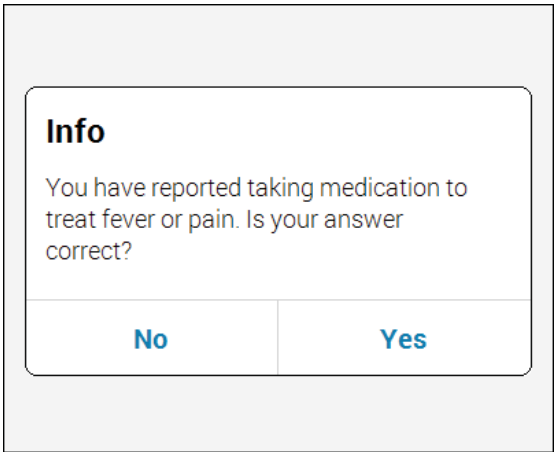
Screen 40



Screen 41



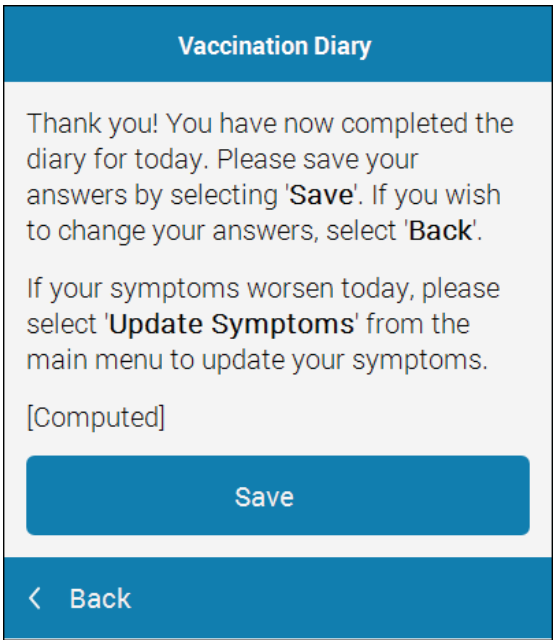
Screen 42



Message 2

090177e194d02327\Approved\Approved On: 02-Sep-2020 17:58 (GMT)

FDA-CBER-2021-5683-0024475

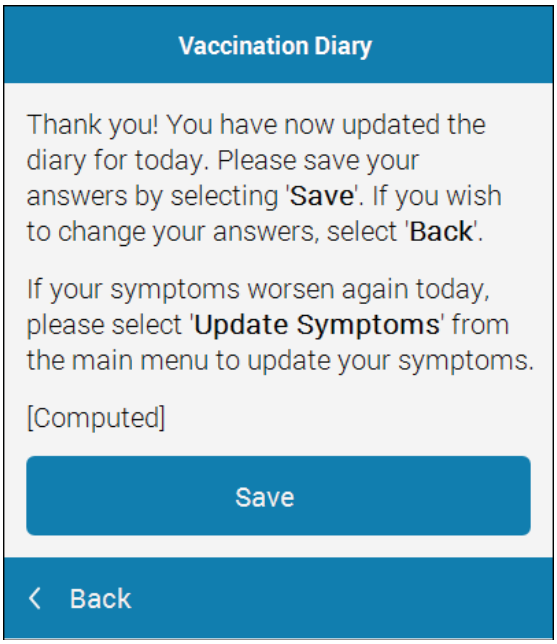


Screen 43

[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 44

[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).

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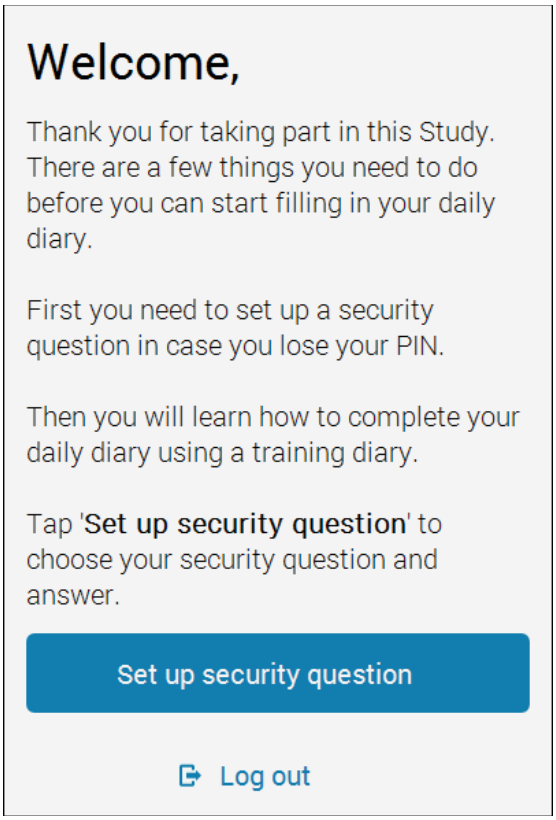
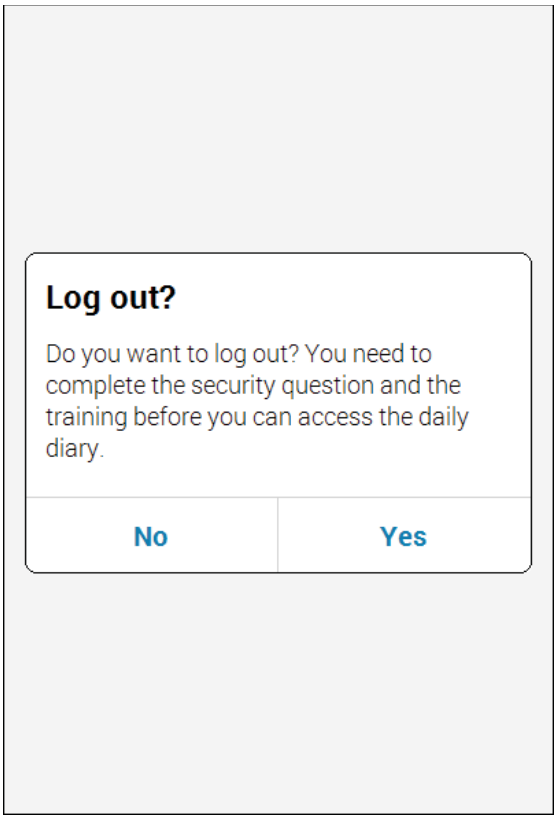
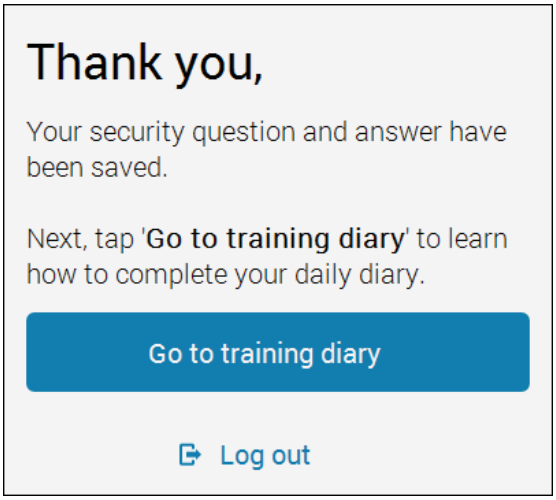
4 Form: Patient Main Menu



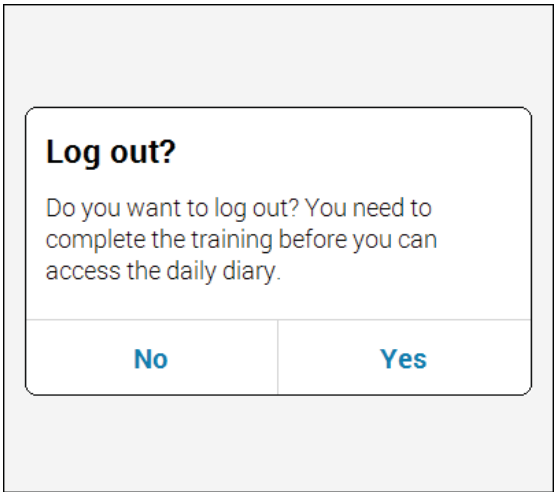
Screen 1



Message 1



Screen 2



Message 1

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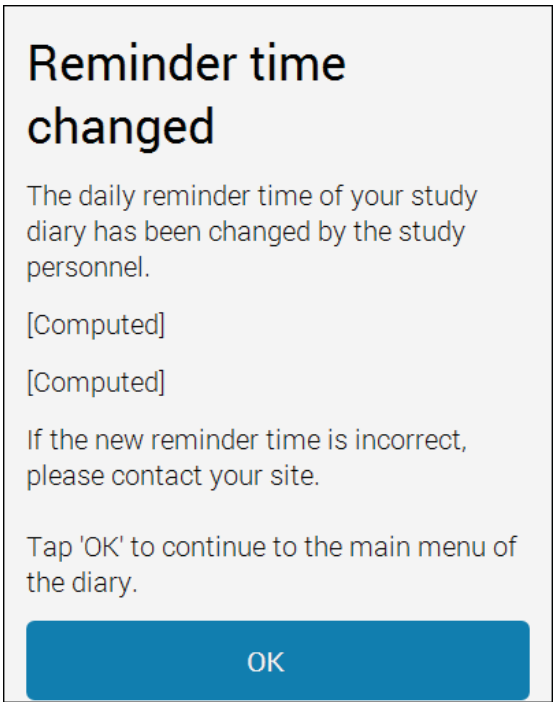
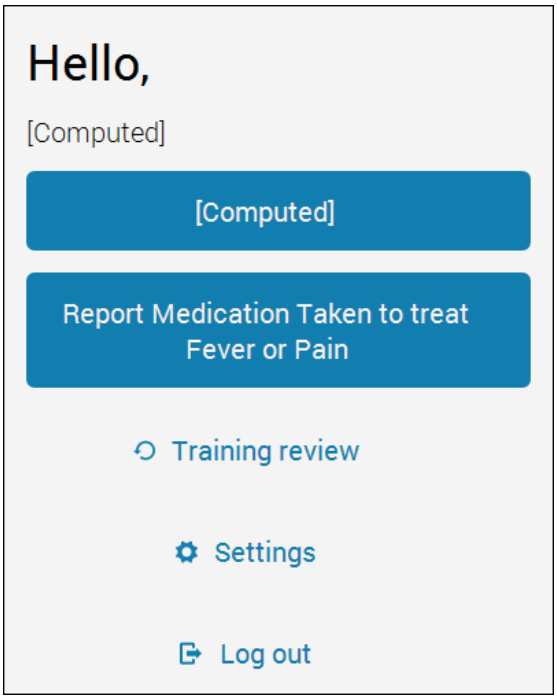


Screen 3

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

[Computed] text below Hello, will either display: "There are no Vaccination Diaries expected", "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 Vaccination Diary before midnight". The [Computed] text within the button will read "Update Symptoms" or "Vaccination Diary"

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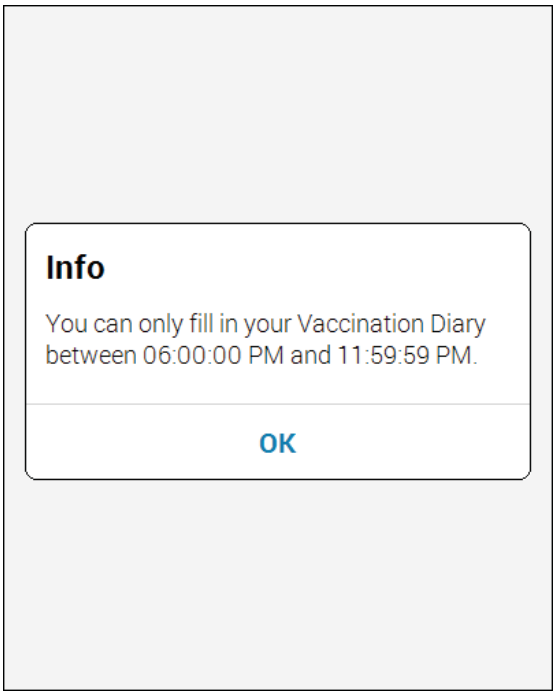
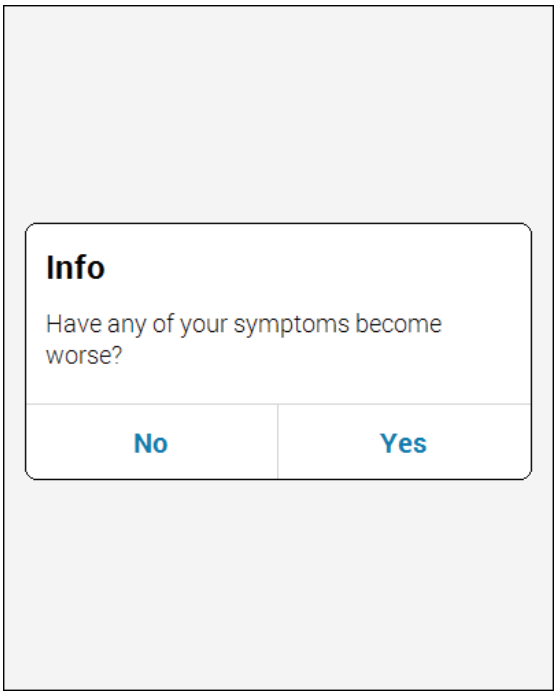


Message 1

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



Message 2

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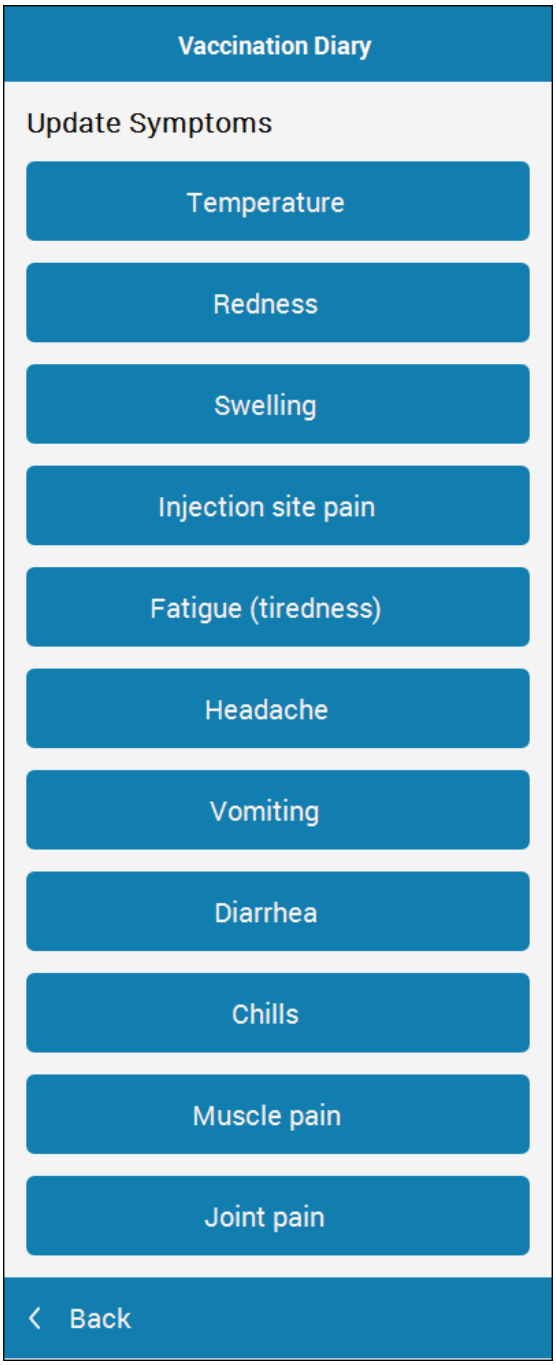
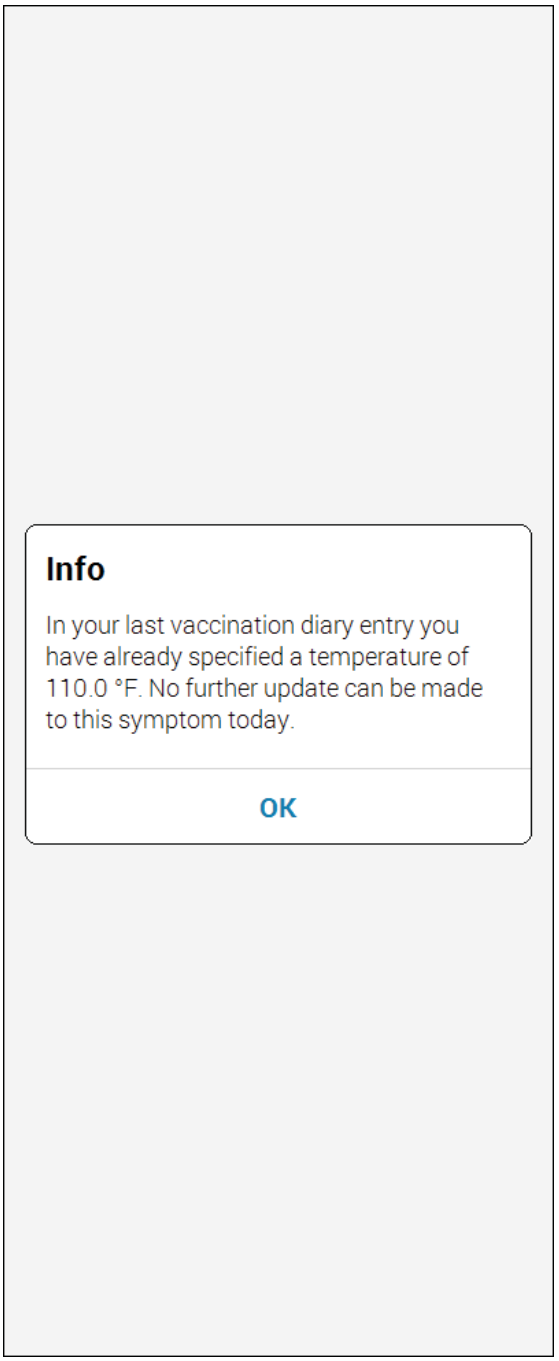
FDA-CBER-2021-5683-0024479



Screen 5



Message 2

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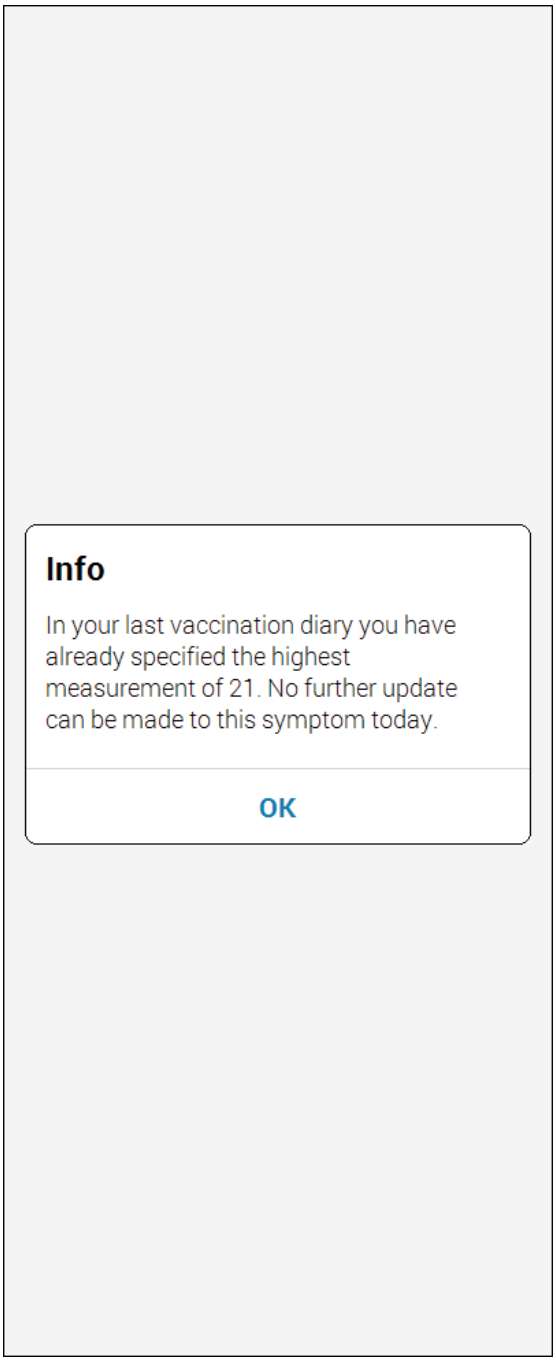
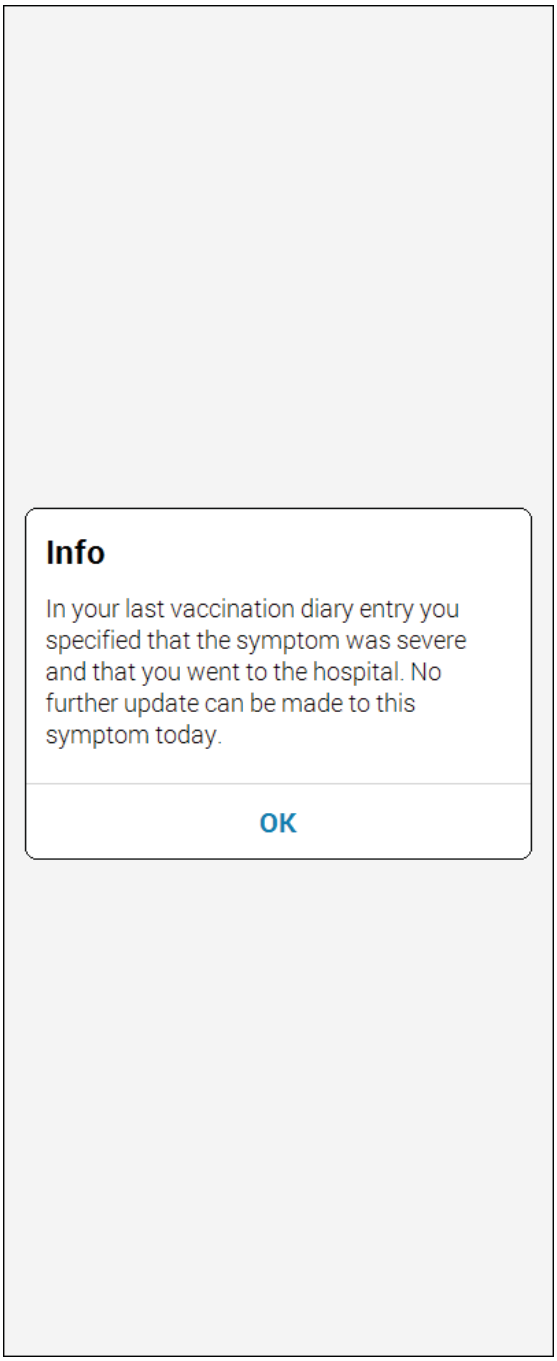


Message 4



Message 8

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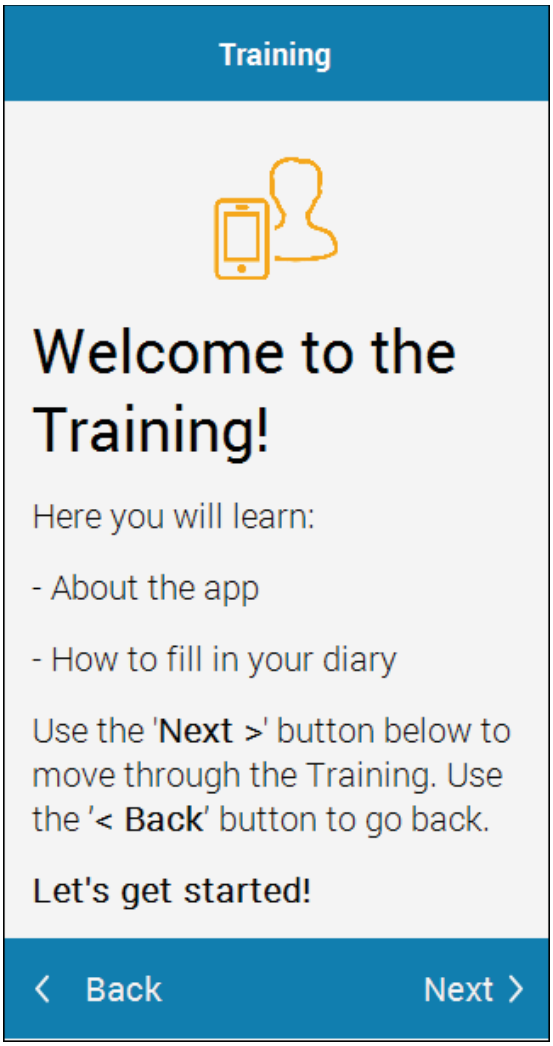
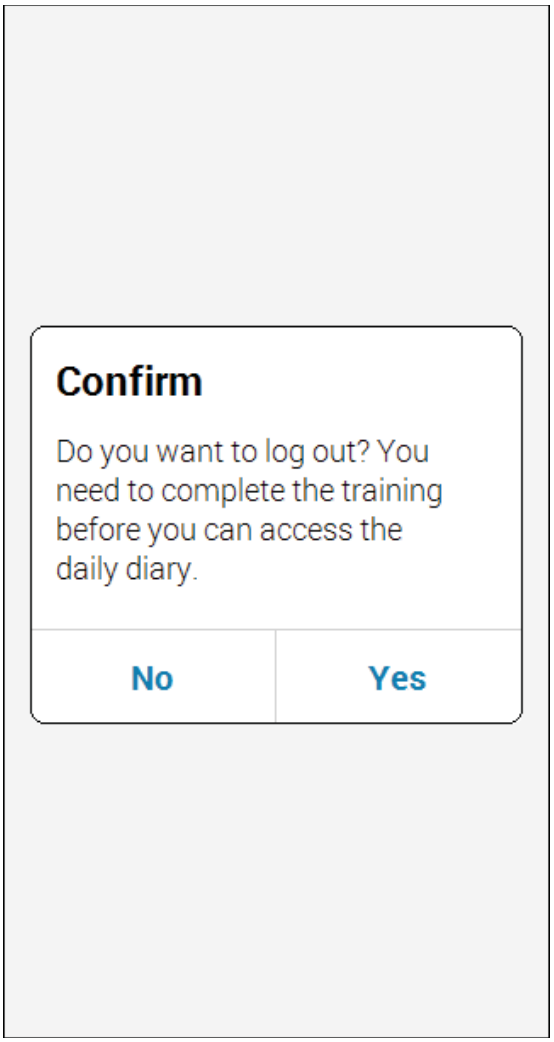
5 Form: Subject training diary



Screen 1



Message 1

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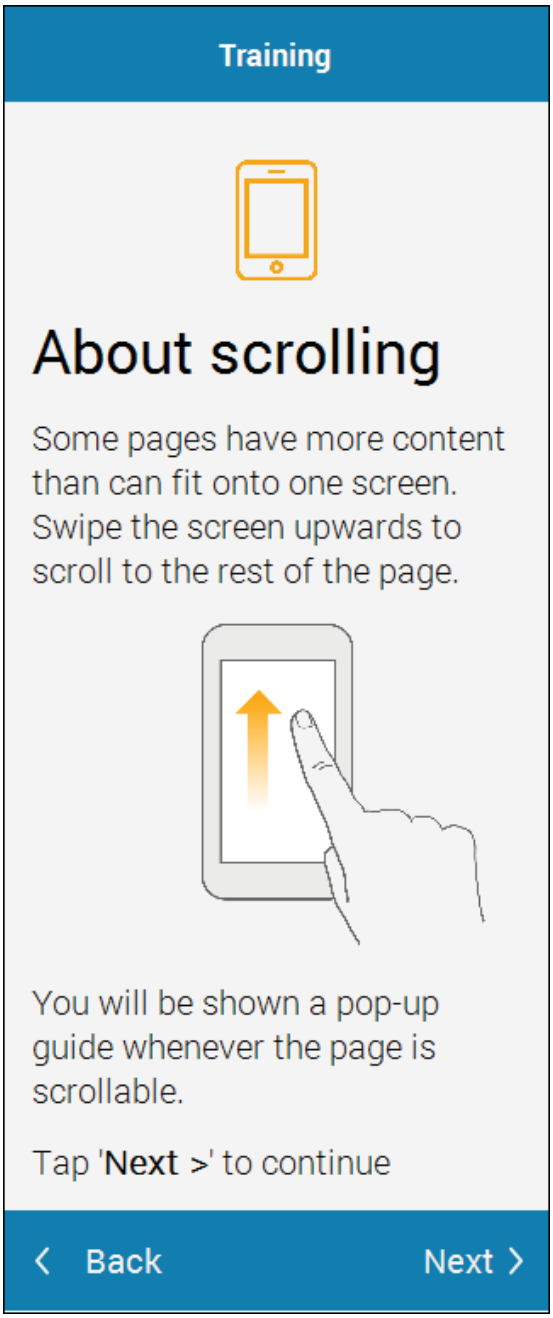
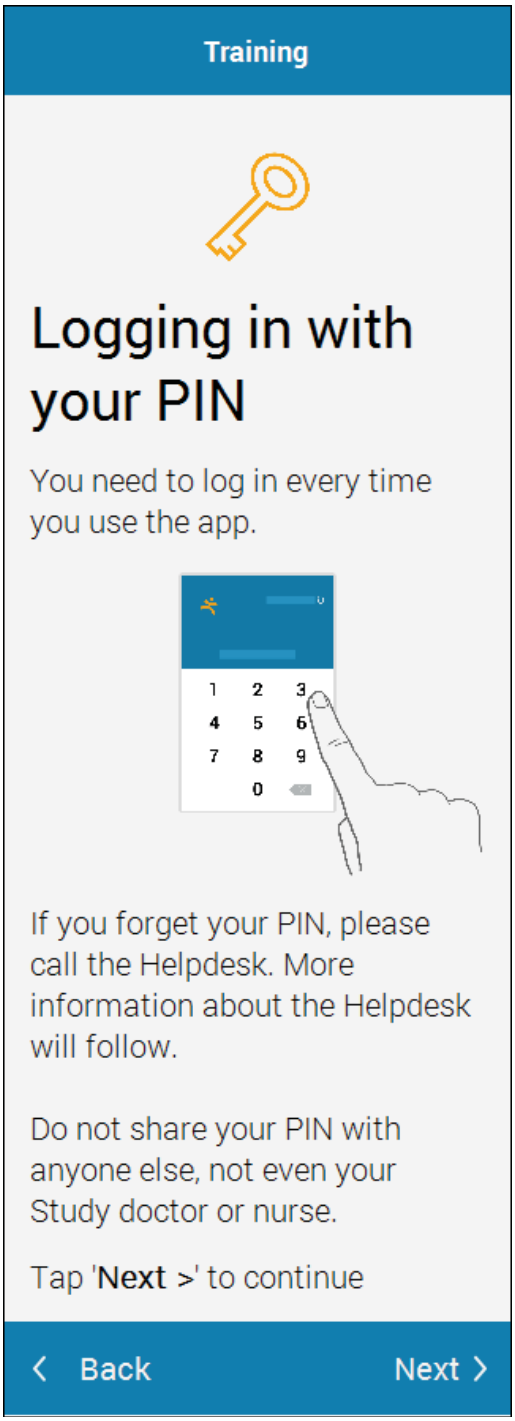


Screen 2



Screen 3

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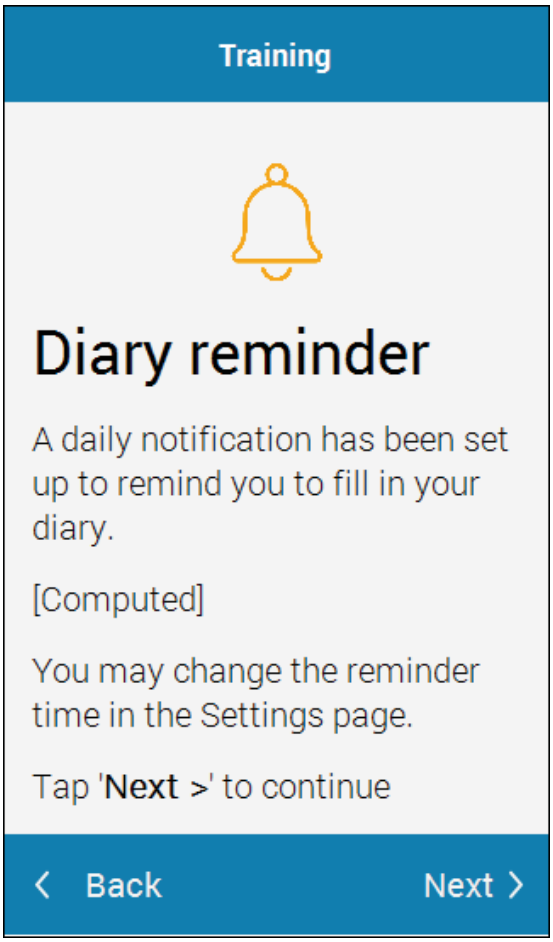
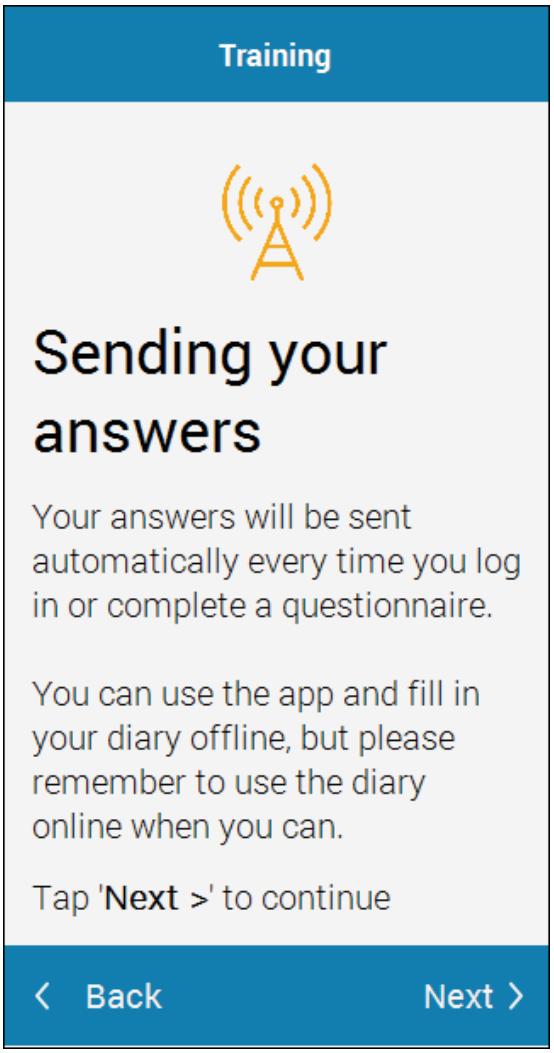
FDA-CBER-2021-5683-0024483



Screen 4

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



Screen 5

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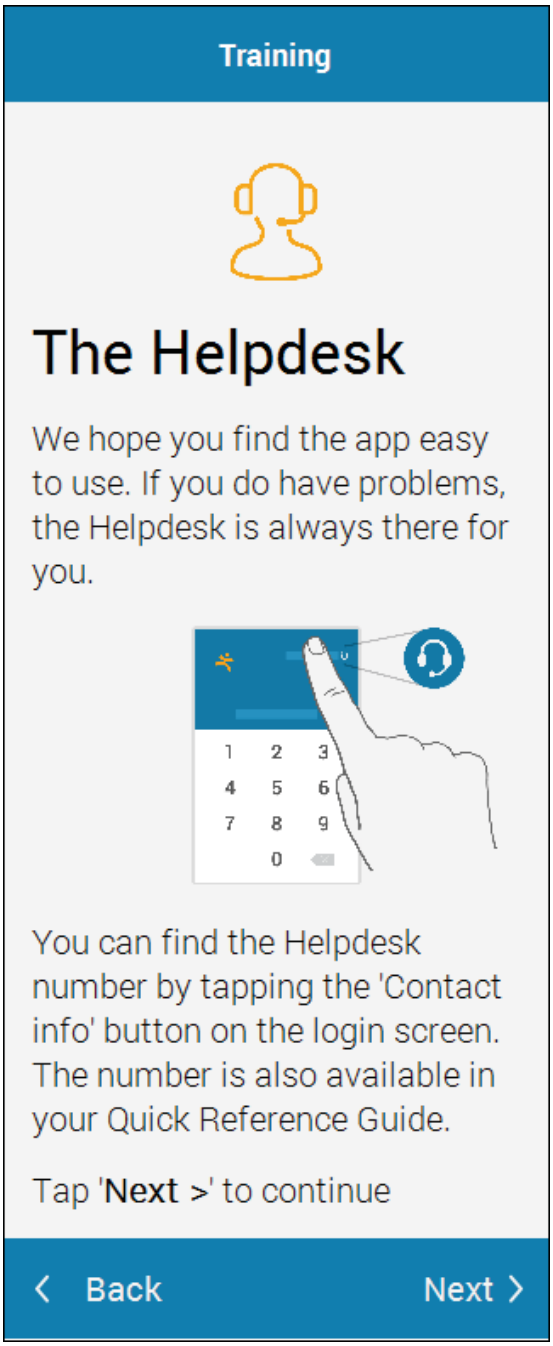
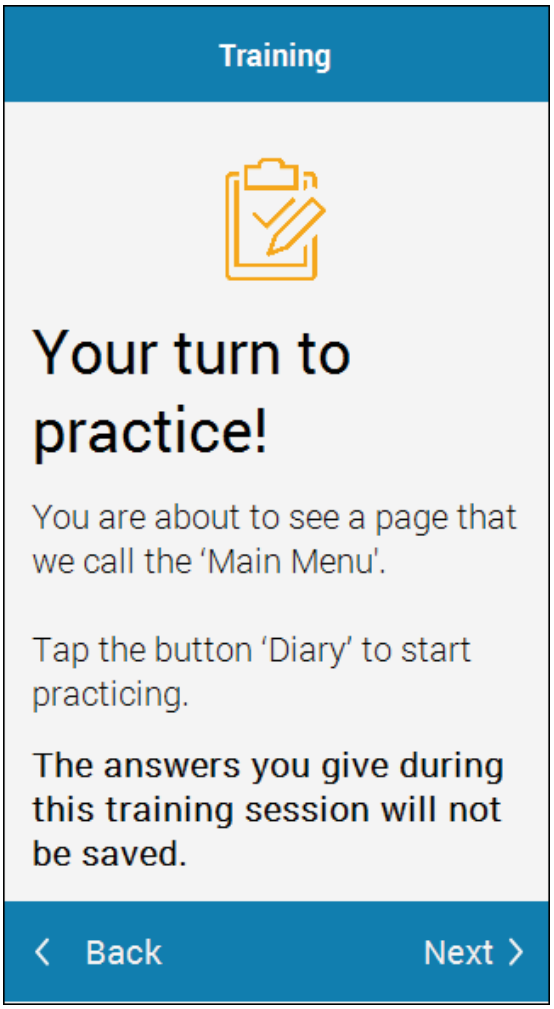
FDA-CBER-2021-5683-0024484



Screen 6



Screen 7

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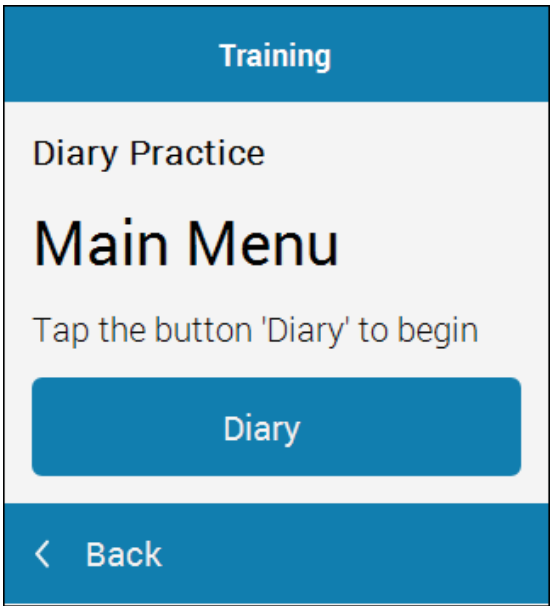
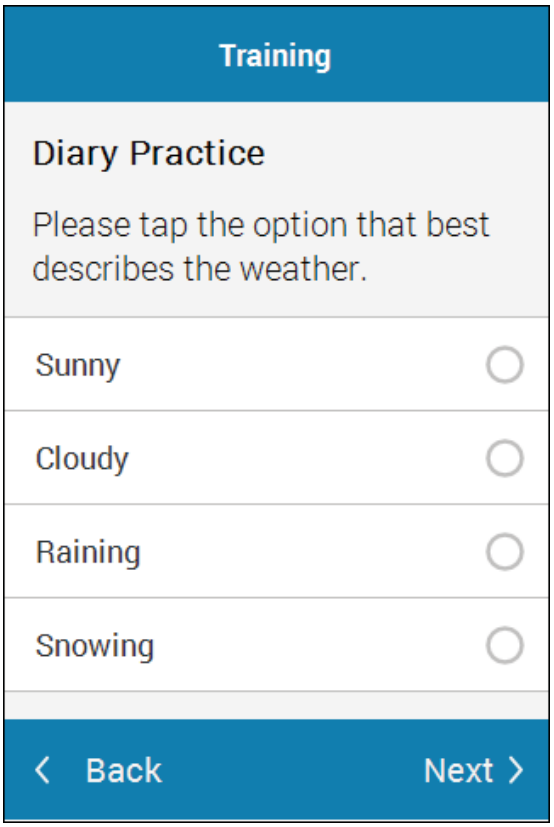


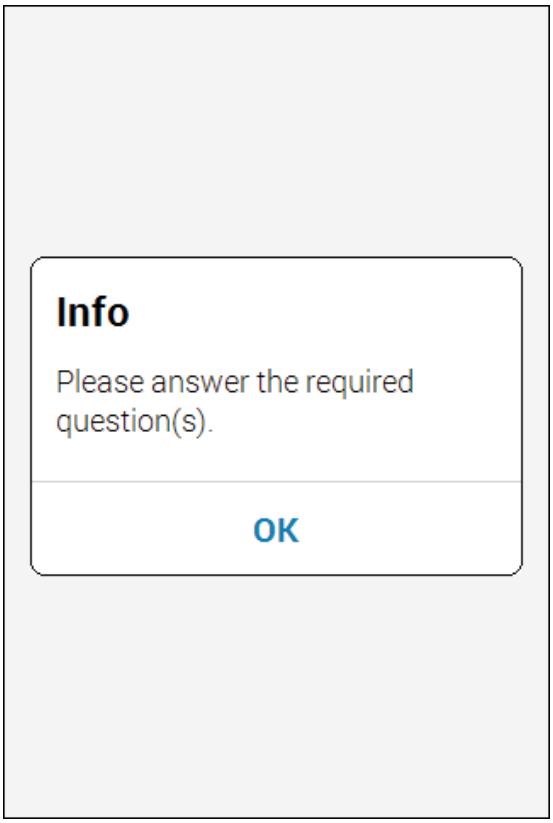
Screen 8



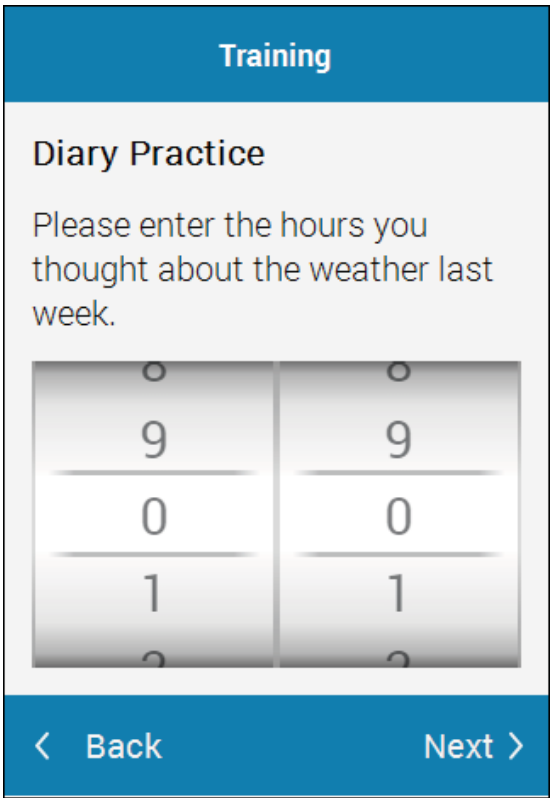
Screen 9

090177e194d02327\Approved\Approved On: 02-Sep-2020 17:58 (GMT)

FDA-CBER-2021-5683-0024486



Message 1



Screen 10

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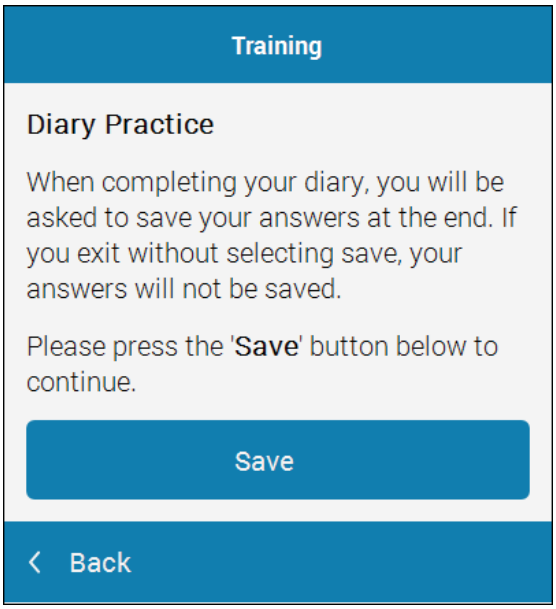
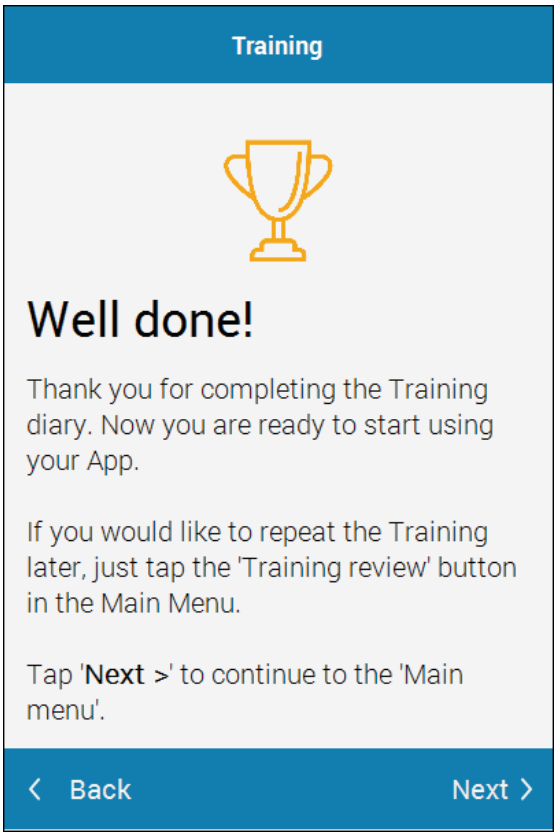
FDA-CBER-2021-5683-0024487



Screen 11



Screen 12

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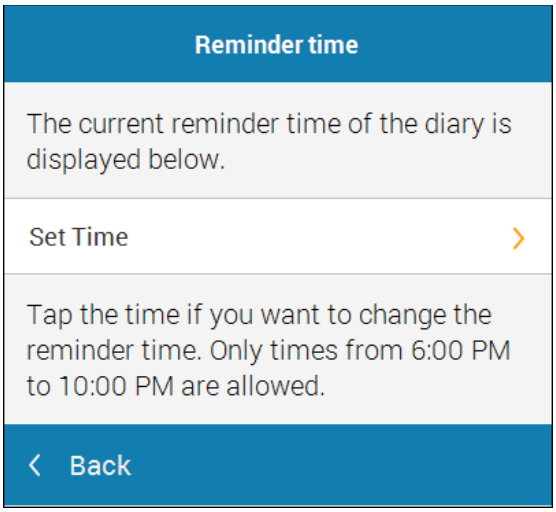
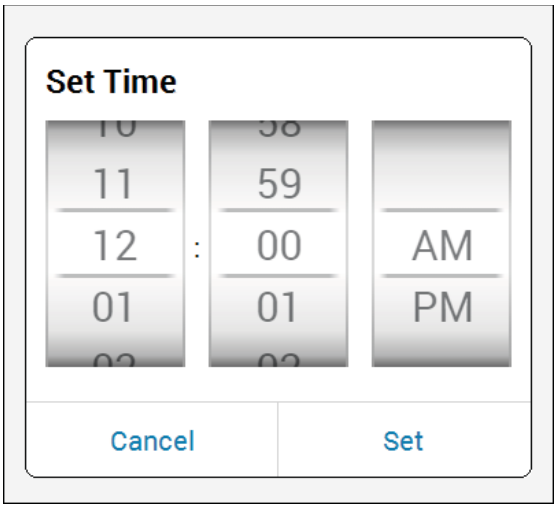
6 Form: Settings



Screen 1



Popup input 1

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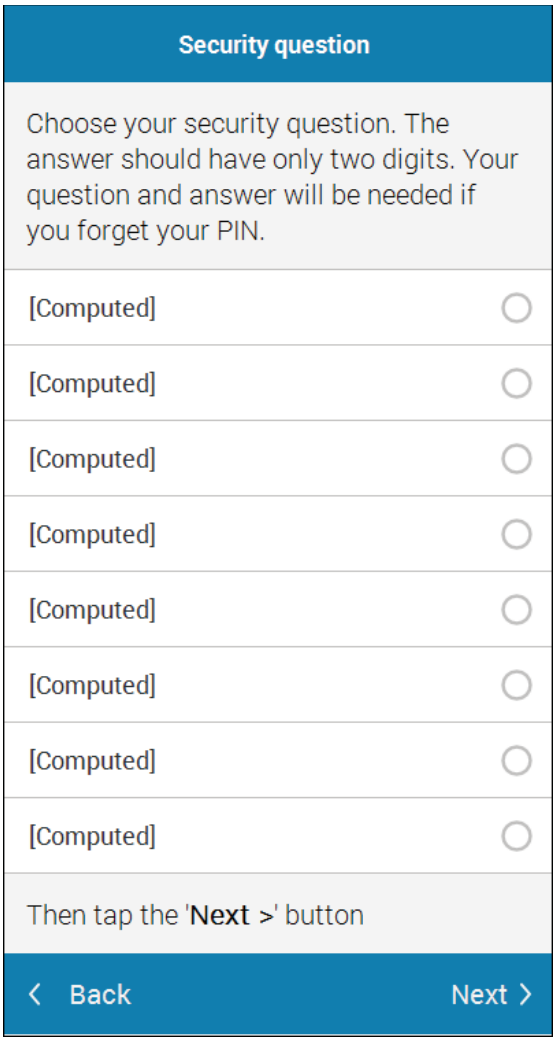
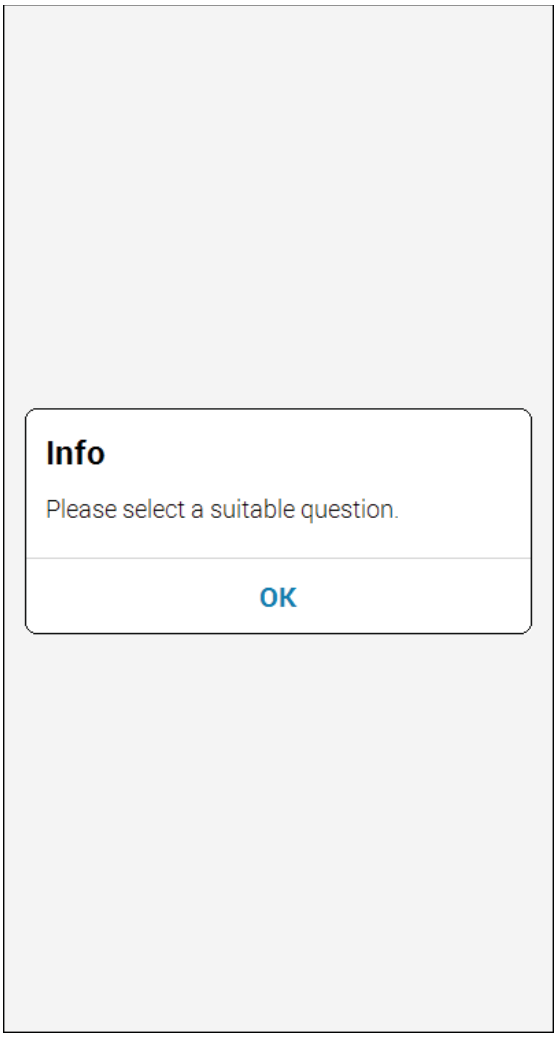
7 Form: Security question



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)'

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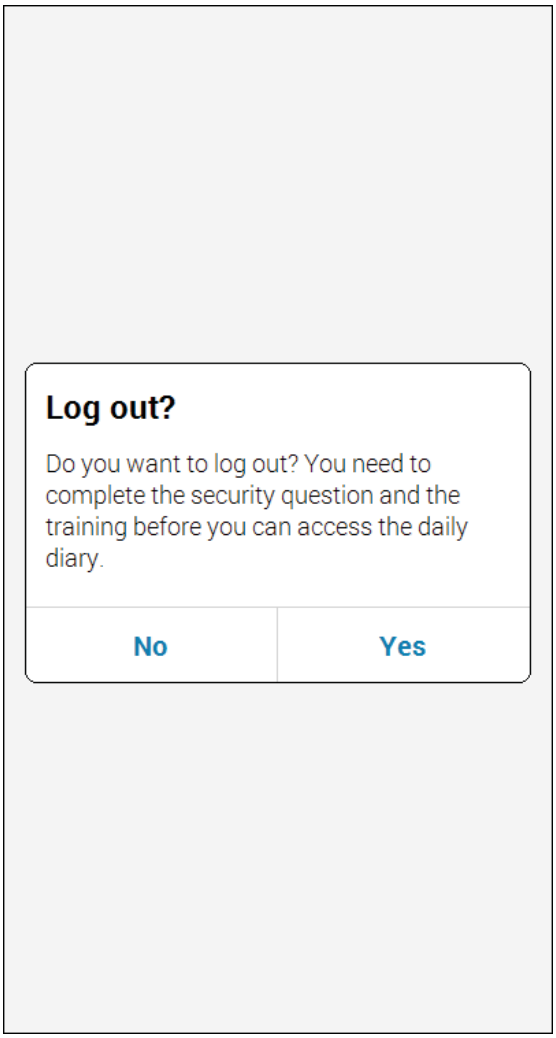
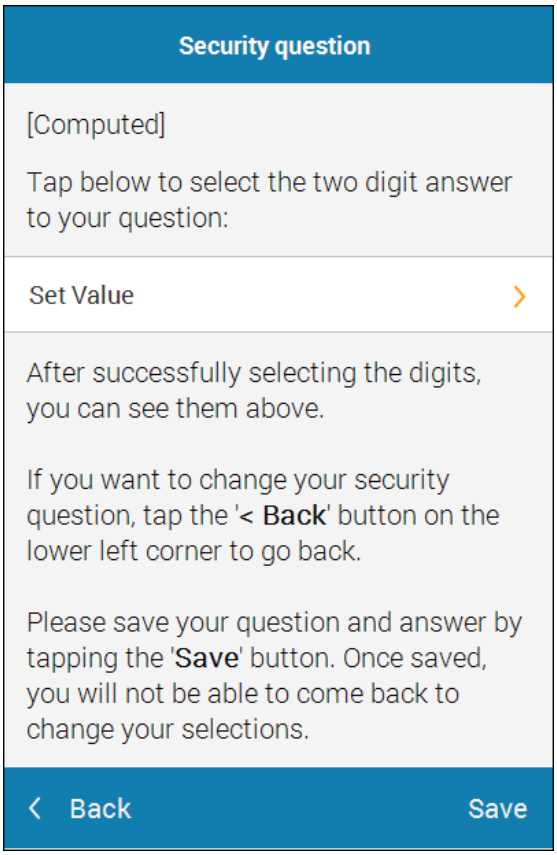


Message 2



Screen 2

[Computed] will display

'Your question:

{1}'

{1} will show the question selected on Screen 1

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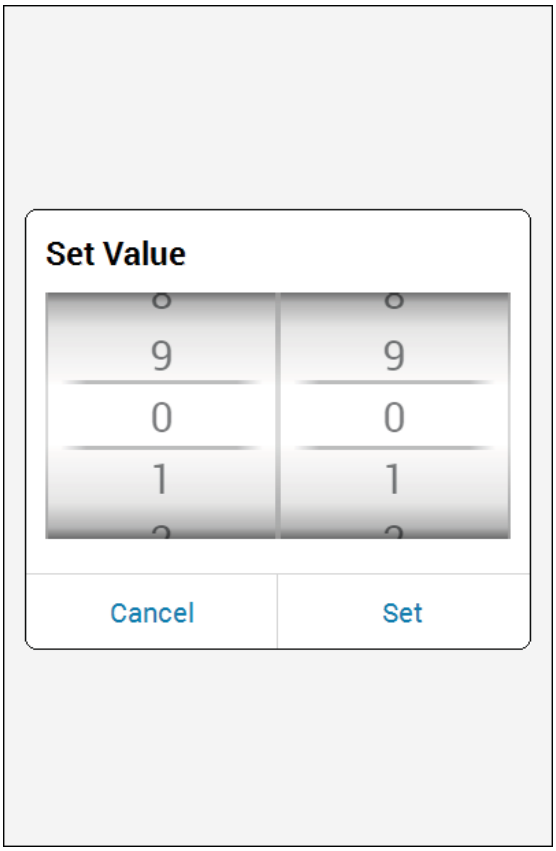
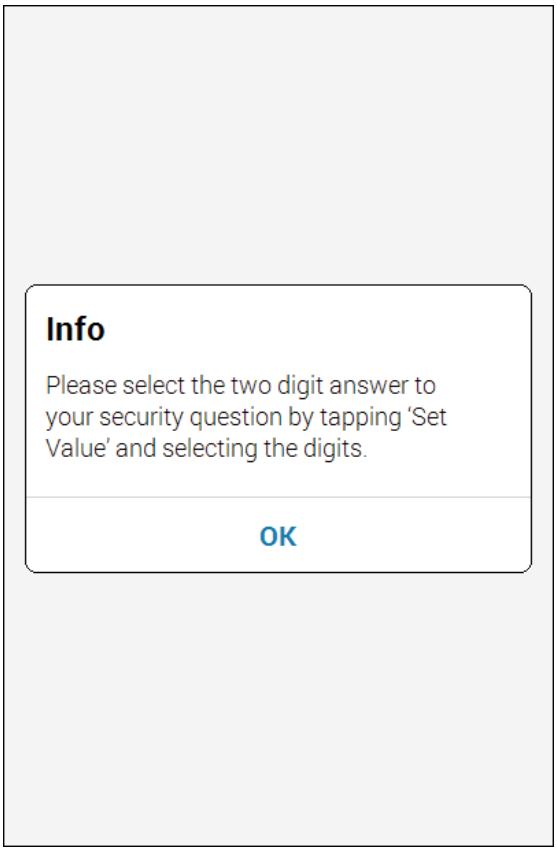


Popup input 1



Message 1

090177e194d02327\Approved\Approved On: 02-Sep-2020 17:58 (GMT)

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SCREEN REPORT APPROVAL

Content for Approval					
Language	English for United States				
Site Screen Report	A-1426-0082_5270SR_enUS_v2	**Version**	2	**Date**	03-Apr-2020

CUSTOMER

Approval		
Name and Title: Kathleen Snyder		Signature:
Company: Pfizer	Role: Study Manager	Date: DocuSigned by: Kathleen Snyder 23F5428A29294D3... 03-Apr-2020 | 21:11 EDT

SIGNANT HEALTH

Approval	
Name: Brittany Hayes	Signature:
Title: Project Manager II	Date: DocuSigned by: Brittany Hayes C4D491375B6548E... 03-Apr-2020 | 21:10 EDT

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