

Annotated Study Book for Study Design: C4591001

Study Design Version: 16.0

Sponsor: Pfizer

Protocol: C4591001

Sponsor Drug Name: BLINDED THERAPY

C4591001 - COVID19

Generated by Central Designer™

February 22, 2021 8:10AM

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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]	<input type="radio"/> ADVERSE EVENT													
2.	AE ID: [AE Identifier]	<input type="text"/>													
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms) [Adverse Event]	<input type="text"/>													
4.	Start Date Time: [Start Date]	/ / : 24-hour clock													
5.	Is the adverse event still ongoing? [Is the Adverse Event Still Ongoing]	<input type="radio"/> YES <input type="radio"/> NO End Date Time: / / : 24-hour clock													
6.	Toxicity Grade: [Toxicity Grade]	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4													
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes). [Serious]	<input type="radio"/> YES Is this serious event associated with congenital anomaly or birth defect? <input type="radio"/> YES <input type="radio"/> NO Did this serious event result in death? <input type="radio"/> YES <input type="radio"/> NO Did this serious event require or prolong hospitalization? <input type="radio"/> YES <input type="radio"/> NO Did this serious event result in persistent or significant disability/incapacity? <input type="radio"/> YES <input type="radio"/> NO Is this serious event life threatening? <input type="radio"/> YES <input type="radio"/> NO Other medically important serious event <input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> NO													
8.	Is this adverse	<input type="radio"/> YES													

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	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]	<input type="radio"/> NO
9.	Is this event related to study treatment: [Relationship to Study Treatment]	<input type="radio"/> NOT RELATED If Not Related to study treatment(s), this event is due to: <input type="radio"/> CONCOMITANT DRUG TREATMENT <input type="radio"/> CONCOMITANT NON-DRUG TREATMENT <input type="radio"/> OTHER If Other, specify: <input style="width: 400px; height: 20px;" type="text"/> <input type="radio"/> RELATED
10.	Latest Action Taken with Study Treatment: [Action Taken with Study Treatment]	<input type="radio"/> DRUG WITHDRAWN <input type="radio"/> NOT APPLICABLE
11.	Was a Concomitant Medication given? [Concomitant Medication Given]	<input type="radio"/> YES <input type="radio"/> NO
12.	Was a Non-Drug Treatment given? [Non-Drug Treatment Given]	<input type="radio"/> YES <input type="radio"/> NO
13.	What was the outcome of this adverse event?: [Outcome]	<input type="radio"/> FATAL <input type="radio"/> NOT RECOVERED/NOT RESOLVED <input type="radio"/> RECOVERED/RESOLVED <input type="radio"/> RECOVERED/RESOLVED WITH SEQUELAE <input type="radio"/> RECOVERING/RESOLVING <input type="radio"/> UNKNOWN
14.	Did the adverse event cause the subject to be discontinued from the study? [Caused Study Discontinuation]	<input type="radio"/> YES <input type="radio"/> NO
15.	Serious Adverse Event Number: For Pfizer Use Only [Serious Adverse Event Number]	<input style="width: 150px; height: 20px;" type="text"/>
16.	Comparison Term [hidden] [Comparison Term]	<input style="width: 400px; height: 80px;" type="text"/>
17.	Lowest Level Term [hidden]	<input style="width: 400px; height: 30px;" type="text"/>

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	[Lowest Level Term]	
18.	Lowest Level Term Code <i>[hidden]</i> [Lowest Level Term Code]	<input type="text"/>
19.	Dictionary-Derived Term <i>[hidden]</i> [Dictionary-Derived Term]	<input type="text"/>
20.	Preferred Term Code <i>[hidden]</i> [Preferred Term Code]	<input type="text"/>
21.	High Level Term <i>[hidden]</i> [High Level Term]	<input type="text"/>
22.	High Level Term Code <i>[hidden]</i> [High Level Term Code]	<input type="text"/>
23.	High Level Group Term <i>[hidden]</i> [High Level Group Term]	<input type="text"/>
24.	High Level Group Term Code <i>[hidden]</i> [High Level Group Term Code]	<input type="text"/>
25.	Primary System Organ Class <i>[hidden]</i> [Primary System Organ Class]	<input type="text"/>
26.	Primary System Organ Class Code <i>[hidden]</i> [Primary System Organ Class Code]	<input type="text"/>

C4591001: INFORMED CONSENT - BOOSTER (BOOST CONS)	
Informed Consent - Booster	
1. Consent Was: [Consent Was:]	<input type="radio"/> OBTAINED Date Written Consent Obtained <input type="text"/> / <input type="text"/> / <input type="text"/>

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C4591001: INCLUSION/EXCLUSION CRITERIA - BOOSTER (BOOST IE)	
Criterion Description	
1.	
Inclusion Criteria Not Met Entry	
1.1	Description of Inclusion Criterion Not Met [Criterion Description] <input type="button" value="v"/>
Criterion Description	
2.	
Exclusion Criteria Met Entry	
2.1	Description of Exclusion Criterion Met [Criterion Description] <input type="button" value="v"/>

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C4591001: BOOSTER DOSE TRIGGER FORM (BOOST TRIG)	
Booster Dose Trigger Form	
1. Select appropriate response - Will the participant return for consent/eligibility assessment for the booster dose visit? [Trigger Response 13]	<input type="radio"/> The participant will return for consent/eligibility assessment for the booster dose visit <input type="radio"/> The participant will NOT return for consent/eligibility assessment for the booster dose visit

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C4591001: LABORATORY DATA - HEMATOLOGY (CD4)					
Laboratory Data Hematology					
1. Lab Panel: [Category for Lab Test]	<input type="radio"/> HEMATOLOGY				
2. Laboratory Name and Address [Vendor Name (DERIVED)]	<input type="text"/>				
3. Collect on Date: [Collection Date:]	<input type="text"/> / <input type="text"/> / <input type="text"/>				
4. Specimen Type: [Specimen Type]	<input type="radio"/> 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]	<input type="text"/>				
5.2 Test: [Test:]	<input type="radio"/> CD4_PX4722				
5.3 Result: [Result:]	<input type="text"/>				
5.4 Not Done: <i>[hidden]</i> [Not Done:]	<input type="radio"/> NOT DONE				
5.5 LNMT [Lab Normal Range]	Low <input type="text"/> High <input type="text"/> Unit <input type="radio"/> 10 ³ /mm ³ <input type="radio"/> /uL <input type="radio"/> %				

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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]	<input type="button" value="v"/>
2. Select appropriate response - What cohort does the subject belong to? [Trigger Response 10]	<input type="radio"/> STAGE 1 SENTINEL COHORTS <input type="radio"/> STAGE 1 NONSENTINEL COHORTS <input type="radio"/> STAGE 2 COHORTS <input type="radio"/> 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 identifier? [Sponsor-Defined Identifier]		<input type="text"/>							
2.	Category: [Category for Medication]		<input type="radio"/> GENERAL CONCOMITANT MEDICATIONS							
3.	Concomitant Medications Pre-specified: [Concomitant Medications Pre-specified]		<input type="radio"/> NO							
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation). [Name of Medication]		<input type="text"/>							
5.	Dose: [Dose Description]		<input type="text"/>							
6.	Dose Unit: [Dose Unit]		<input type="text" value="v"/>							
7.	Dose Frequency: [Dose Frequency]		<input type="text" value="v"/>							
8.	Route: [Route]		<input type="text" value="v"/>							
9.	Start Date: [Start Date]		<input type="text" value="v"/> / <input type="text" value="v"/> / <input type="text" value="v"/>							
10.	Comparison Term <i>[hidden]</i> [Comparison Term]		<input type="text"/>							
11.	Standardized Medication Name - Dictionary derived. <i>[hidden]</i> [Standardized Medication Name]		<input type="text"/>							
12.	Standardized Medication Code - Dictionary derived <i>[hidden]</i> [Standardized Medication Code]		<input type="text"/>							

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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]	<input type="text"/>			
2.	Category: [Category for Medication]	<input type="radio"/> VACCINATIONS			
3.	Concomitant Medications Pre-specified: [Concomitant Medications Pre-specified]	<input type="radio"/> NO			
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation). [Name of Medication]	<input type="text"/>			
5.	Date: [Start Date]	<input type="text"/> / <input type="text"/> / <input type="text"/>			
6.	Comparison Term <i>[hidden]</i> [Comparison Term]	<input type="text"/>			
7.	Standardized Medication Name - Dictionary derived. <i>[hidden]</i> [Standardized Medication Name]	<input type="text"/>			
8.	Standardized Medication Code - Dictionary derived <i>[hidden]</i> [Standardized Medication Code]	<input type="text"/>			

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C4591001: MAIN INFORMED CONSENT (CONSENT)	
Informed Consent	
1. Consent Was: [Consent Was:]	<input type="radio"/> 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]	<input type="radio"/> CONTACT OUTCOME
2. Contact Type: [Type of Contact/Visit]	<input type="radio"/> CLINIC VISIT <input type="radio"/> TELEHEALTH VISIT
3. Was contact made? [Was Contact Made]	<input type="radio"/> YES Date of Contact: <input type="text"/> / <input type="text"/> / <input type="text"/> <input type="radio"/> NO If No, why? <input type="text"/>
4. Comments: [Comments/Findings/Details]	<input type="text"/>

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

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

C4591001: CONTACT OUTCOME - UNPLANNED (CONTACT UV)	
Contact Outcome	
1. Follow-Up Contact Category [hidden] [Follow Up Contact Category]	<input type="radio"/> CONTACT OUTCOME
2. Contact Type: [Type of Contact/Visit]	<input type="radio"/> TELEPHONE VISIT
3. Was contact made? [Was Contact Made]	<input type="radio"/> YES Date of Contact: <input type="text"/> / <input type="text"/> / <input type="text"/> Contact Outcome: <input type="radio"/> VISIT ARRANGED <input type="radio"/> VISIT ARRANGED, BUT NOT ATTENDED <input type="radio"/> VISIT NOT ARRANGED, REACTION NO LONGER PRESENT <input type="radio"/> VISIT NOT ARRANGED, UNABLE TO ATTEND <input type="radio"/> VISIT NOT REQUIRED, DATA ENTRY ERROR IN E-DIARY <input type="radio"/> VISIT NOT REQUIRED, INVESTIGATOR DECISION <input type="radio"/> NO If No, why? <input type="text"/>
4. Comments: [Comments/Findings/Details]	<input type="text"/>

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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 Collect on: [Date of Collect on]	<input type="text" value=""/> / <input type="text" value=""/> / <input type="text" value=""/>				
2.	Specimen Type: [Specimen Type]	<input type="radio"/> SERUM <input type="radio"/> BLOOD <input type="radio"/> PLASMA				
3.	Assay Code and Description: [Assay Code and Description]	<input type="radio"/> SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2				
4.	Dev ce Type: [Dev ce Type]	<input type="radio"/> SARS-COV-2 DIAGNOSTIC TEST				
5.	Test Result: [Result]	<input type="radio"/> POSITIVE <input type="radio"/> NEGATIVE <input type="radio"/> INDETERMINATE				
6.	Comments/Findings/Details: [Comments:]	<div style="border: 1px solid black; height: 50px;"></div>				

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

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C4591001: DEATH DETAILS CODED (DEATH DTL)					
Death Details					
1.	Date of Collection / Notification of Death: [Date of Collect on / Notification of Death] <input type="text"/> / <input type="text"/> / <input type="text"/>				
2.	<table border="1" style="width:100%"> <thead> <tr> <th style="width:50%">Cause of Death Status</th> <th style="width:50%">Cause of Death</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> </tr> </tbody> </table>	Cause of Death Status	Cause of Death		
Cause of Death Status	Cause of Death				
Cause of Death Entry					
2.1	Cause of Death Status: [Cause of Death Status] <input type="radio"/> PRIMARY CAUSE OF DEATH <input type="radio"/> SECONDARY CAUSE OF DEATH				
2.2	Cause of Death: [Cause of Death] <input style="width:100%" type="text"/>				
2.3	Comparison Term [hidden] [Comparison Term] <input style="width:100%" type="text"/>				
2.4	Lowest Level Term [hidden] [Lowest Level Term] <input style="width:100%" type="text"/>				
2.5	Lowest Level Term Code [hidden] [Lowest Level Term Code] <input style="width:100%" type="text"/>				
2.6	Dictionary-Derived Term [hidden] [Dictionary-Derived Term] <input style="width:100%" type="text"/>				
2.7	Preferred Term Code [hidden] [Preferred Term Code] <input style="width:100%" type="text"/>				
2.8	High Level Term [hidden] [High Level Term] <input style="width:100%" type="text"/>				
2.9	High Level Term Code [hidden] [High Level Term Code] <input style="width:100%" type="text"/>				
2.10	High Level Group Term [hidden] [High Level Group Term] <input style="width:100%" type="text"/>				
2.11	High Level Group Term Code [hidden] [High Level Group Term Code] <input style="width:100%" type="text"/>				
2.12	Primary System Organ Class [hidden] [Primary System Organ Class] <input style="width:100%" type="text"/>				
2.13	Primary System Organ Class Code [hidden] [Primary System Organ Class Code] <input style="width:100%" type="text"/>				

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C4591001: DEMOGRAPHY (DEMOG)	
Demography	
1. Subject ID [Subject ID]	<input type="text"/>
2. Birth Date: [Birth Date]	<input type="text"/> / <input type="text"/> / <input type="text"/>
3. Sex: [Sex]	<input type="radio"/> FEMALE <input type="radio"/> MALE
4. Ethnicity: [Ethn c ty]	<input type="radio"/> HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN <input type="radio"/> NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN <input type="radio"/> NOT REPORTED
5. Race: (Check X all that apply): [Race Of Subject]	<input type="checkbox"/> BLACK OR AFRICAN AMERICAN <input type="checkbox"/> AMERICAN INDIAN OR ALASKA NATIVE <input type="checkbox"/> ASIAN <input type="checkbox"/> NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER <input type="checkbox"/> WHITE <input type="checkbox"/> NOT REPORTED
6. Racial Designation: [Racial Designation]	<input type="radio"/> JAPANESE <input type="radio"/> OTHER

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

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C4591001: DISPOSITION - FOLLOW-UP (DISP FUP)	
Disposition - Follow-Up	
1. Date of Completion/Discontinuation/Death : [Date of Completion/Discontinuation/Death :]	<input type="text"/> / <input type="text"/> / <input type="text"/>
2. Phase of Disposition: [Disposition Phase]	<input type="radio"/> FOLLOW-UP
3. Status: [Status]	<input type="text"/>
4. Specify Status: [Specify Status]	<input type="text"/>

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

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C4591001: DISPOSITION - SCREENING (DISP SCR)	
Disposition - Screening	
1. Date of Completion/Discontinuation/Death [Date of Completion/Discontinuat on/Death]	<input type="text" value=""/> / <input type="text" value=""/> / <input type="text" value=""/>
2. Phase of Disposit on: [Disposition Phase]	<input checked="" type="radio"/> SCREENING
3. Status: [Status]	<input type="text" value=""/>
4. Specify Status: [Specify Status]	<input type="text"/>

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C4591001: DISPOSITION - TREATMENT (DISP TRT)	
Disposition - Treatment	
1. Date of Completion/Discontinuation/Death : [Date of Completion/Discontinuation/Death :]	<div style="display: flex; justify-content: space-around;"> ▼ / ▼ / ▼ </div>
2. Phase of Disposition: [Disposition Phase]	<input type="radio"/> VACCINATION <input type="radio"/> OPEN LABEL TREATMENT <input type="radio"/> SUBSTUDY
3. Status: [Status]	<div style="border: 1px solid black; padding: 2px;">▼</div>
4. Specify Status: [Specify Status]	<div style="border: 1px solid black; height: 20px; width: 100%;"></div>

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C4591001: DATE OF VISIT (DOV)	
Date of Visit	
1. Date of Visit [Date of Visit]	<input type="text" value=""/> / <input type="text" value=""/> / <input type="text" value=""/>
2. Erroneous Visit [Vis t Error]	<input type="radio"/> ERRONEOUS VISIT

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C4591001: DATE OF VISIT - ILLNESS CONVALESCENT (DOV CONV)	
Date of Visit	
1. Date of Visit [Date of Visit]	<input type="text" value=""/> / <input type="text" value=""/> / <input type="text" value=""/>
2. Erroneous Visit [Vis t Error]	<input type="radio"/> ERRONEOUS VISIT
COVID-19 Illness Visit	
3. COVID-19 Illness Vis t: [COVID-19 Illness Visit]	<input type="text" value=""/>

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C4591001: DATE OF VISIT - ILLNESS ONSET (DOV ILL)	
Date of Visit	
1. Date of Visit [Date of Visit]	<input type="text" value=""/> / <input type="text" value=""/> / <input type="text" value=""/>
2. Erroneous Visit [Vis t Error]	<input type="radio"/> ERRONEOUS VISIT
COVID-19 Illness Visit	
3. COVID-19 Illness Vis t: [COVID-19 Illness Visit]	<input type="text" value=""/>

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C4591001: DATE OF VISIT - ASYMPTOMATIC SURVEILLANCE (DOV SURV)	
Date of Visit	
1. Date of Visit [Date of Visit]	<input type="text"/> / <input type="text"/> / <input type="text"/>
2. Erroneous Visit [Vis t Error]	<input type="radio"/> ERRONEOUS VISIT
COVID-19 Surveillance Visit	
3. COVID-19 Surveillance Vis t: [COVID-19 Surveillance Vis t]	<input type="text"/>

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C4591001: DATE OF VISIT - REPEAT SWAB (DOV SWAB)	
Date of Visit	
1. Date of Visit [Date of Visit]	<input type="text" value=""/> / <input type="text" value=""/> / <input type="text" value=""/>
2. Erroneous Visit [Vis t Error]	<input type="radio"/> ERRONEOUS VISIT
COVID-19 Repeat Swab	
3. COVID-19 Repeat Swab: [COVID-19 Repeat Swab]	<input type="text" value=""/>

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C4591001: INFORM ENROLLMENT (ENROLL)	
InForm Enrollment	
1. Subject ID [Subject ID]	<input type="text"/>

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C4591001: HIV STATUS (HIV)	
HIV Status	
1. Select appropriate response - What is the subject HIV status? [Trigger Response 2]	<input type="radio"/> The subject is known to be HIV POSITIVE <input type="radio"/> 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]	<input type="radio"/> CLINICAL CHEMISTRY				
2. Laboratory Name and Address [Vendor Name]	<input type="text"/>				
3. Collect on Date: [Collection Date:]	<input type="text"/> / <input type="text"/> / <input type="text"/>				
4. Specimen Type: [Specimen Type]	<input type="radio"/> 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]	<input type="text"/>				
5.2 Test: [Test:]	<input type="radio"/> HIV RNA (Ultrasensitive)				
5.3 Result: [Result:]	<input type="text"/>				
5.4 Not Done: <i>[hidden]</i> [Not Done:]	<input type="radio"/> NOT DONE				
5.5 LNMT [Lab Normal Range]	Low <input type="text"/> High <input type="text"/> Unit <input type="radio"/> /mL				

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C4591001: HEALTH CARE UTILIZATION (HLTHCARE)			
Health Care Utilization			
1.	Evaluation Interval: <i>[hidden]</i> [Evaluation Interval]	<input type="radio"/> SINCE THE START OF THE RESPIRATORY ILLNESS EPISODE	
2.	Disease Name: <i>[hidden]</i> [Disease Name]	<input type="radio"/> 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: <i>[hidden]</i> [Pre-Specified]	<input type="radio"/> YES	
3.2	Physician or Healthcare Professional: [Type of Practitioner]	<input type="radio"/> SPECIALIST <input type="radio"/> EMERGENCY ROOM <input type="radio"/> PRIMARY CARE PHYSICIAN <input type="radio"/> URGENT CARE <input type="radio"/> TELEPHONE CONSULTATION <input type="radio"/> OTHER	
3.3	Occurrence of Visits or Contacts: [Occurrence of Visits or Contacts]	<input type="radio"/> YES Number of Visits or Contacts: <input type="text"/> <input type="radio"/> NO	
Health Care Utilization Other			
4.	Other Type of Practitioner Specify: [Other Type of Practitioner Specify]	<input type="text"/>	
Health Care Utilization			
5.	Has the subject been hospitalized due to potential COVID-19 illness? [Been Hospitalized]	<input type="radio"/> YES Has the subject been in intensive care due to potential COVID-19 illness? <input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> NO	

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C4591001: HOSPITALIZATION DETAILS (HOSP) - Repeating Form				
#	Hospitalization Category	Hospitalization Term	Admission Date	Ongoing
1				
Hospitalization Details				
1.	Hospitalization Category: [Hospitalization Category]	<input type="radio"/> HOSPITALIZATION STATUS		
2.	Hospitalization Term: [Hospitalization Term]	<input type="radio"/> ICU <input type="radio"/> HOSPITAL		
3.	Admission Date: [Admission Date]	<input type="text" value="▼"/> / <input type="text" value="▼"/> / <input type="text" value="▼"/>		
4.	Ongoing? [Ongoing]	<input type="radio"/> YES <input type="radio"/> NO Discharge Date: <input type="text" value="▼"/> / <input type="text" value="▼"/> / <input type="text" value="▼"/>		

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C4591001: ILLNESS DETAILS (ILL POTEN)	
Illness Details	
1. Category of Clinical Event: [Category of Clinical Event:]	<input type="radio"/> POTENTIAL COVID-19 ILLNESS
2. Was a diagnosis obtained for Potential COVID-19 Illness? [Diagnosis Obtained]	<input type="radio"/> YES Respiratory Illness Diagnosis: <input type="text"/> Date of Diagnosis: <input type="text"/> / <input type="text"/> / <input type="text"/> <input type="radio"/> NO
3. Toxicity Grade: [Toxicity Grade]	<input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5
4. Comparison Term: <i>[hidden]</i> [Comparison Term]	<input type="text"/>
5. Lowest Level Term <i>[hidden]</i> [Lowest Level Term]	<input type="text"/>
6. Lowest Level Term Code <i>[hidden]</i> [Lowest Level Term Code]	<input type="text"/>
7. Dictionary Derived Term <i>[hidden]</i> [Dictionary Derived Term]	<input type="text"/>
8. Preferred Term Code <i>[hidden]</i> [Preferred Term Code]	<input type="text"/>
9. High Level Term <i>[hidden]</i> [High Level Term]	<input type="text"/>
10. High Level Term Code <i>[hidden]</i> [High Level Term Code]	<input type="text"/>
11. High Level Group Term <i>[hidden]</i> [High Level Group Term]	<input type="text"/>
12. High Level Group Term Code <i>[hidden]</i> [High Level Group Term Code]	<input type="text"/>
13. Primary System Organ Class <i>[hidden]</i> [Primary System Organ Class]	<input type="text"/>
14. Primary System Organ Class Code <i>[hidden]</i> [Primary System Organ Class Code]	<input type="text"/>

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C4591001: ILLNESS DETAILS - SEVERE (ILL SEVERE)	
Illness Details	
1. Category of Clinical Event: [Category of Clinical Event:]	<input type="radio"/> SEVERE COVID-19 ILLNESS
2. Subcategory of Clinical Event: [Subcategory of Clinical Event]	<input type="radio"/> SIGNIFICANT ACUTE RENAL DYSFUNCTION <input type="radio"/> SIGNIFICANT ACUTE HEPATIC DYSFUNCTION <input type="radio"/> SIGNIFICANT ACUTE NEUROLOGIC DYSFUNCTION
3. Was a diagnosis obtained? [Diagnosis Obtained]	<input type="radio"/> YES Diagnosis: <input type="text"/> Start Date: <input type="text"/> / <input type="text"/> / <input type="text"/> Ongoing?: <input type="radio"/> YES <input type="radio"/> NO End Date: <input type="text"/> / <input type="text"/> / <input type="text"/> <input type="radio"/> NO
4. Toxicity Grade: [Tox c ty Grade]	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5
5. Comparison Term: <i>[hidden]</i> [Comparison Term]	<input type="text"/>
6. Lowest Level Term <i>[hidden]</i> [Lowest Level Term]	<input type="text"/>
7. Lowest Level Term Code <i>[hidden]</i> [Lowest Level Term Code]	<input type="text"/>
8. Dictionary Derived Term <i>[hidden]</i> [Dictionary Derived Term]	<input type="text"/>
9. Preferred Term Code <i>[hidden]</i> [Preferred Term Code]	<input type="text"/>
10. High Level Term <i>[hidden]</i> [High Level Term]	<input type="text"/>
11. High Level Term Code <i>[hidden]</i> [High Level Term Code]	<input type="text"/>
12. High Level Group Term <i>[hidden]</i> [High Level Group Term]	<input type="text"/>
13. High Level Group Term Code <i>[hidden]</i> [High Level Group Term Code]	<input type="text"/>
14. Primary System Organ Class <i>[hidden]</i> [Primary System Organ Class]	<input type="text"/>

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

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	[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]	<input type="text"/> / <input type="text"/> / <input type="text"/>		
2.	Location of Assessment: [Location of Assessment]	<input type="radio"/> CHEST <input type="radio"/> HEAD <input type="radio"/> OTHER If other, specify: <input type="text"/>		
3.	Type of Imaging Exam: [Imaging Method]	<input type="radio"/> CT SCAN <input type="radio"/> X-RAY <input type="radio"/> ULTRASOUND <input type="radio"/> MRI <input type="radio"/> OTHER If other, specify: <input type="text"/>		
4.	Assessment: [Overall Assessment]	<input type="radio"/> ABNORMAL If abnormal, specify findings: <input type="text"/> <input type="radio"/> INDETERMINATE <input type="radio"/> NORMAL <input type="radio"/> UNKNOWN <input type="radio"/> NOT EVALUABLE		

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C4591001: INCLUSION/EXCLUSION CRITERIA (IN EX STG3)				
Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclus on criteria (NO).				
Inclusion Criteria				
#	Inclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
1.a	1	Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)		IN01A00
1.b	2	Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures		IN02A00
1.c	3	Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study		IN03A00
1.d	4	Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol		IN04A00
Inclusion Criteria Entry				
1.1	Inclusion Number: [Inclusion Number]	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4		
1.2	Criterion Description: [Criterion Description]	<input type="checkbox"/>		
1.3	Criterion met? [Criterion met?]	<input type="radio"/> YES <input type="radio"/> NO Describe details if relevant <div style="border: 1px solid black; height: 40px; width: 100%;"></div>		
1.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	<input type="radio"/> IN01A00 <input type="radio"/> IN02A00 <input type="radio"/> IN03A00 <input type="radio"/> 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 ideation/behavior/lab abnormality that may increase the risk of study participation		EX01A00
2.b	2	Known infection with 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 medications intended to prevent COVID-19		EX04A00
2.e	8	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination		EX08A00
2.f	9	Individuals with a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention		EX09A00
2.g	10	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection		EX10A00
2.h	11	Women who are pregnant or breastfeeding		EX11A00
2.i	12	Previous vaccination with any coronavirus vaccine		EX12A00
2.j	13	Individuals who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids. Inhaled/nebulized, intra-articular, intrabursal, or topical corticosteroids are permitted		EX13A00
2.k	14	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study		EX14A00

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

Exclusion Criteria Entry

2.1	Exclusion Number: [Exclusion Number]	<input type="button" value="v"/>
2.2	Criterion Description: [Criterion Description]	<input type="button" value="v"/>
2.3	Criterion met? [Criterion met?]	<input type="radio"/> YES Describe details if relevant <div style="border: 1px solid black; height: 40px; width: 100%;"></div> <input type="radio"/> NO
2.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	<input type="button" value="v"/>

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C4591001: INCLUSION/EXCLUSION CRITERIA (IN EX STG3)				
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Inclusion Criteria				
#	Inclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
1.a	1	Male or female part cipants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)		IN01A00
1.b	2	Participants who are willing and able to comply w th all scheduled visits, vaccination plan, laboratory tests, lifestyle considerat ons, and other study procedures		IN02A00
1.c	3	Healthy participants who are determined by medical history, physical examination, and clin cal judgment of the investigator to be eligible for inclus on in the study		IN03A00
1.d	4	Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol		IN04A00
Inclusion Criteria Entry				
1.1	Inclusion Number: [Inclus on Number]	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4		
1.2	Cr iter on Description: [Cr iter on Description]	<input type="checkbox"/>		
1.3	Cr iter on met?: [Cr iter on met?]	<input type="radio"/> YES <input type="radio"/> NO Describe details if relevant <div style="border: 1px solid black; height: 40px; width: 100%;"></div>		
1.4	Cr iter on ID: (For Pfizer use only) [Cr iter on ID: (For Pfizer use only)]	<input type="radio"/> IN01A00 <input type="radio"/> IN02A00 <input type="radio"/> IN03A00 <input type="radio"/> IN04A00		
Exclusion Criteria				
#	Exclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
2.a	1	Other medical or psychiatric condition incl. recent (within past year) or active suicidal deation/behavior/lab abnormality that may increase the risk of study participation		EX01A00
2.b	2	Known infect on with human immunodef ciency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)		EX02A00
2.c	3	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)		EX03A00
2.d	4	Receipt of medications intended to prevent COVID-19		EX04A00
2.e	8	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination		EX08A00
2.f	10	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection		EX10A00
2.g	11	Women who are pregnant or breastfeeding		EX11A00
2.h	12	Prev ous vaccinat on with any coronavirus vaccine		EX12A00
2.i	13	Subjects who receive immunosuppressive therapy, such as cytotox c agents or system c corticosteroids		EX13A01
2.j	15	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervent on administration or planned receipt throughout the study		EX14A01
2.k	16	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participat on		EX15A01
2.l	17	Previous participation in other studies involving study intervention containing lipid nanoparticles		EX16A01

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2.m	22	Investigator site 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]	<input type="button" value="v"/>		
2.2	Criteria on Description: [Criteria on Description]	<input type="button" value="v"/>		
2.3	Criteria on met? [Criteria on met?]	<input type="radio"/> YES Describe details if relevant <div style="border: 1px solid #ccc; height: 40px; width: 100%;"></div> <input type="radio"/> NO		
2.4	Criteria on ID: (For Pfizer use only) [Criteria on ID: (For Pfizer use only)]	<input type="button" value="v"/>		

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C4591001: INCLUSION/EXCLUSION CRITERIA (IN EX STG3)				
Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclus on criteria (NO).				
Inclusion Criteria				
#	Inclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
1.a	1	Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)		IN01A00
1.b	2	Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures		IN02A00
1.c	3	Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study		IN03A00
1.d	4	Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol		IN04A00
Inclusion Criteria Entry				
1.1	Inclusion Number: [Inclusion Number]	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4		
1.2	Criterion Description: [Criterion Description]	<input type="checkbox"/>		
1.3	Criterion met? [Criterion met?]	<input type="radio"/> YES <input type="radio"/> NO Describe details if relevant <div style="border: 1px solid black; height: 40px; width: 100%;"></div>		
1.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	<input type="radio"/> IN01A00 <input type="radio"/> IN02A00 <input type="radio"/> IN03A00 <input type="radio"/> 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 ideation/behavior/lab abnormality that may increase the risk of study participation		EX01A00
2.b	2	Known infection with 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 medications intended to prevent COVID-19		EX04A00
2.e	8	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination		EX08A00
2.f	9	Individuals with a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention		EX09A00
2.g	10	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection		EX10A00
2.h	11	Women who are pregnant or breastfeeding		EX11A00
2.i	12	Previous vaccination with any coronavirus vaccine		EX12A00
2.j	13	Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids		EX13A01
2.k	15	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study		EX14A01
2.l	16	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation		EX15A01

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2.m	17	Previous participation in other studies involving study intervention containing lipid nanoparticles	EX16A01
2.n	22	Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members	EX21A01
Exclusion Criteria Entry			
2.1	Exclusion Number: [Exclusion Number]	<input type="text" value=""/>	
2.2	Criterion Description: [Criterion Description]	<input type="text" value=""/>	
2.3	Criterion met? [Criterion met?]	<input type="radio"/> YES Describe details if relevant <input type="text" value=""/> <input type="radio"/> NO	
2.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	<input type="text" value=""/>	

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C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC)	
	Criterion Description
1.	
Inclusion Criteria Not Met Entry	
1.1	Description of Inclusion Criterion Not Met [Criterion Description] <input type="button" value="v"/>
	Criterion Description
2.	
Exclusion Criteria Met Entry	
2.1	Description of Exclusion Criterion Met [Criterion Description] <input type="button" value="v"/>

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C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC NS)				
Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclus on criteria (NO).				
Inclusion Criteria				
#	Inclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
1.a	1	Male or female part cipants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)		IN01A00
1.b	2	Participants who are willing and able to comply w th all scheduled visits, vaccination plan, laboratory tests, lifestyle considerat ons, and other study procedures		IN02A00
1.c	3	Healthy participants who are determined by medical history, physical examination, and clin cal judgment of the investigator to be eligible for inclus on in the study		IN03A00
1.d	4	Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol		IN04A00
Inclusion Criteria Entry				
1.1	Inclusion Number: [Inclus on Number]	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4		
1.2	Criter on Description: [Criter on Description]	<input type="checkbox"/>		
1.3	Criter on met? [Criter on met?]	<input type="radio"/> YES <input type="radio"/> NO Describe details if relevant <div style="border: 1px solid black; height: 40px; width: 100%;"></div>		
1.4	Criter on ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	<input type="radio"/> IN01A00 <input type="radio"/> IN02A00 <input type="radio"/> IN03A00 <input type="radio"/> IN04A00		
Exclusion Criteria				
#	Exclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
2.a	1	Other medical or psychiatric condition incl. recent (within past year) or active suicidal deation/behavior/lab abnormality that may increase the risk of study participation		EX01A00
2.b	2	Known infect on with human immunodef ciency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)		EX02A00
2.c	3	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)		EX03A00
2.d	4	Receipt of medications intended to prevent COVID-19		EX04A00
2.e	5	Stages 1 and 2 only: Previous clin cal or microb olog cal diagnosis of COVID-19		EX05A00
2.f	8	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination		EX08A00
2.g	10	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection		EX10A00
2.h	11	Women who are pregnant or breastfeeding		EX11A00
2.i	12	Prev ous vaccinat on with any coronavirus vaccine		EX12A00
2.j	13	Subjects who receive immunosuppressive therapy, such as cytotox c agents or system c corticosteroids		EX13A01
2.k	15	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervent on administration or planned receipt throughout the study		EX14A01
2.l	16	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participat on		EX15A01

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2.m	17	Previous participation in other studies involving study intervention containing lipid nanoparticles	EX16A01
2.n	22	Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members	EX21A01
Exclusion Criteria Entry			
2.1	Exclusion Number: [Exclusion Number]	<input type="button" value="v"/>	
2.2	Criterion Description: [Criterion Description]	<input type="button" value="v"/>	
2.3	Criterion met? [Criterion met?]	<input type="radio"/> YES Describe details if relevant <div style="border: 1px solid black; height: 40px; width: 100%;"></div> <input type="radio"/> NO	
2.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	<input type="button" value="v"/>	

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C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC NS)				
Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclus on criteria (NO).				
Inclusion Criteria				
#	Inclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
1.a	1	Male or female part cipants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)		IN01A00
1.b	2	Participants who are willing and able to comply w th all scheduled visits, vaccination plan, laboratory tests, lifestyle considerat ons, and other study procedures		IN02A00
1.c	3	Healthy participants who are determined by medical history, physical examination, and clin cal judgment of the investigator to be eligible for inclus on in the study		IN03A00
1.d	4	Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol		IN04A00
Inclusion Criteria Entry				
1.1	Inclusion Number: [Inclus on Number]	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4		
1.2	Cr iter on Description: [Cr iter on Description]	<input type="checkbox"/>		
1.3	Cr iter on met? [Cr iter on met?]	<input type="radio"/> YES <input type="radio"/> NO Describe details if relevant <div style="border: 1px solid black; height: 40px; width: 100%;"></div>		
1.4	Cr iter on ID: (For Pfizer use only) [Cr iter on ID: (For Pfizer use only)]	<input type="radio"/> IN01A00 <input type="radio"/> IN02A00 <input type="radio"/> IN03A00 <input type="radio"/> IN04A00		
Exclusion Criteria				
#	Exclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
2.a	1	Other medical or psychiatric condition incl. recent (within past year) or active suicidal deation/behavior/lab abnormality that may increase the risk of study participation		EX01A00
2.b	2	Known infect on with human immunodef ciency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)		EX02A00
2.c	3	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)		EX03A00
2.d	4	Receipt of medications intended to prevent COVID-19		EX04A00
2.e	5	Stages 1 and 2 only: Previous clin cal or microb olog cal diagnosis of COVID-19		EX05A00
2.f	8	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination		EX08A00
2.g	9	Indiv duals with a history of autoimmune disease or an active autoimmune disease requiring therapeut c intervention		EX09A00
2.h	10	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection		EX10A00
2.i	11	Women who are pregnant or breastfeeding		EX11A00
2.j	12	Prev ous vaccinat on with any coronavirus vaccine		EX12A00
2.k	13	Subjects who receive immunosuppressive therapy, such as cytotox c agents or system c corticosteroids		EX13A01
2.l	15	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervent on administration or planned receipt throughout the study		EX14A01

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

Exclusion Criteria Entry	
2.1	Exclusion Number: [Exclusion Number] <input type="text"/>
2.2	Criterion Description: [Criterion Description] <input type="text"/>
2.3	Criterion met? [Criterion met?] <input type="radio"/> YES Describe details if relevant <input type="text"/> <input type="radio"/> NO
2.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)] <input type="text"/>

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C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC NS)				
Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclus on criteria (NO).				
Inclusion Criteria				
#	Inclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
1.a	1	Male or female part cipants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)		IN01A00
1.b	2	Participants who are willing and able to comply w th all scheduled visits, vaccination plan, laboratory tests, lifestyle considerat ons, and other study procedures		IN02A00
1.c	3	Healthy participants who are determined by medical history, physical examination, and clin cal judgment of the investigator to be eligible for inclus on in the study		IN03A00
1.d	4	Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol		IN04A00
Inclusion Criteria Entry				
1.1	Inclusion Number: [Inclus on Number]	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4		
1.2	Cr iter on Description: [Cr iter on Description]	<input type="checkbox"/>		
1.3	Cr iter on met? [Cr iter on met?]	<input type="radio"/> YES <input type="radio"/> NO Describe details if relevant <div style="border: 1px solid black; height: 40px; width: 100%;"></div>		
1.4	Cr iter on ID: (For Pfizer use only) [Cr iter on ID: (For Pfizer use only)]	<input type="radio"/> IN01A00 <input type="radio"/> IN02A00 <input type="radio"/> IN03A00 <input type="radio"/> IN04A00		
Exclusion Criteria				
#	Exclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
2.a	1	Other medical or psychiatric condition incl. recent (within past year) or active suicidal deation/behavior/lab abnormality that may increase the risk of study participation		EX01A00
2.b	2	Known infect on with human immunodef ciency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)		EX02A00
2.c	3	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)		EX03A00
2.d	4	Receipt of medications intended to prevent COVID-19		EX04A00
2.e	5	Stages 1 and 2 only: Previous clin cal or microb olog cal diagnosis of COVID-19		EX05A00
2.f	8	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination		EX08A00
2.g	9	Indiv duals with a history of autoimmune disease or an active autoimmune disease requiring therapeut c intervention		EX09A00
2.h	10	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection		EX10A00
2.i	11	Women who are pregnant or breastfeeding		EX11A00
2.j	12	Prev ous vaccinat on with any coronavirus vaccine		EX12A00
2.k	13	Indiv duals who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids. Inhaled/nebulized, Intra-articular, intrabursal, or topical corticosteroids are permitted		EX13A00
2.l	14	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervent on administration or planned receipt throughout the		EX14A00

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

Exclusion Criteria Entry	
2.1 Exclusion Number: [Exclusion Number]	<input type="text"/>
2.2 Criterion Description: [Criterion Description]	<input type="text"/>
2.3 Criterion met? [Criterion met?]	<input type="radio"/> YES Describe details if relevant <input type="text"/> <input type="radio"/> NO
2.4 Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	<input type="text"/>

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C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC S)				
Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclus on criteria (NO).				
Inclusion Criteria				
#	Inclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
1.a	1	Male or female part cipants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)		IN01A00
1.b	2	Participants who are willing and able to comply w th all scheduled visits, vaccination plan, laboratory tests, lifestyle considerat ons, and other study procedures		IN02A00
1.c	3	Healthy participants who are determined by medical history, physical examination, and clin cal judgment of the investigator to be eligible for inclus on in the study		IN03A00
1.d	4	Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol		IN04A00
Inclusion Criteria Entry				
1.1	Inclusion Number: [Inclus on Number]	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4		
1.2	Cr iter on Description: [Cr iter on Description]	<input type="checkbox"/>		
1.3	Cr iter on met?: [Cr iter on met?]	<input type="radio"/> YES <input type="radio"/> NO Describe details if relevant <div style="border: 1px solid black; height: 40px; width: 100%;"></div>		
1.4	Cr iter on ID: (For Pfizer use only) [Cr iter on ID: (For Pfizer use only)]	<input type="radio"/> IN01A00 <input type="radio"/> IN02A00 <input type="radio"/> IN03A00 <input type="radio"/> IN04A00		
Exclusion Criteria				
#	Exclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
2.a	1	Other medical or psychiatric condition incl. recent (within past year) or active suicidal deation/behavior/lab abnormality that may increase the risk of study participation		EX01A00
2.b	2	Known infect on with human immunodef ciency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)		EX02A00
2.c	3	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)		EX03A00
2.d	4	Receipt of medications intended to prevent COVID-19		EX04A00
2.e	5	Stages 1 and 2 only: Previous clin cal or microb olog cal diagnosis of COVID-19		EX05A00
2.f	6	Sentinel participants in Stage 1 only: Individ uals at high risk for severe COVID-19 (full details in protocol)		EX06A01
2.g	7	Sentinel participants in Stage 1 only: Individ uals currently working in occupat ons with high risk of exposure to SARS-CoV-2 (eg, healthcare worker, emergency response personnel)		EX07A00
2.h	8	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination		EX08A00
2.i	9	Sentinel participants in Stage 1 only: Individ uals w th a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention		EX09A04
2.j	10	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection		EX10A00
2.k	11	Women who are pregnant or breastfeeding		EX11A00

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2.l	12	Previous vaccination with any coronavirus vaccine	EX12A00
2.m	13	Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids	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 administration or planned receipt throughout the study	EX14A01
2.p	16	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation	EX15A01
2.q	17	Previous participation in other studies involving study intervention containing lipid nanoparticles	EX16A01
2.r	18	Sentinel participants 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 participants in Stage 1 only: Screening hematology/blood chemistry lab \geq Grade 1 abnormality. Except Bilirubin, other stable Grade 1 abnormalities may be considered eligible by Investigator	EX18A01
2.t	20	Sentinel participants in Stage 1 only: Positive test for HIV, hepatitis B surface antigen (HBsAg), hepatitis B core antibodies (HBc Abs), or hepatitis C virus antibodies (HCV Abs) at screening visit	EX19A01
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 site 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]	<input type="text"/>
2.2	Criterion Description: [Criterion Description]	<input type="text"/>
2.3	Criterion met? [Criterion met?]	<input type="radio"/> YES Describe details if relevant <input type="text"/> <input type="radio"/> NO
2.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	<input type="text"/>

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C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC S)				
Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclus on criteria (NO).				
Inclusion Criteria				
#	Inclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
1.a	1	Male or female part cipants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)		IN01A00
1.b	2	Participants who are willing and able to comply w th all scheduled visits, vaccination plan, laboratory tests, lifestyle considerat ons, and other study procedures		IN02A00
1.c	3	Healthy participants who are determined by medical history, physical examination, and clin cal judgment of the investigator to be eligible for inclus on in the study		IN03A00
1.d	4	Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol		IN04A00
Inclusion Criteria Entry				
1.1	Inclusion Number: [Inclus on Number]	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4		
1.2	Criteria on Description: [Criteria on Description]	<input type="checkbox"/>		
1.3	Criteria on met? [Criteria on met?]	<input type="radio"/> YES <input type="radio"/> NO Describe details if relevant <div style="border: 1px solid black; height: 40px; width: 100%;"></div>		
1.4	Criteria on ID: (For Pfizer use only) [Criteria on ID: (For Pfizer use only)]	<input type="radio"/> IN01A00 <input type="radio"/> IN02A00 <input type="radio"/> IN03A00 <input type="radio"/> IN04A00		
Exclusion Criteria				
#	Exclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
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2.b	2	Known infect on with human immunodef ciency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)		EX02A00
2.c	3	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)		EX03A00
2.d	4	Receipt of medications intended to prevent COVID-19		EX04A00
2.e	5	Stages 1 and 2 only: Previous clin cal or microb olog cal diagnosis of COVID-19		EX05A00
2.f	6	Sentinel participants in Stage 1 only: Individ uals at high risk for severe COVID-19		EX06A00
2.g	7	Sentinel participants in Stage 1 only: Individ uals currently working in occupat ons with high risk of exposure to SARS-CoV-2 (eg, healthcare worker, emergency response personnel)		EX07A00
2.h	8	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination		EX08A00
2.i	9	Indiv duals with a history of autoimmune disease or an active autoimmune disease requiring therapeut c intervention		EX09A00
2.j	10	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection		EX10A00
2.k	11	Women who are pregnant or breastfeeding		EX11A00
2.l	12	Prev ous vaccinat on with any coronavirus vaccine		EX12A00

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2.m	13	Individuals who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids. Inhaled/nebulized, Intra-articular, intrabursal, or topical corticosteroids are permitted	EX13A00
2.n	14	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention on administration or planned receipt throughout the study	EX14A00
2.o	15	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation	EX15A00
2.p	16	Previous participation in other studies involving study intervention containing lipid nanoparticles	EX16A00
2.q	17	Sentinel participants 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 participants in Stage 1 only: Screening hematology/blood chemistry lab \geq Grade 1 abnormality. Except Bilirubin, other stable Grade 1 abnormality may be considered eligible by Investigator	EX18A00
2.s	19	Sentinel participants in Stage 1 only: Positive test for HIV, hepatitis B surface antigen (HBsAg), hepatitis B core antibodies (HBc Abs), or hepatitis C virus antibodies (HCV Abs) at screening visit	EX19A00
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 site 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]	<input type="text"/>
2.2 Criterion Description: [Criterion Description]	<input type="text"/>
2.3 Criterion met? [Criterion met?]	<input type="radio"/> YES Describe details if relevant <input type="text"/> <input type="radio"/> NO
2.4 Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	<input type="text"/>

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C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC S)				
Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclus on criteria (NO).				
Inclusion Criteria				
#	Inclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
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1.b	2	Participants who are willing and able to comply w th all scheduled visits, vaccination plan, laboratory tests, lifestyle considerat ons, and other study procedures		IN02A00
1.c	3	Healthy participants who are determined by medical history, physical examination, and clin cal judgment of the investigator to be eligible for inclus on in the study		IN03A00
1.d	4	Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol		IN04A00
Inclusion Criteria Entry				
1.1	Inclusion Number: [Inclus on Number]	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4		
1.2	Criteria on Description: [Criteria on Description]	<input type="checkbox"/>		
1.3	Criteria on met? [Criteria on met?]	<input type="radio"/> YES <input type="radio"/> NO Describe details if relevant <div style="border: 1px solid #ccc; height: 40px; width: 100%;"></div>		
1.4	Criteria on ID: (For Pfizer use only) [Criteria on ID: (For Pfizer use only)]	<input type="radio"/> IN01A00 <input type="radio"/> IN02A00 <input type="radio"/> IN03A00 <input type="radio"/> IN04A00		
Exclusion Criteria				
#	Exclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
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2.b	2	Known infect on with human immunodef ciency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)		EX02A00
2.c	3	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)		EX03A00
2.d	4	Receipt of medications intended to prevent COVID-19		EX04A00
2.e	5	Stages 1 and 2 only: Previous clin cal or microb olog cal diagnosis of COVID-19		EX05A00
2.f	6	Sentinel participants in Stage 1 only: Individ uals at high risk for severe COVID-19 (full details in protocol)		EX06A01
2.g	7	Sentinel participants in Stage 1 only: Individ uals currently working in occupat ons with high risk of exposure to SARS-CoV-2 (eg, healthcare worker, emergency response personnel)		EX07A00
2.h	8	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination		EX08A00
2.i	9	Individ uals with a history of autoimmune disease or an active autoimmune disease requiring therapeut c intervention		EX09A00
2.j	10	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection		EX10A00
2.k	11	Women who are pregnant or breastfeeding		EX11A00
2.l	12	Prev ous vaccinat on with any coronavirus vaccine		EX12A00

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2.m	13	Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids	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 on administration or planned receipt throughout the study	EX14A01
2.p	16	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation	EX15A01
2.q	17	Previous participation in other studies involving study intervention containing lipid nanoparticles	EX16A01
2.r	18	Sentinel participants 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 participants in Stage 1 only: Screening hematology/blood chemistry lab \geq Grade 1 abnormality. Except Bilirubin, other stable Grade 1 abnormalities may be considered eligible by Investigator	EX18A01
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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 site 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]	<input type="text"/>
2.2	Criterion Description: [Criterion Description]	<input type="text"/>
2.3	Criterion met? [Criterion met?]	<input checked="" type="radio"/> YES Describe details if relevant <input type="text"/> <input type="radio"/> NO
2.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	<input type="text"/>

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C4591001: CASEBOOK SIGNATURE FORM (INVSIG)	
Casebook Signature Form	
1. Casebook Signature [Casebook Signature]	<input type="radio"/> Click Here to Enable

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C4591001: CENTRAL LAB SAMPLE COLLECTION (LAB)			
Central Lab Sample Collection			
1.	Collect on Date: [Collection Date:]		<input type="text"/> / <input type="text"/> / <input type="text"/>
2.	Specimen Type: [Specimen Type]	<input checked="" type="radio"/> 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]	<input type="radio"/> HEMATOLOGY <input type="radio"/> CLINICAL CHEMISTRY	
3.2	Lab Sub-Panel: [Subcategory for Lab Test]	<input type="radio"/> DIFFERENTIAL <input type="radio"/> BLOOD CHEMISTRY	
3.3	Was the lab sub-panel collected?: [Lab Sub-Panel Collected]	<input type="radio"/> YES <input type="radio"/> NO	

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C4591001: CENTRAL LAB SAMPLE COLLECTION - BASELINE (LAB BSL)			
Central Lab Sample Collection			
1.	Collect on Date: [Collection Date:]		<input type="text"/> / <input type="text"/> / <input type="text"/>
2.	Specimen Type: [Specimen Type]	<input checked="" type="radio"/> 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]	<input type="radio"/> HEMATOLOGY <input type="radio"/> CLINICAL CHEMISTRY	
3.2	Lab Sub-Panel: [Subcategory for Lab Test]	<input type="radio"/> DIFFERENTIAL <input type="radio"/> BLOOD CHEMISTRY <input type="radio"/> VIROLOGY	
3.3	Was the lab sub-panel collected?: [Lab Sub-Panel Collected]	<input type="radio"/> YES <input type="radio"/> 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]	<input type="radio"/> CLINICAL CHEMISTRY			
2.	Laboratory Name and Address [Vendor Name]	<input type="text"/>			
3.	Collect on Date: [Collection Date:]	<input type="text"/> / <input type="text"/> / <input type="text"/>			
4.	Specimen Type: [Specimen Type]	<input type="radio"/> 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]	<input type="text"/>			
5.2	Test: [Test:]	<input type="text"/>			
5.3	Result: [Result:]	<input type="text"/>			
5.4	Not Done: [Not Done:]	<input type="radio"/> NOT DONE			
5.5	LNMT [Lab Normal Range]	Low <input type="text"/> High <input type="text"/> Unit <input type="text"/>			

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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]	<input type="radio"/> CLINICAL CHEMISTRY			
2.	Laboratory Name and Address [Vendor Name]	<input type="text"/>			
3.	Collect on Date: [Collection Date:]	<input type="text"/> / <input type="text"/> / <input type="text"/>			
4.	Specimen Type: [Specimen Type]	<input type="radio"/> 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]	<input type="text"/>			
5.2	Test: [Test:]	<input type="radio"/> C Reactive Protein_PX329			
5.3	Result: [Result:]	<input type="text"/>			
5.4	Not Done: <i>[hidden]</i> [Not Done:]	<input type="radio"/> NOT DONE			
5.5	LNMT [Lab Normal Range]	Low <input type="text"/> High <input type="text"/> Unit <input type="text"/>			

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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]	<input type="radio"/> HEMATOLOGY			
2.	Laboratory Name and Address [Vendor Name (DERIVED)]	<input type="text"/>			
3.	Collect on Date: [Collection Date:]	<input type="text"/> / <input type="text"/> / <input type="text"/>			
4.	Specimen Type: [Specimen Type]	<input type="radio"/> 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]	<input type="text"/>			
5.2	Test: [Test:]	<input type="text"/>			
5.3	Result: [Result:]	<input type="text"/>			
5.4	Not Done: [Not Done:]	<input type="radio"/> NOT DONE			
5.5	LNMT [Lab Normal Range]	Low <input type="text"/> High <input type="text"/> Unit <input type="text"/>			

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C4591001: LAB URINALYSIS - PREGNANCY TEST (LAB PREG)				
Lab Urinalysis				
1. Lab Panel: [Category for Lab Test]	<input type="radio"/> URINALYSIS			
2. Lab Sub-Panel: [Subcategory for Lab Test]	<input type="radio"/> PREGNANCY			
3. Collect on Date: [Collection Date:]	<input type="text"/> / <input type="text"/> / <input type="text"/>			
4. Laboratory Name and Address (Derived) [Vendor Name (DERIVED)]	<input type="text"/>			
5. Specimen Type: [Specimen Type]	<input type="radio"/> URINE			
Lab Result				
#	Sponsor-Defined Identifier	Test:	Result:	Not Done:
6.a		Choriogonadotropin Beta_PX113		
Lab Result Entry				
6.1 Sponsor ID: [Sponsor-Defined Identifier]	<input type="text"/>			
6.2 Test: [Test:]	<input type="radio"/> Chor ogonadotropin Beta_PX113			
6.3 Result: [Result:]	<input type="radio"/> NEGATIVE <input type="radio"/> POSITIVE			
6.4 Not Done: [Not Done:]	<input type="radio"/> 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]	<input type="radio"/> MEDICATION ERROR								
2.	Medication Error (Type of Medication Error): [Medication Error]	<input type="text"/>								
3.	If this is a dispensing error, record the incorrect container number that was dispensed/administered to the subject: [hidden] [Incorrect package ID]	<input type="text"/>								
4.	Start Date: [Start Date]	<input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>								
5.	Is the medication error still ongoing? [Is the medication error Still Ongoing]	<input type="radio"/> YES <input type="radio"/> NO End Date: <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>								
6.	Latest Action Taken with Study Treatment: [Study Medication Errors Action]	<input type="radio"/> NO ACTION TAKEN <input type="radio"/> PERMANENTLY DISCONTINUED								
7.	Was a Concomitant Medication given? [Concomitant Medication Given]	<input type="radio"/> YES <input type="radio"/> NO								
8.	Was a Non-Drug Treatment given? [Non-Drug Treatment Given]	<input type="radio"/> YES <input type="radio"/> NO								
9.	Did the Medication Error cause the subject to be discontinued from the study? [Caused Study Discontinuation]	<input type="radio"/> YES <input type="radio"/> NO								
10.	Was this medication error associated with any adverse events? [Medication Error Associated With AE]	<input type="radio"/> YES AE ID: <input type="text"/> AE ID: <input type="text"/> AE ID: <input type="text"/> AE ID: <input type="text"/> AE ID: <input type="text"/> <input type="radio"/> NO								
11.	Serious Adverse Event	<input type="text"/>								

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	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.	Dictionary-Derived Term [hidden] [Dictionary-Derived Term]	
16.	Preferred Term Code [hidden] [Preferred Term Code]	
17.	High Level Term [hidden] [High Level Term]	
18.	High Level Term Code [hidden] [High Level Term Code]	
19.	High Level Group Term [hidden] [High Level Group Term]	
20.	High Level Group Term Code [hidden] [High Level Group Term Code]	
21.	Primary System Organ Class [hidden] [Primary System Organ Class]	
22.	Primary System Organ Class Code [hidden] [Primary System Organ Class Code]	

C4591001: GENERAL MEDICAL HISTORY (MEDHX)			
Line/MH Number	Medical History Term	Start Date	Ongoing
1.			
Medical History Details Entry			
1.1	Line/MH Number: [Line/MH Number]	<input type="text"/>	
1.2	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies: [Medical History Term]	<input type="text"/>	
1.3	Start Date: [Start Date]	<input type="text"/> / <input type="text"/> / <input type="text"/>	
1.4	Ongoing: [Ongoing]	<input type="radio"/> YES <input type="radio"/> NO End Date: <input type="text"/> / <input type="text"/> / <input type="text"/>	
1.5	Comparison Term <i>[hidden]</i> [Comparison Term]	<input type="text"/>	
1.6	Lowest Level Term <i>[hidden]</i> [Lowest Level Term]	<input type="text"/>	
1.7	Lowest Level Term Code <i>[hidden]</i> [Lowest Level Term Code]	<input type="text"/>	
1.8	Dictionary Derived Term <i>[hidden]</i> [Dictionary Derived Term]	<input type="text"/>	
1.9	Preferred Term Code <i>[hidden]</i> [Preferred Term Code]	<input type="text"/>	
1.10	High Level Term <i>[hidden]</i> [High Level Term]	<input type="text"/>	
1.11	High Level Term Code <i>[hidden]</i> [High Level Term Code]	<input type="text"/>	
1.12	High Level Group Term <i>[hidden]</i> [High Level Group Term]	<input type="text"/>	
1.13	High Level Group Term Code <i>[hidden]</i> [High Level Group Term Code]	<input type="text"/>	
1.14	Primary System Organ Class <i>[hidden]</i> [Primary System Organ Class]	<input type="text"/>	
1.15	Primary System Organ Class Code <i>[hidden]</i> [Primary System Organ Class Code]	<input type="text"/>	

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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]	<input type="text"/> / <input type="text"/> / <input type="text"/> <input type="text"/> : <input type="text"/> 24-hour clock	
2.	Arterial Blood Gases PaO2 (mmHg): [Arterial Blood Gases PaO2]	<input type="text"/>	
3.	FiO2 (Fract on of Inhaled Oxygen): [FiO2 (Fract on of Inhaled Oxygen)]	<input type="text"/>	

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C4591001: PHYSICAL EXAMINATION (PHYS EXAM)		
Physical Examination		
1. Exam Date: [Exam Date]		<div style="display: flex; gap: 10px;"> ▼ / ▼ / ▼ </div>
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]		<div style="display: flex; align-items: center;"> ▼ </div>
2.2 Result: [Result]		<p> <input type="radio"/> NORMAL <input type="radio"/> ABNORMAL If abnormal findings, specify: (If clinically significant, record on the Medical History or Adverse Event CRF as appropriate). </p> <div style="border: 1px solid #ccc; height: 40px; margin-bottom: 10px;"></div> <p>Are there clinically significant findings?</p> <p> <input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> NOT DONE </p>

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C4591001: ELECTRONIC SAMPLE TRACKING - PRIOR COVID-19 INFECTION (PRIORCOV19)	
Electronic Sample Tracking	
1. Data Origin [Data Origin]	<input type="radio"/> SITE
2. Sample Type [Sample Type]	<input type="radio"/> SERUM
3. Sample Collected? [Sample Collected]	<input type="radio"/> NO <input type="radio"/> YES Date of Collect on: <input type="text"/> / <input type="text"/> / <input type="text"/>
4. If no sample was collected or sample was not collected according to protocol, please provide reason: [Reason sample not collected]	<div style="border: 1px solid black; height: 50px;"></div>
Sample ID	
5.	
Aliquot Entry	
Please enter barcode for each aliquot.	
5.1 Sample ID [Sample ID]	<div style="border: 1px solid black; width: 300px; height: 20px;"></div>

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 identifier? [Sponsor-Defined Identifier]		<input type="text"/>							
2.	Category: [Category for Medication]		<input type="radio"/> CONCOMITANT IMMUNOSUPPRESSIVE THERAPY <input type="radio"/> CORTICOSTEROIDS <input type="radio"/> IMMUNOGLOBULINS							
3.	Concomitant Medications Pre-specified: [Concomitant Medications Pre-specified]		<input type="radio"/> NO							
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation). [Name of Medication]		<input type="text"/>							
5.	Dose: [Dose Description]		<input type="text"/>							
6.	Dose Unit: [Dose Unit]		<input type="button" value="v"/>							
7.	Dose Frequency: [Dose Frequency]		<input type="button" value="v"/>							
8.	Route: [Route]		<input type="button" value="v"/>							
9.	Start Date: [Start Date]		<input type="button" value="v"/> / <input type="button" value="v"/> / <input type="button" value="v"/>							
10.	Ongoing? [Ongoing]		<input type="radio"/> YES <input type="radio"/> NO End Date: <input type="button" value="v"/> / <input type="button" value="v"/> / <input type="button" value="v"/>							
11.	Comparison Term <i>[hidden]</i> [Comparison Term]		<input type="text"/>							
12.	Standardized Medication Name - Dictionary derived. <i>[hidden]</i> [Standardized Medication Name]		<input type="text"/>							
13.	Standardized Medication Code - Dictionary derived <i>[hidden]</i> [Standardized Medication Code]		<input type="text"/>							

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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]	<input type="radio"/> RADIATION THERAPY				
2.	What is the treatment Identifier? [Treatment Identifier]	<input type="text"/>				
3.	Concomitant Non-drug Treatment Pre-specified: [Con Non-Drug Treatments Pre-specified]	<input type="radio"/> YES				
4.	Treatment: [Treatment]	<input type="text"/>				
5.	Start Date: [Start Date]	<input type="text"/> / <input type="text"/> / <input type="text"/>				
6.	Ongoing? [Ongoing?]	<input type="radio"/> YES <input type="radio"/> NO End Date: <input type="text"/> / <input type="text"/> / <input type="text"/>				
7.	Comparison Term <i>[hidden]</i> [Comparison Term]	<input type="text"/>				
8.	Lowest Level Term <i>[hidden]</i> [Lowest Level Term]	<input type="text"/>				
9.	Lowest Level Term Code <i>[hidden]</i> [Lowest Level Term Code]	<input type="text"/>				
10.	Dictionary Derived Term <i>[hidden]</i> [Dictionary Derived Term]	<input type="text"/>				
11.	Preferred Term Code <i>[hidden]</i> [Preferred Term Code]	<input type="text"/>				
12.	High Level Term <i>[hidden]</i> [High Level Term]	<input type="text"/>				
13.	High Level Term Code <i>[hidden]</i> [High Level Term Code]	<input type="text"/>				
14.	High Level Group Term <i>[hidden]</i> [High Level Group Term]	<input type="text"/>				
15.	High Level Group Term Code <i>[hidden]</i> [High Level Group Term Code]	<input type="text"/>				
16.	Primary System Organ Class <i>[hidden]</i> [Primary System Organ Class]	<input type="text"/>				
17.	Primary System Organ Class Code <i>[hidden]</i> [Primary System Organ Class Code]	<input type="text"/>				

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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:]	<input type="text" value=""/> / <input type="text" value=""/> / <input type="text" value=""/>
Vital Signs Details		
#	Record Identifier:	Oxygen Saturation
2.a	1	
Vital Signs Details Entry		
2.1	Record Identifier: [Record Identifier:]	<input type="radio"/> 1
2.2	SPO2 Pulse Oximetry % [Oxygen Saturat on]	<input type="text"/>

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C4591001: RANDOMIZATION (RAND)	
Disposition	
1. Randomizat on Date : [Randomizat on Date :]	<input type="text" value=""/> / <input type="text" value=""/> / <input type="text" value=""/>
2. Randomizat on Number: [Randomizat on Number]	<input type="text"/>
3. Randomizat on Group: [Randomizat on Group]	<input type="text"/>

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C4591001: REACTOGENICITY DIARY (REAC DIARY)	
Reactogenicity Diary	
1. Select appropriate response - Reactogen c ty diary collection [Trigger Response 9]	<input type="radio"/> YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT <input type="radio"/> 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]	<input type="radio"/> UNPLANNED ASSESSMENT OF LOCAL REACTION/SYSTEMIC EVENT	
2. Date of Assessment: [Date of Assessment]	<input type="text" value=""/> / <input type="text" value=""/> / <input type="text" value=""/>	
3. Inject on Site Location [Inject on Site Location]	<input type="radio"/> DELTOID MUSCLE	
4. Inject on Site Body Side: [Inject on Site Body Side]	<input type="radio"/> LEFT <input type="radio"/> RIGHT	
Reaction		
#	Reaction:	Reaction Present:
5.a	REDNESS	
5.b	SWELLING	
Reaction Entry		
5.1 React on: [Reaction:]	<input type="radio"/> REDNESS <input type="radio"/> SWELLING	
5.2 React on Present: [Reaction Present:]	<input type="radio"/> YES Maximum Diameter (cm): <input type="text"/> Minimum Diameter (cm): <input type="text"/> Meets Grade 4 Reaction Criteria: <input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> 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 WORSENERED MUSCLE PAIN	
6.g	NEW OR WORSENERED JOINT PAIN	
6.h	CHILLS	
Symptom Entry		
6.1 Symptom: [Symptom:]	<input type="text" value=""/>	
6.2 Symptom Present: [Symptom Present:]	<input type="radio"/> YES Symptom Grade: <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 Event related to Study Treatment? <input type="radio"/> YES	

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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]	<input type="text"/>				
2.	Concomitant Non-drug Treatment Pre-specified: [Con Non-Drug Treatments Pre-specified]	<input type="radio"/> YES				
3.	Treatment: [Treatment]	<input type="radio"/> INTUBATION <input type="radio"/> NON-INVASIVE POSITIVE PRESSURE VENTILATION <input type="radio"/> CPAP <input type="radio"/> OXYGEN THERAPY				
4.	Treatment: [Treatment]	<input type="text"/>				
5.	Start Date: [Start Date]	<input type="text" value="▼"/> / <input type="text" value="▼"/> / <input type="text" value="▼"/>				
6.	Ongoing? [Ongoing?]	<input type="radio"/> YES <input type="radio"/> NO End Date: <input type="text" value="▼"/> / <input type="text" value="▼"/> / <input type="text" value="▼"/>				
7.	Comparison Term [hidden] [Comparison Term]	<input type="text"/>				
8.	Lowest Level Term [hidden] [Lowest Level Term]	<input type="text"/>				
9.	Lowest Level Term Code [hidden] [Lowest Level Term Code]	<input type="text"/>				
10.	Dictionary Derived Term [hidden] [Dictionary Derived Term]	<input type="text"/>				
11.	Preferred Term Code [hidden] [Preferred Term Code]	<input type="text"/>				
12.	High Level Term [hidden] [High Level Term]	<input type="text"/>				
13.	High Level Term Code [hidden] [High Level Term Code]	<input type="text"/>				
14.	High Level Group Term [hidden] [High Level Group Term]	<input type="text"/>				
15.	High Level Group Term Code [hidden] [High Level Group Term Code]	<input type="text"/>				
16.	Primary System Organ Class [hidden] [Primary System Organ Class]	<input type="text"/>				
17.	Primary System Organ Class Code [hidden] [Primary System Organ Class Code]	<input type="text"/>				

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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]	<input type="text"/>				
2.	Concomitant Non-drug Treatment Pre-specified: [Con Non-Drug Treatments Pre-specified]	<input type="radio"/> YES				
3.	Treatment: [Treatment]	<input type="radio"/> NON-INVASIVE POSITIVE PRESSURE VENTILATION <input type="radio"/> CPAP <input type="radio"/> MECHANICAL VENTILATION <input type="radio"/> EXTRACORPOREAL MEMBRANE OXYGENATION <input type="radio"/> HIGH FLOW OXYGEN THERAPY				
4.	Treatment: [Treatment]	<input type="text"/>				
5.	Start Date: [Start Date]	<input type="text" value=""/> / <input type="text" value=""/> / <input type="text" value=""/>				
6.	Ongoing? [Ongoing?]	<input type="radio"/> YES <input type="radio"/> NO End Date: <input type="text" value=""/> / <input type="text" value=""/> / <input type="text" value=""/>				
7.	Comparison Term <i>[hidden]</i> [Comparison Term]	<input type="text"/>				
8.	Lowest Level Term <i>[hidden]</i> [Lowest Level Term]	<input type="text"/>				
9.	Lowest Level Term Code <i>[hidden]</i> [Lowest Level Term Code]	<input type="text"/>				
10.	Dictionary Derived Term <i>[hidden]</i> [Dictionary Derived Term]	<input type="text"/>				
11.	Preferred Term Code <i>[hidden]</i> [Preferred Term Code]	<input type="text"/>				
12.	High Level Term <i>[hidden]</i> [High Level Term]	<input type="text"/>				
13.	High Level Term Code <i>[hidden]</i> [High Level Term Code]	<input type="text"/>				
14.	High Level Group Term <i>[hidden]</i> [High Level Group Term]	<input type="text"/>				
15.	High Level Group Term Code <i>[hidden]</i> [High Level Group Term Code]	<input type="text"/>				
16.	Primary System Organ Class <i>[hidden]</i> [Primary System Organ Class]	<input type="text"/>				
17.	Primary System Organ Class Code <i>[hidden]</i> [Primary System Organ Class Code]	<input type="text"/>				

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C4591001: FURTHER VACCINATION CONFIRMATION (REVAX CONF)	
Further Vaccination Confirmation	
1. Select appropriate response - Is participant willing to return for Vaccination 3? [Trigger Response 1]	<input type="radio"/> Participant is willing to return for Vaccination 3 Participant is: <input type="radio"/> eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2 <input type="radio"/> eligible per other protocol allowance(s) and confirmed to have received only placebo at Vaccination 1/2 <input type="radio"/> eligible and NOT confirmed to have received only placebo at Vaccination 1/2 <input type="radio"/> Participant is NOT willing to return for Vaccination 3 OR otherwise not eligible

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C4591001: INFORMED CONSENT - FURTHER VACCINATION (REVAX CONS)	
Informed Consent - Further Vaccination	
1. Consent Was: [Consent Was:]	<input type="radio"/> OBTAINED Date Written Consent Obtained <input type="text"/> / <input type="text"/> / <input type="text"/>

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C4591001: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION (REVAX IE)	
Criterion Description	
1.	
Inclusion Criteria Not Met Entry	
1.1	Description of Inclusion Criterion Not Met [Criterion Description] <input type="button" value="v"/>
Criterion Description	
2.	
Exclusion Criteria Met Entry	
2.1	Description of Exclusion Criterion Met [Criterion Description] <input type="button" value="v"/>

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C4591001: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB (RSWAB)	
Electronic Sample Tracking	
1. Data Origin [Data Origin]	<input type="radio"/> SITE
2. Sample Type [Sample Type]	<input type="radio"/> NASAL_SWAB <input type="radio"/> NASAL_SWAB_SELF
3. Sample Collected? [Sample Collected]	<input type="radio"/> NO <input type="radio"/> YES Date of Collect on: <input type="text"/> / <input type="text"/> / <input type="text"/>
4. If no sample was collected or sample was not collected according to protocol, please provide reason: [Reason sample not collected]	<div style="border: 1px solid black; height: 50px;"></div>
Sample ID	
5.	
Aliquot Entry	
Please enter barcode for each aliquot.	
5.1 Sample ID [Sample ID]	<div style="border: 1px solid black; width: 300px; height: 20px;"></div>

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C4591001: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY (SAMP TRK)	
Electronic Sample Tracking	
1. Data Origin [Data Origin]	<input type="radio"/> SITE
2. Sample Type [Sample Type]	<input type="radio"/> SERUM
3. Sample Collected? [Sample Collected]	<input type="radio"/> NO <input type="radio"/> YES Date of Collect on: <input type="text"/> / <input type="text"/> / <input type="text"/>
4. If no sample was collected or sample was not collected according to protocol, please provide reason: [Reason sample not collected]	<div style="border: 1px solid black; height: 50px;"></div>
Sample ID	
5.	
Aliquot Entry	
Please enter barcode for each aliquot.	
5.1 Sample ID [Sample ID]	<div style="border: 1px solid black; width: 300px; height: 20px;"></div>

C4591001: INFORM SCREENING (SCREEN)	
InForm Screening	
1. InForm Initials <i>[hidden]</i> [InForm Initials]	<input type="text"/>
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]	<input type="radio"/> SITE
2. Sample Type [Sample Type]	<input type="radio"/> NASAL_SWAB_SELF
3. Sample Collected? [Sample Collected]	<input type="radio"/> NO <input type="radio"/> YES Date of Collect on: <input type="text"/> / <input type="text"/> / <input type="text"/>
4. If no sample was collected or sample was not collected according to protocol, please provide reason: [Reason sample not collected]	<div style="border: 1px solid black; height: 50px;"></div>
Sample ID	
5.	
Aliquot Entry	
Please enter barcode for each aliquot.	
5.1 Sample ID [Sample ID]	<div style="border: 1px solid black; width: 300px; height: 20px;"></div>

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]	<input type="radio"/> YES <input type="radio"/> 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: <i>[hidden]</i> [Event Pre-specified]	<input type="radio"/> YES	
4.2	Symptoms: [Symptoms]		
4.3	Was symptom present? [Symptom Present]	<input type="radio"/> YES <input type="radio"/> NO	
Symptoms - Other			
5.			
Symptoms - Other Entry			
5.1	Symptoms - Other Text: [Symptoms - Other]		
5.2	Comparison Term: <i>[hidden]</i> [Comparison Term]		
5.3	Lowest Level Term <i>[hidden]</i> [Lowest Level Term]		
5.4	Lowest Level Term Code <i>[hidden]</i> [Lowest Level Term Code]		
5.5	Dictionary Derived Term <i>[hidden]</i> [Dictionary Derived Term]		

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5.6	Preferred Term Code <i>[hidden]</i> [Preferred Term Code]	<input type="text"/>
5.7	High Level Term <i>[hidden]</i> [High Level Term]	<input type="text"/>
5.8	High Level Term Code <i>[hidden]</i> [High Level Term Code]	<input type="text"/>
5.9	High Level Group Term <i>[hidden]</i> [High Level Group Term]	<input type="text"/>
5.10	High Level Group Term Code <i>[hidden]</i> [High Level Group Term Code]	<input type="text"/>
5.11	Primary System Organ Class <i>[hidden]</i> [Primary System Organ Class]	<input type="text"/>
5.12	Primary System Organ Class Code <i>[hidden]</i> [Primary System Organ Class Code]	<input type="text"/>

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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]	<input type="radio"/> YES <input type="radio"/> 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: <i>[hidden]</i> [Event Pre-specified]	<input type="radio"/> YES	
4.2	Symptoms: [Symptoms]		
4.3	Was symptom present? [Symptom Present]	<input type="radio"/> YES <input type="radio"/> NO	
Symptoms - Other			
5.			
Symptoms - Other Entry			
5.1	Symptoms - Other Text: [Symptoms - Other]		
5.2	Comparison Term: <i>[hidden]</i> [Comparison Term]		
5.3	Lowest Level Term <i>[hidden]</i> [Lowest Level Term]		
5.4	Lowest Level Term Code <i>[hidden]</i> [Lowest Level Term Code]		
5.5	Dictionary Derived Term <i>[hidden]</i> [Dictionary Derived Term]		

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5.6	Preferred Term Code <i>[hidden]</i> [Preferred Term Code]	<input type="text"/>
5.7	High Level Term <i>[hidden]</i> [High Level Term]	<input type="text"/>
5.8	High Level Term Code <i>[hidden]</i> [High Level Term Code]	<input type="text"/>
5.9	High Level Group Term <i>[hidden]</i> [High Level Group Term]	<input type="text"/>
5.10	High Level Group Term Code <i>[hidden]</i> [High Level Group Term Code]	<input type="text"/>
5.11	Primary System Organ Class <i>[hidden]</i> [Primary System Organ Class]	<input type="text"/>
5.12	Primary System Organ Class Code <i>[hidden]</i> [Primary System Organ Class Code]	<input type="text"/>

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C4591001: STRATIFICATION (STRAT)	
Stratification	
1. Select appropriate response - Randomizat on Stage [Trigger Response 3]	<input type="radio"/> Non-Sentinel Stage 1
2. Select appropriate response - Randomizat on Age Group [Trigger Response 4]	<input type="radio"/> Age 18 to 55 <input type="radio"/> Age 65 to 85
3. Select appropriate response - Randomizat on Dose [Trigger Response 5]	<input type="radio"/> 10 mcg <input type="radio"/> 20 mcg <input type="radio"/> 30 mcg
4. Select appropriate response - Randomizat on Dose Group [Trigger Response 8]	<input type="radio"/> 21 Day <input type="radio"/> 60 Day
5. Select appropriate response - BNT Number [Trigger Response 7]	<input type="radio"/> (BNT162b1 or PBO) <input type="radio"/> (BNT162b2 or PBO) <input type="radio"/> (BNT162b3 or PBO)

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C4591001: STRATIFICATION (STRAT)	
Stratification	
1. Select appropriate response - Randomizat on Stage [Trigger Response 3]	<input type="radio"/> Stage 2
2. Select appropriate response - Randomizat on Age Group [Trigger Response 4]	<input type="radio"/> Age 18 to 55 <input type="radio"/> Age 56 to 85
3. Select appropriate response - Randomizat on Dose [Trigger Response 5]	<input type="radio"/> 10 mcg <input type="radio"/> 20 mcg <input type="radio"/> 30 mcg
4. Select appropriate response - BNT Number [Trigger Response 7]	<input type="radio"/> (BNT162b1 or PBO) <input type="radio"/> (BNT162b2 or PBO) <input type="radio"/> (BNT162b3 or PBO)

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C4591001: STRATIFICATION (STRAT)	
Stratification	
1. Select appropriate response - Randomizat on Stage [Trigger Response 3]	<input type="radio"/> Stage 1 <input type="radio"/> Stage 2
2. Select appropriate response - Randomizat on Age Group [Trigger Response 4]	<input type="radio"/> Age 18 to 55 <input type="radio"/> Age 56 to 85 <input type="radio"/> Age 65 to 85
3. Select appropriate response - Randomizat on Dose [Trigger Response 5]	<input type="radio"/> Low dose level (3mcg) <input type="radio"/> Medium dose level (10mcg) <input type="radio"/> High dose level (30mcg) <input type="radio"/> Low dose level (10mcg) <input type="radio"/> Medium dose level (30mcg) <input type="radio"/> High dose level (100mcg) <input type="radio"/> Low dose level (0.1mcg) <input type="radio"/> Medium dose level (0.3mcg) <input type="radio"/> High dose level (1mcg) <input type="radio"/> Mid-High dose level (50mcg) <input type="radio"/> Low-M d dose level (20mcg)
4. Select appropriate response - Randomizat on Dose Group [hidden] [Trigger Response 6]	<input type="radio"/> 21 Day 2-dose group <input type="radio"/> 60 Day 2-dose group <input type="radio"/> 1-dose group
5. Select appropriate response - Randomizat on Dose Group [Trigger Response 8]	<input type="radio"/> 21 Day <input type="radio"/> 60 Day
6. Select appropriate response - BNT Number [Trigger Response 7]	<input type="radio"/> (BNT162a1 or PBO) <input type="radio"/> (BNT162b1 or PBO) <input type="radio"/> (BNT162b2 or PBO) <input type="radio"/> (BNT162c2 or PBO) <input type="radio"/> (BNT162b3 or PBO)

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C4591001: SUBJECT STATUS (SUB STATU)	
Subject Status	
1. Subject Status [Subject Status]	<input type="text" value="▼"/>
2. Subject Status Date [Status Date]	<input type="text" value="▼"/> / <input type="text" value="▼"/> / <input type="text" value="▼"/>

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C4591001: INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE (SURV CONS)	
Informed Consent - Asymptomatic Surveillance	
1. Consent Was: [Consent Was:]	<input type="radio"/> OBTAINED Date Written Consent Obtained <input type="text"/> / <input type="text"/> / <input type="text"/>

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C4591001: ELECTRONIC SAMPLE TRACKING - NASAL SWAB (SWAB PFE)	
Electronic Sample Tracking	
1. Data Origin [Data Origin]	<input type="radio"/> SITE
2. Sample Type [Sample Type]	<input type="radio"/> NASAL_SWAB
3. Sample Collected? [Sample Collected]	<input type="radio"/> NO <input type="radio"/> YES Date of Collect on: <input type="text"/> / <input type="text"/> / <input type="text"/>
4. If no sample was collected or sample was not collected according to protocol, please provide reason: [Reason sample not collected]	<div style="border: 1px solid black; height: 40px;"></div>
Sample ID	
5.	
Aliquot Entry	
Please enter barcode for each aliquot.	
5.1 Sample ID [Sample ID]	<div style="border: 1px solid black; width: 100%; height: 20px;"></div>

C4591001: MICROBIOLOGY SPECIMEN (SWAB SITE) - Repeating Form								
#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Trade Name	Result	Comments:
1								
Microbiology Specimen								
1.	Actual Date of Collect on: [Date of Collect on]	<input type="text" value=""/> / <input type="text" value=""/> / <input type="text" value=""/>						
2.	Specimen Type: [Specimen Type]	<input type="radio"/> SWABBED MATERIAL						
3.	Specimen Collect on Location: [Specimen Collection Location]	<input type="radio"/> NASAL CAVITY						
4.	Assay Code and Description: [Assay Code and Description]	<input type="radio"/> SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2						
5.	Dev ce Type: [Dev ce Type]	<input type="radio"/> SARS-COV-2 DIAGNOSTIC TEST						
6.	Trade Name: [Trade Name]	<input type="radio"/> CEPHEID XPRT XPRESS SARS-COV-2 TEST						
7.	Test Result: [Result]	<input type="radio"/> POSITIVE <input type="radio"/> NEGATIVE <input type="radio"/> INDETERMINATE						
8.	Comments/Findings/Details: [Comments:]	<div style="border: 1px solid black; height: 40px;"></div>						

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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]	<input type="radio"/> YES Ongoing? <input type="radio"/> YES <input type="radio"/> NO Stop Date: <input type="text" value=""/> / <input type="text" value=""/> / <input type="text" value=""/> <input type="radio"/> 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 WORSENERED MUSCLE PAIN	
2.h	NEW OR WORSENERED JOINT PAIN	

2.1	Symptom: [Symptom:]	<input type="text" value=""/>
-----	------------------------	-------------------------------

2.2	Were fever or systemic symptoms present on the last day the Subject Diary was completed? [Were fever or systemic symptoms present on the last day the Subject Diary was completed?]	<input type="radio"/> YES Ongoing? <input type="radio"/> YES <input type="radio"/> NO Stop Date: <input type="text" value=""/> / <input type="text" value=""/> / <input type="text" value=""/> <input type="radio"/> NO
-----	--	--

3.	Inject on Site Location: [Inject on Site Location:]	<input type="radio"/> DELTOID MUSCLE
----	--	--------------------------------------

4.	Inject on Site Body Side: [Inject on Site Body Side:]	<input type="radio"/> LEFT <input type="radio"/> RIGHT
----	--	---

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

5.1	Injection Site Reaction: [Injection Site Reaction:]	<input type="radio"/> REDNESS <input type="radio"/> SWELLING <input type="radio"/> PAIN AT INJECTION SITE
-----	--	---

5.2	Were injection site reactions present on the last day the Subject Diary was completed? [Were injection site reactions present on the last day the Subject Diary was completed?]	<input type="radio"/> YES Ongoing? <input type="radio"/> YES <input type="radio"/> NO Stop Date: <input type="text" value=""/> / <input type="text" value=""/> / <input type="text" value=""/> <input type="radio"/> NO
-----	--	--

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C4591001: TRANSFUSIONS (TRANSFUSE) - Repeating Form	
#	Date of Transfusion
1	
1. Transfusion Type: [Transfusion Type]	<input type="radio"/> PACKED RBC <input type="radio"/> PLATELETS <input type="radio"/> WHOLE BLOOD <input type="radio"/> PLASMA <input type="radio"/> OTHER Specify: <input type="text"/>
2. Date of Transfusion: [Date of Transfus on]	<input type="text"/> / <input type="text"/> / <input type="text"/>

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C4591001: TREATMENT UNBLINDED (TRN UNBLN)	
Treatment Unblinded	
1. Date Treatment Unblinded : [Date Treatment Unblinded :]	<input type="text"/> / <input type="text"/> / <input type="text"/>
2. Primary Reason for Unblinding: [Primary Reason for Unblinding]	<input type="radio"/> SUBJECT SAFETY CONCERN <input type="radio"/> OTHER If other, specify: <input type="text"/> <input type="radio"/> ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

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C4591001: UNPLANNED VISIT (UNPL)	
Unplanned Assessments	
1. Assessments [Assessments]	<input type="checkbox"/> CONTACT OUTCOME

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C4591001: VACCINATION (VACIN TRT)	
Vaccination	
1. Was there a temporary delay of vaccination? [Temporary Delay of Vaccination]	<input type="radio"/> YES Date of First Delay: <input type="text"/> / <input type="text"/> / <input type="text"/> Reason(s) for Temporary Delay of Vaccination <input type="checkbox"/> FEVER OR ACUTE ILLNESS <input type="checkbox"/> RECENT SYSTEMIC CORTICOSTEROID TREATMENT <input type="checkbox"/> RECENT NON-STUDY VACCINATION <input type="checkbox"/> ANTICIPATED NON-STUDY VACCINATION <input type="radio"/> NO
2. Treatment Name [Treatment Name]	<input type="text"/>
3. Formulat on: [Formulat on:]	<input type="radio"/> INJECTION
4. Dose Date Time: [Dose Date Time:]	<input type="text"/> / <input type="text"/> / <input type="text"/> <input type="text"/> : <input type="text"/> 24-hour clock
5. Anatomical Locat on: [Anatom cal Location:]	<input type="radio"/> DELTOID MUSCLE
6. Body S de: [Body S de:]	<input type="radio"/> LEFT <input type="radio"/> RIGHT
7. Route: [Route:]	<input type="radio"/> INTRAMUSCULAR
8. Planned Dose: [Planned Dose]	<input type="text"/>
9. Planned Dose Unit: [Planned Dose Unit]	<input type="radio"/> ug
10. Actual Dose: [Actual Dose:]	<input type="text"/>
11. Unit: [Unit:]	<input type="radio"/> ug
12. Was the Actual Dose adjusted from planned? [Dose Adjusted From Planned]	<input type="radio"/> YES What was the reason the dose was adjusted? <input type="radio"/> ADVERSE EVENT(S) <input type="radio"/> INSUFFICIENT CLINICAL RESPONSE <input type="radio"/> OTHER SPECIFY If other, specify: <input type="text"/> <input type="radio"/> NO
13. Timeframe Subject Was Observed [Timeframe Subject Was Observed]	<input type="radio"/> THE PROTOCOL SPECIFIED OBSERVATION PERIOD
14. Was the subject observed for at least the protocol specified observation period after investigational product	<input type="radio"/> YES <input type="radio"/> NO If No, specify reason: <input type="text"/>

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	administration? [Observed Post Dose For Specified Time]	
15.	Comparison Term <i>[hidden]</i> [Comparison Term]	
16.	Standardized Medication Name - Dictionary Derived. <i>[hidden]</i> [Standardized Medication Name]	
17.	Standardized Medication Code - Dictionary Derived <i>[hidden]</i> [Standardized Medication Code]	

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C4591001: VACCINATION (VACIN TRT)	
Vaccination	
1. Was there a temporary delay of vaccination? [Temporary Delay of Vaccination]	<input type="radio"/> YES Date of First Delay: <input type="text"/> / <input type="text"/> / <input type="text"/> Reason(s) for Temporary Delay of Vaccination <input type="checkbox"/> FEVER OR ACUTE ILLNESS <input type="checkbox"/> RECENT SYSTEMIC CORTICOSTEROID TREATMENT <input type="checkbox"/> RECENT NON-STUDY VACCINATION <input type="checkbox"/> ANTICIPATED NON-STUDY VACCINATION <input type="radio"/> NO
2. Treatment Name [Treatment Name]	<input type="text"/>
3. Formulat on: [Formulat on:]	<input type="radio"/> INJECTION
4. Dose Date Time: [Dose Date Time:]	<input type="text"/> / <input type="text"/> / <input type="text"/> <input type="text"/> : <input type="text"/> 24-hour clock
5. Anatomical Locat on: [Anatom cal Location:]	<input type="radio"/> DELTOID MUSCLE
6. Body S de: [Body S de:]	<input type="radio"/> LEFT <input type="radio"/> RIGHT
7. Route: [Route:]	<input type="radio"/> INTRAMUSCULAR
8. Container Number: [hidden] [PAC / Kit Number:]	<input type="text"/>
9. Actual Dose: [Actual Dose:]	<input type="text"/>
10. Unit: [Unit:]	<input type="radio"/> mL <input type="radio"/> ug
11. Timeframe Subject Was Observed [Timeframe Subject Was Observed]	<input type="radio"/> THE PROTOCOL SPECIFIED OBSERVATION PERIOD <input type="radio"/> 30 MINUTES
12. Was the subject observed for at least the protocol specified observation period after investigational product administration? [Observed Post Dose For Specified Time]	<input type="radio"/> YES <input type="radio"/> NO If No, specify reason: <input type="text"/>
13. Comparison Term [hidden] [Comparison Term]	<input type="text"/>
14. Standardized	<input type="text"/>

	Medicat on Name - Dict onary Derived. <i>[hidden]</i> [Standardized Medicat on Name]	
15.	Standardized Medicat on Code - Dict onary Derived <i>[hidden]</i> [Standardized Medicat on Code]	<input type="text"/>

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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]	<input type="text"/>				
2.	Category: [Category for Medication]	<input type="radio"/> GENERAL CONCOMITANT MEDICATIONS				
3.	Concomitant Medications Pre-specified: [Concomitant Medications Pre-specified]	<input type="radio"/> NO				
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation). [Name of Medication]	<input type="text"/>				
5.	Start Date: [Start Date]	<input type="text"/> / <input type="text"/> / <input type="text"/>				
6.	Ongoing? [Ongoing]	<input type="radio"/> YES <input type="radio"/> NO End Date: <input type="text"/> / <input type="text"/> / <input type="text"/>				
7.	Comparison Term [hidden] [Comparison Term]	<input type="text"/>				
8.	Standardized Medication Name - Dictionary derived. [hidden] [Standardized Medication Name]	<input type="text"/>				
9.	Standardized Medication Code - Dictionary derived [hidden] [Standardized Medication Code]	<input type="text"/>				

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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:]	<input type="radio"/> 1		
2.2	Temperature: [Temperature]	<input type="text"/>		
2.3	Unit: [Temperature Unit]	<input type="radio"/> F <input type="radio"/> C		
2.4	Temperature Location: [Temperature Location:]	<input type="radio"/> ORAL CAVITY <input type="radio"/> EAR <input type="radio"/> RECTUM <input type="radio"/> AXILLA <input type="radio"/> FOREHEAD		

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C4591001: VITAL SIGNS - BASELINE (VITALS BSL)				
Vital Signs				
1. Date: [Date:]	<input type="text" value=""/> / <input type="text" value=""/> / <input type="text" value=""/>			
2. Weight: [Weight]	<input type="text"/>			
3. Unit: [Weight Unit]	<input type="radio"/> kg <input type="radio"/> LB			
4. Height: [Height]	<input type="text"/>			
5. Unit: [Height Unit]	<input type="radio"/> cm <input type="radio"/> in			
6. Body Mass Index: [Body Mass Index]	<input type="text"/>			
Vital Signs Details				
#	Record Identifier:	Temperature	Temperature Unit	Temperature Location:
7.a	1			
Vital Signs Details Entry				
7.1 Record Identifier: [Record Identifier:]	<input type="radio"/> 1			
7.2 Temperature: [Temperature]	<input type="text"/>			
7.3 Unit: [Temperature Unit]	<input type="radio"/> C <input type="radio"/> F			
7.4 Temperature Location: [Temperature Location:]	<input type="radio"/> ORAL CAVITY <input type="radio"/> EAR <input type="radio"/> RECTUM <input type="radio"/> AXILLA <input type="radio"/> FOREHEAD			

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C4591001: VITAL SIGNS - BASELINE (VITALS BSL)

Vital Signs

1. Date: [Date:]	<input type="text" value=""/> / <input type="text" value=""/> / <input type="text" value=""/>
2. Weight: [Weight]	<input type="text"/>
3. Unit: [Weight Unit]	<input type="radio"/> kg <input type="radio"/> LB
4. Height: [Height]	<input type="text"/>
5. Unit: [Height Unit]	<input type="radio"/> cm <input type="radio"/> in
6. Body Mass Index: [Body Mass Index]	<input type="text"/>

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:]	<input type="radio"/> 1
7.2 Temperature: [Temperature]	<input type="text"/>
7.3 Unit: [Temperature Unit]	<input type="radio"/> C <input type="radio"/> F
7.4 Temperature Location: [Temperature Location:]	<input type="radio"/> ORAL CAVITY <input type="radio"/> EAR <input type="radio"/> RECTUM <input type="radio"/> AXILLA <input type="radio"/> FOREHEAD
7.5 Systolic: [Systolic:]	<input type="text"/>
7.6 Diastolic: [Diastolic:]	<input type="text"/>
7.7 BP Position: [BP Position]	<input checked="" type="radio"/> SITTING
7.8 Pulse: [Pulse:]	<input type="text"/>

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C4591001: VITAL SIGNS - COVID (VITALS COV) - Repeating Form					
#	Date:	Vital Signs Details			
1					
Vital Signs					
1.	Date: [Date:]	<input type="text"/>	<input type="text"/>	<input type="text"/>	
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:]	<input type="radio"/> 1			
2.2	Systolic: [Systolic:]	<input type="text"/>			
2.3	Diastol c: [Diastolic:]	<input type="text"/>			
2.4	Respiratory Rate in respirations/minute: [Respiratory Rate in respirations/minute]	<input type="text"/>			
2.5	Heart Rate in beats/minute: [Heart Rate in beats/minute]	<input type="text"/>			

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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:]	<input type="radio"/> 1						
2.2	Temperature: [Temperature]	<input type="text"/>						
2.3	Unit: [Temperature Unit]	<input type="radio"/> F <input type="radio"/> C						
2.4	Temperature Location: [Temperature Location:]	<input type="radio"/> ORAL CAVITY <input type="radio"/> EAR <input type="radio"/> RECTUM <input type="radio"/> AXILLA <input type="radio"/> FOREHEAD						
2.5	Systolic: [Systolic:]	<input type="text"/>						
2.6	Diastolic: [Diastolic:]	<input type="text"/>						
2.7	BP Position: [BP Position]	<input type="radio"/> SITTING						
2.8	Pulse: [Pulse:]	<input type="text"/>						

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C4591001: WITHDRAWAL OF CONSENT (WOC)

Withdrawal Of Consent

1. W thdrawal 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

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

Month	January	February	March	April	May	June	July	August	September	October	November	December
Abbr.	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Days	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday					
Abbr.	Mon	Tue	Wed	Thu	Fri	Sat	Sun					

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

1 Notifications / Subject card

Email notification/Subject card to provisioned device subjects:

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

Email notification only: [Hello,]

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

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

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

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

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

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

Subject card only: [Participant number: XXXXXXXX]

Subject card only: [Site number: XXXX]

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

Email notification only: [-----]

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

SMS Body for Provisioned Devices:

Welcome to the C4591001-Post-12-July-2020 Study! Activate the TrialMax App with code:

[Activation Code]

Email notification/Subject card to BYOD subjects:

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

Email notification only: [Hello,]

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

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

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

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

[Link]

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

[Activation Code]

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

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

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

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

Subject card only: [Participant number: XXXXXXXX]

Subject card only: [Site number: XXXX]

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

Email notification only: [-----

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 BYOD subjects:

Welcome to the C4591001-Post-12-July-2020 Study! To install the TrialMax App, select the link:

[Link]

Activate the TrialMax App with code:

[Activation Code]

App notification:

Please fill in your diary!

Email notification subject :

COVID-19 Illness Diary Reminder

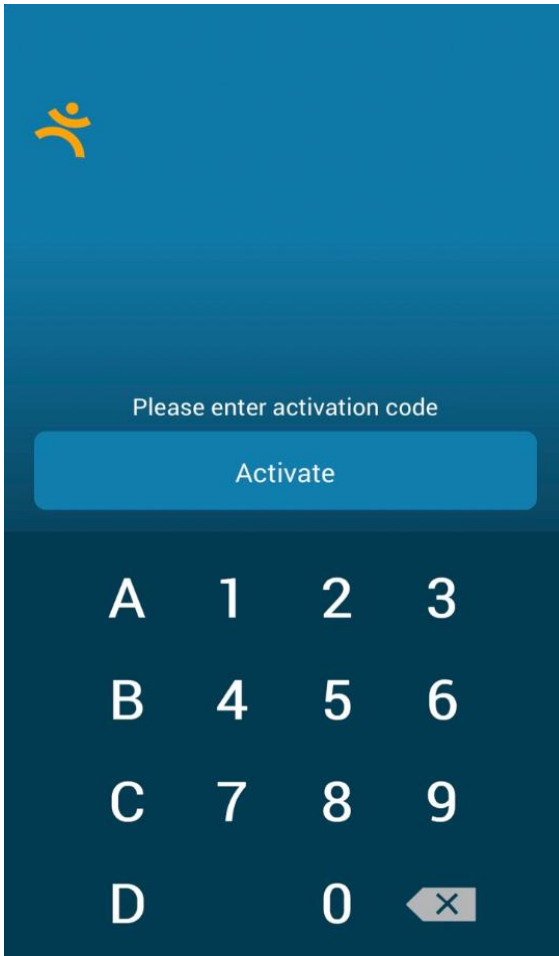
Email and SMS Body for COVID-19 Illness Diary Reminder:

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

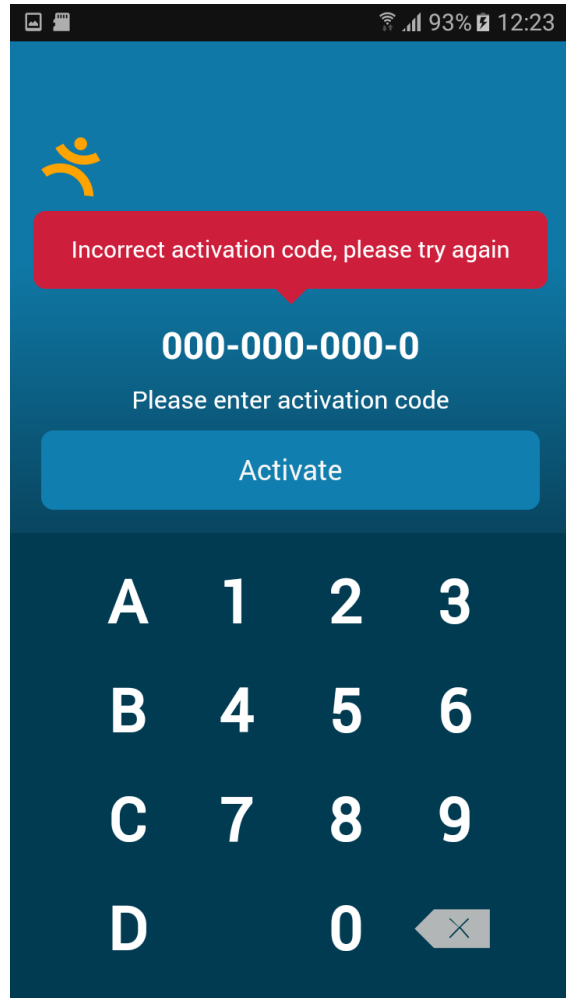
Email notification only: [-----

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

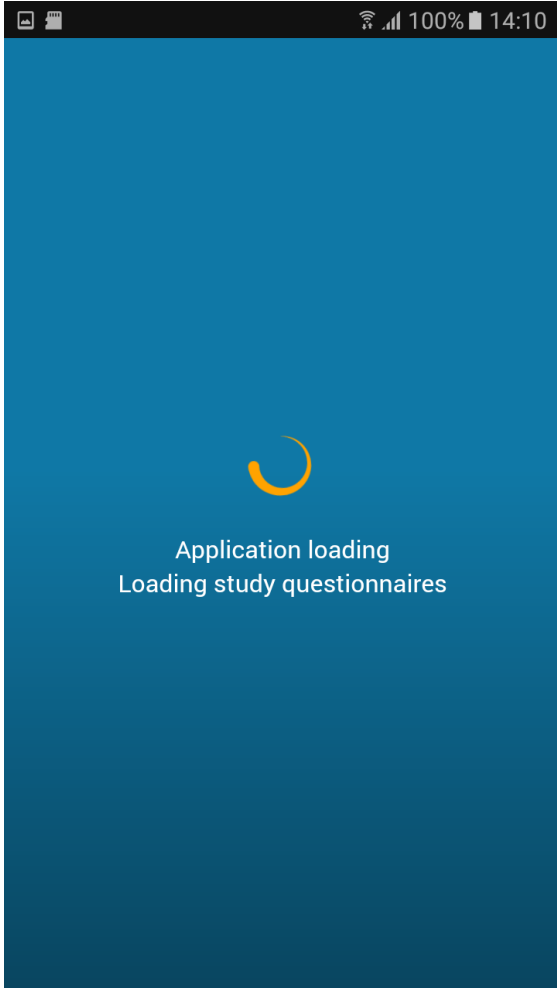
2 Common



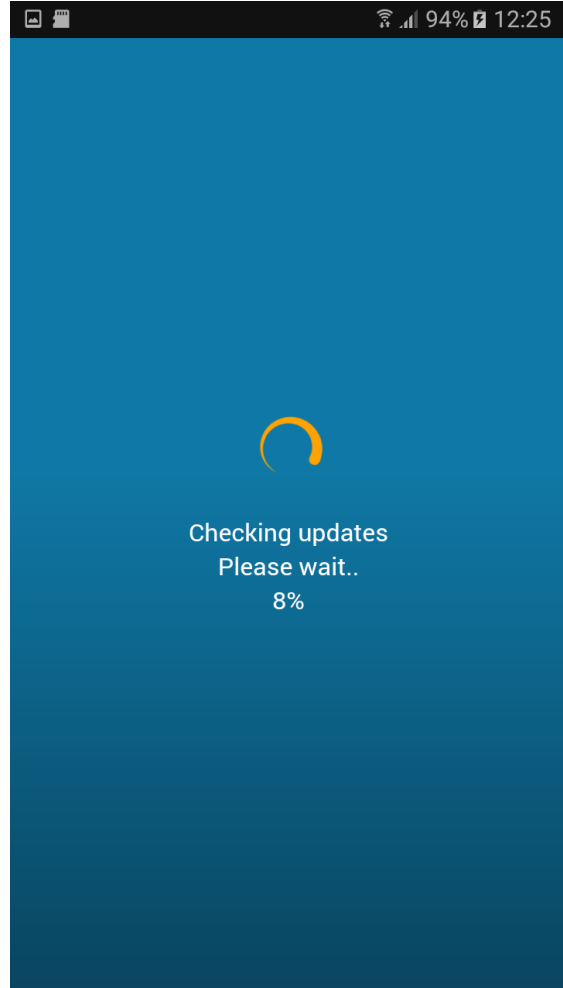
Screen 1



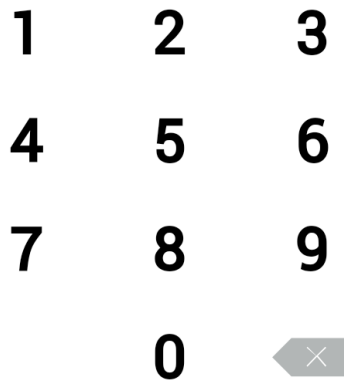
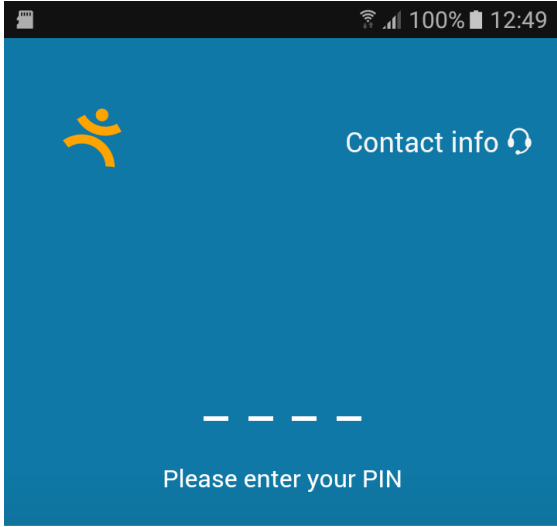
Screen 2



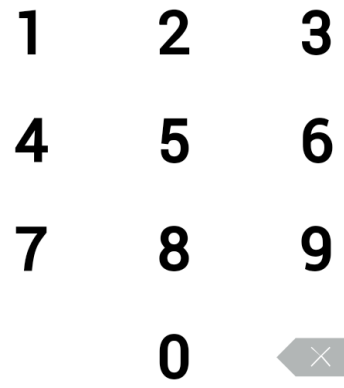
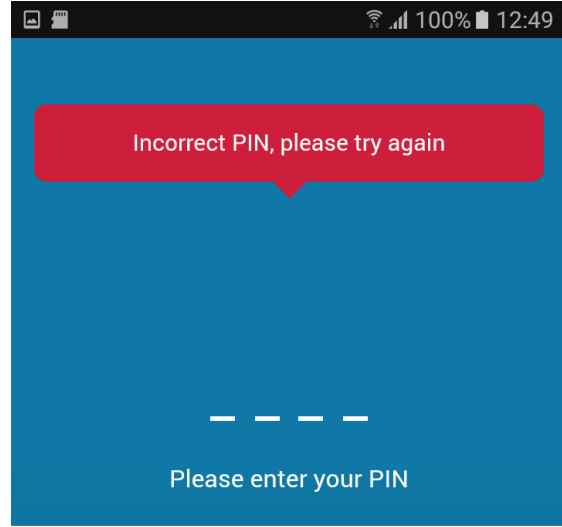
Screen 3



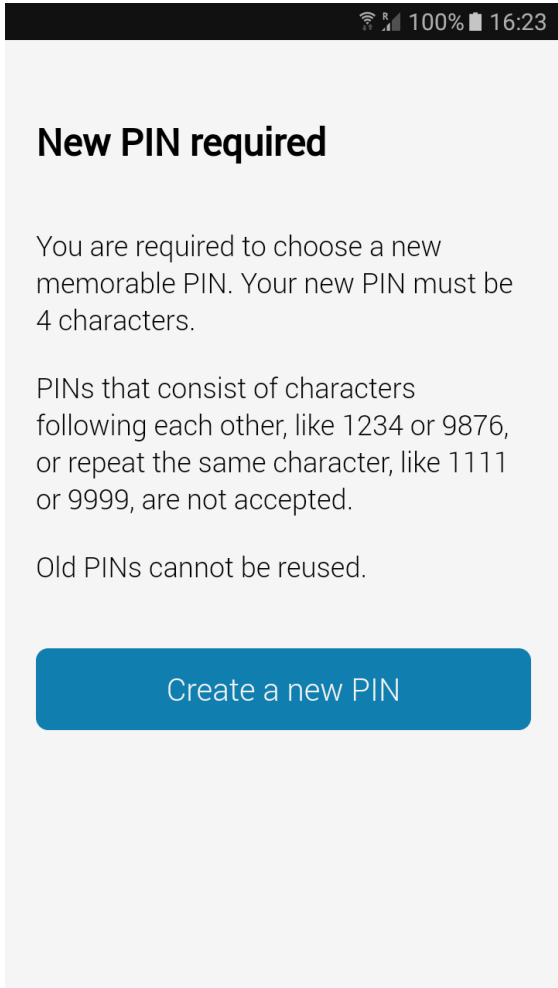
Screen 4



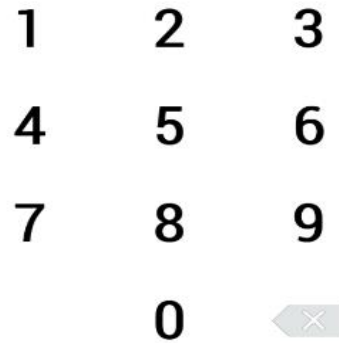
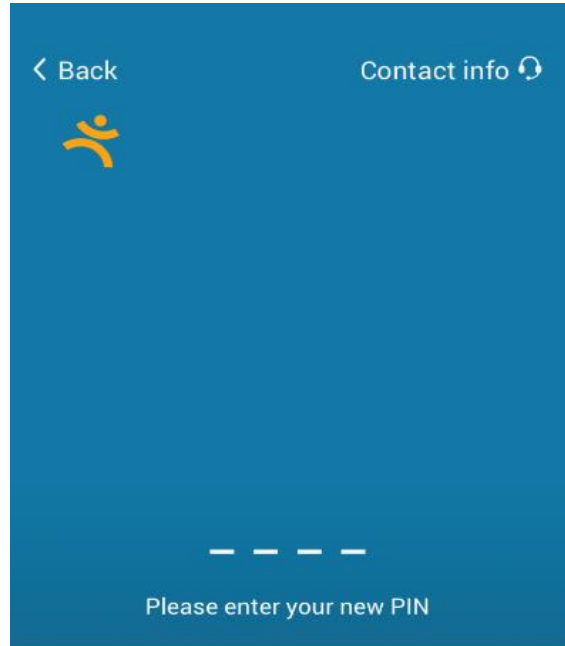
Screen 5



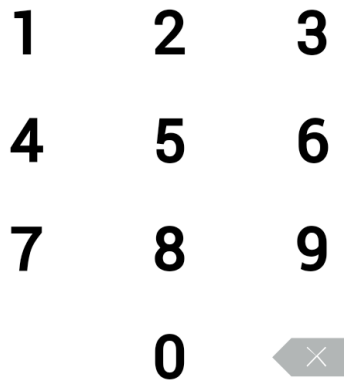
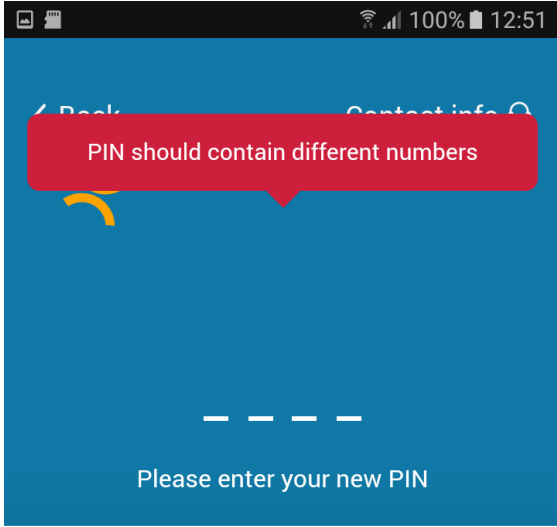
Screen 6



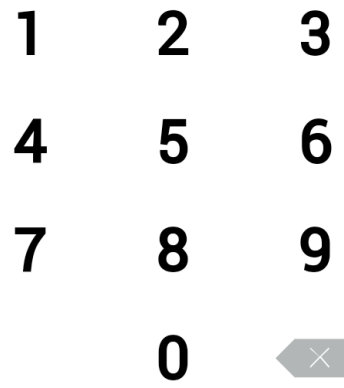
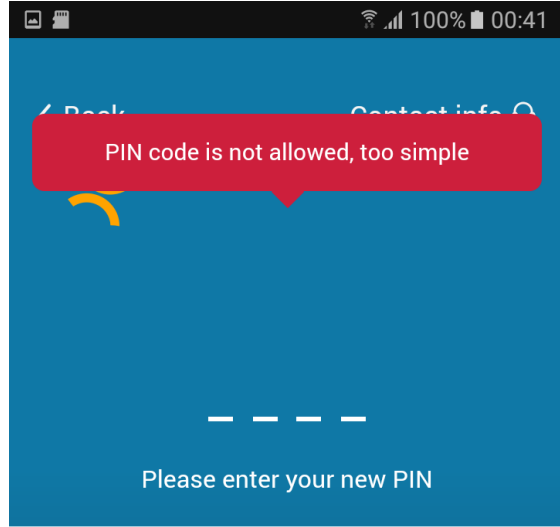
Screen 7



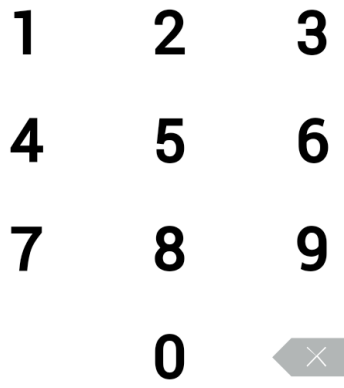
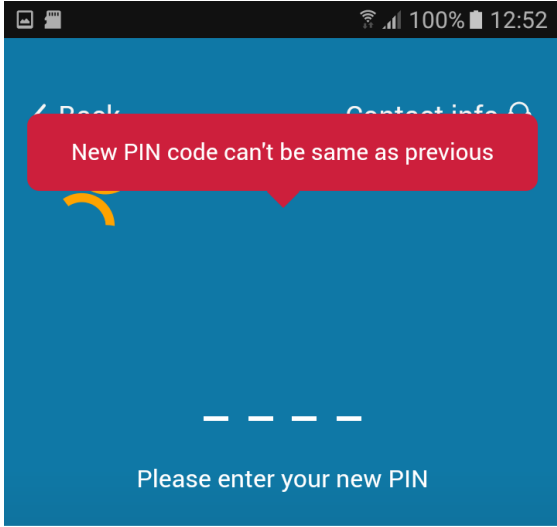
Screen 8



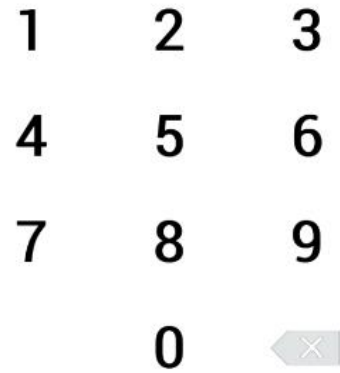
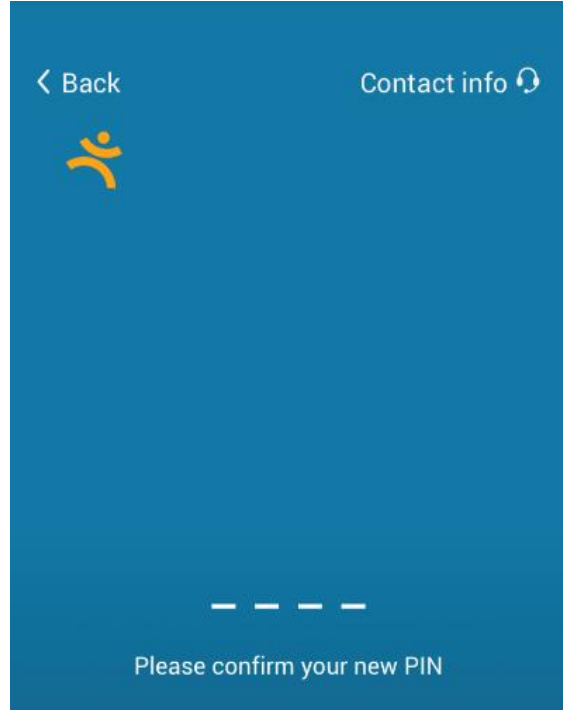
Screen 9



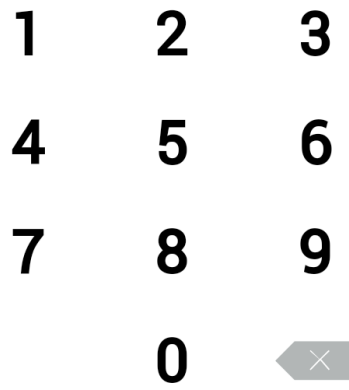
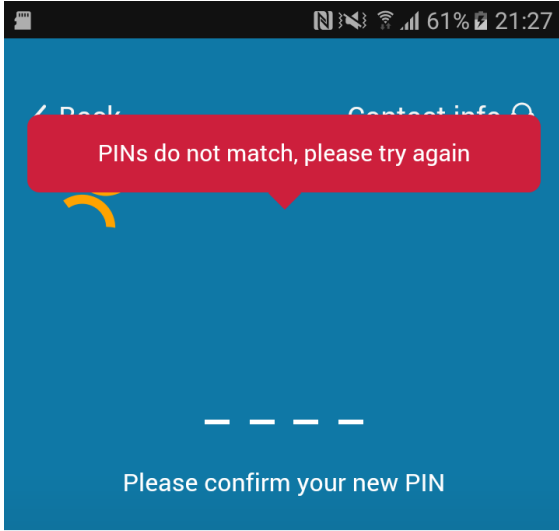
Screen 10



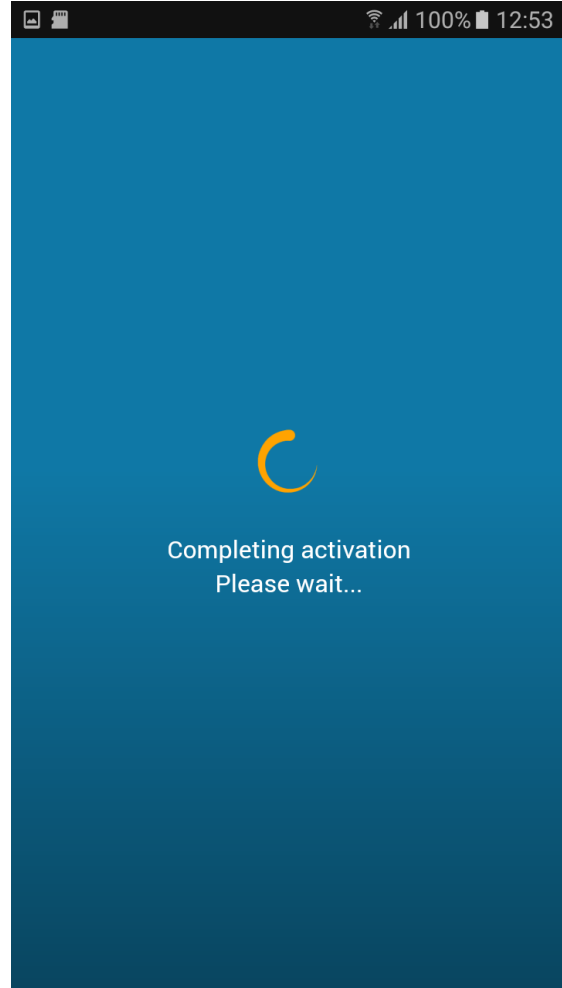
Screen 11



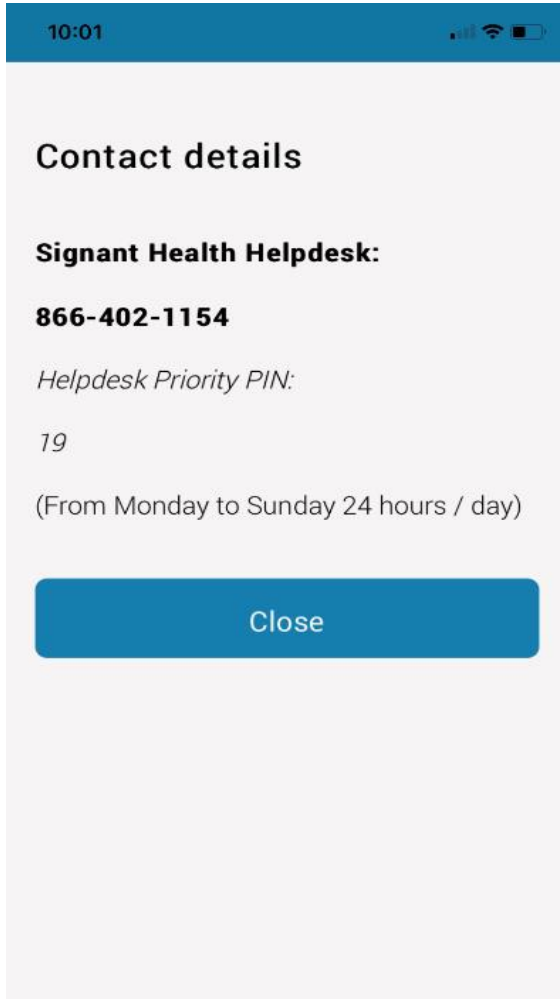
Screen 12



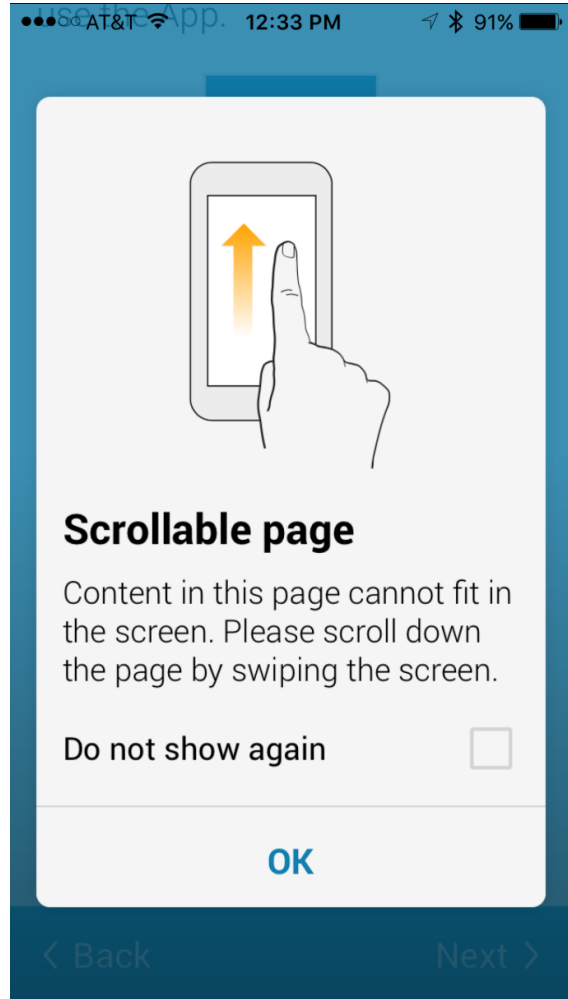
Screen 13



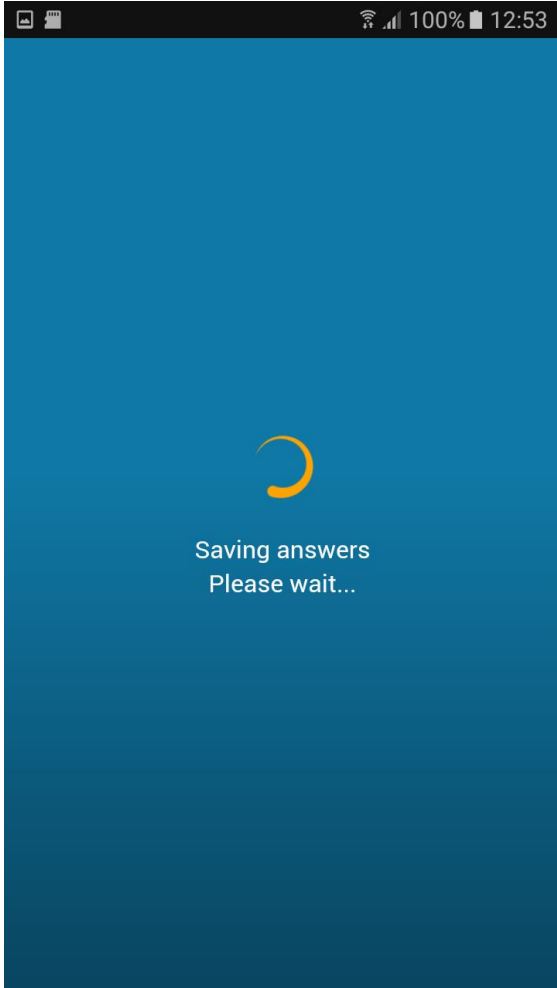
Screen 14



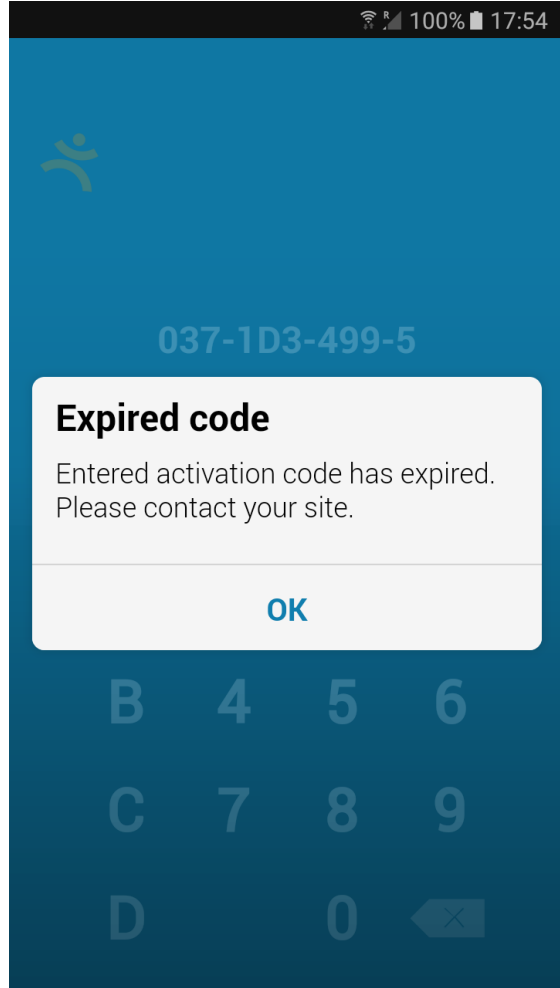
Screen 15



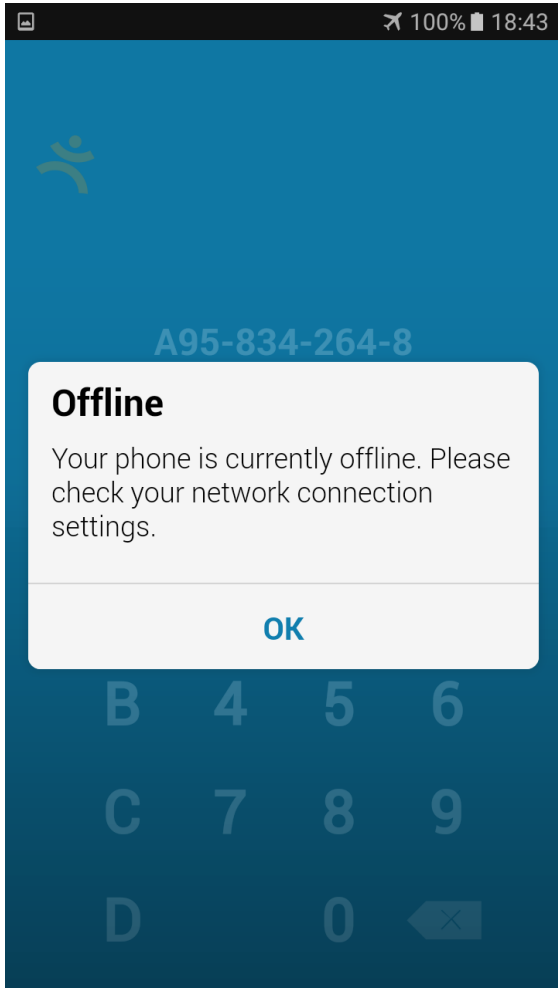
Screen 16



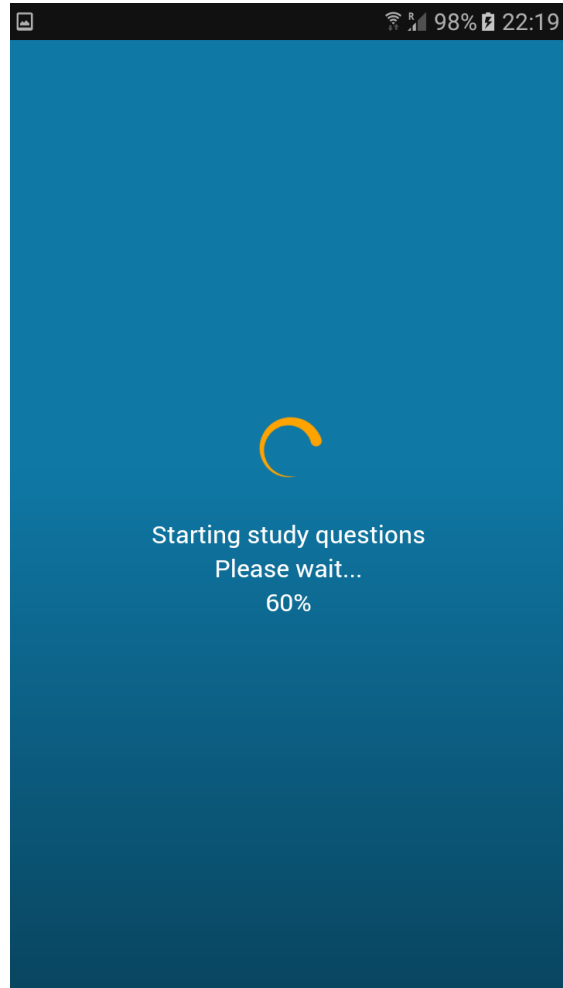
Screen 17



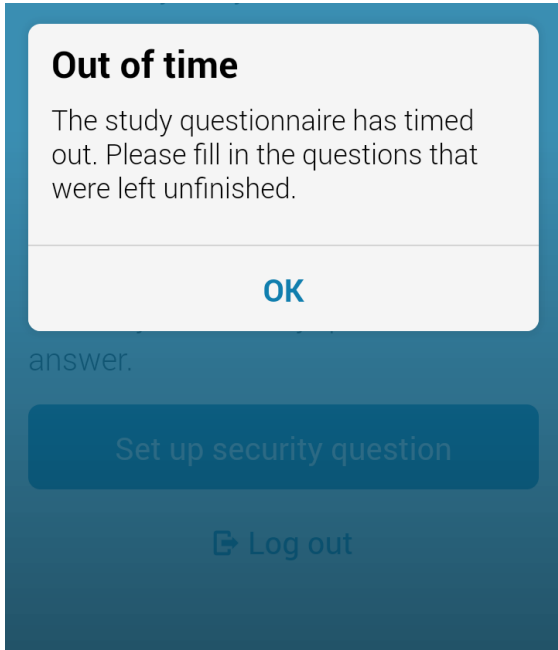
Screen 18



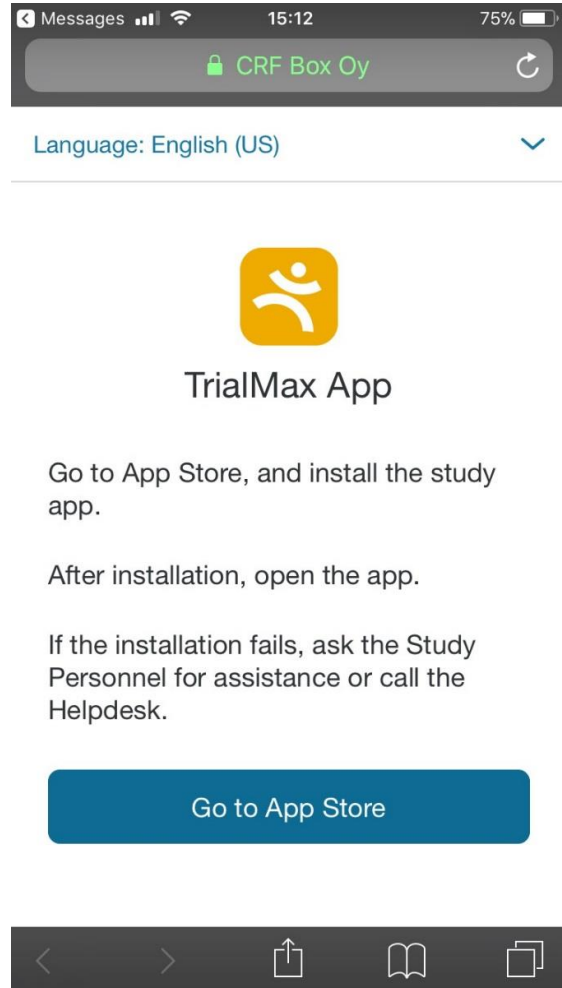
Screen 19



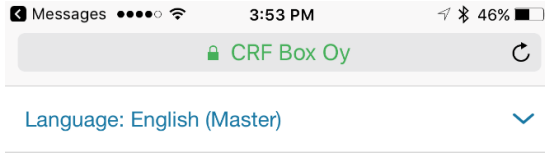
Screen 20



Screen 21



Screen 22

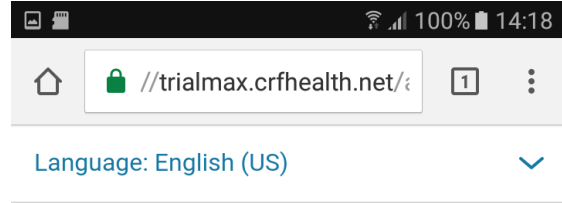


Unfortunately this device cannot run the study app.

Please inform the Study Personnel / contact your site.



Screen 23



TrialMax App

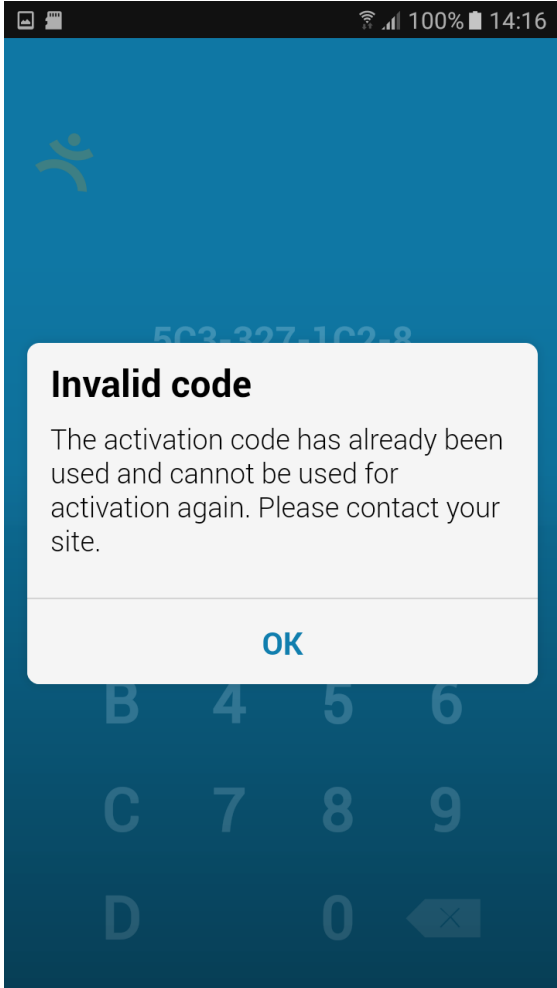
Go to Play Store, and install the study app.

After installation, open the app.

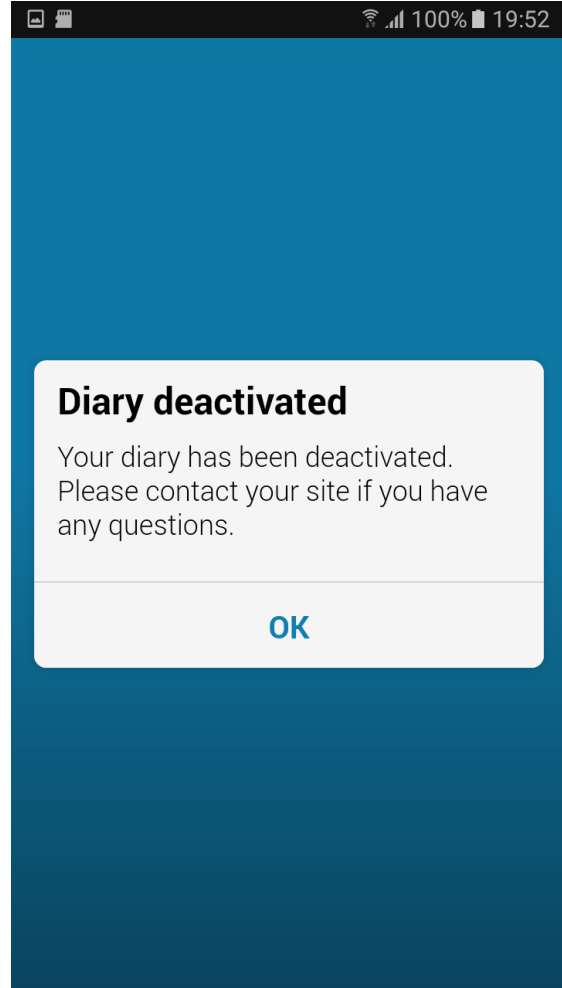
If the installation fails, ask the Study Personnel for assistance or call the Helpdesk.

[Go to Play Store](#)

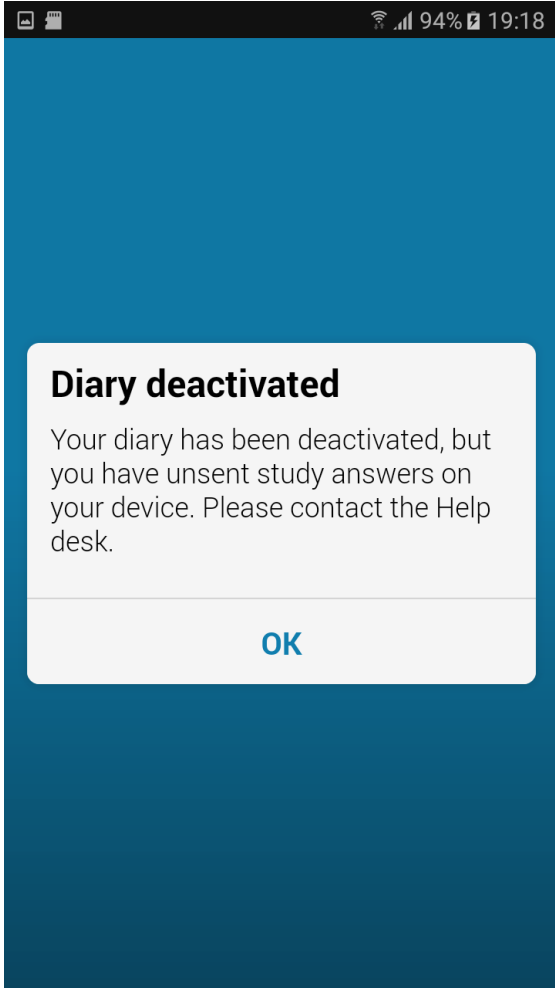
Screen 24



Screen 25



Screen 26



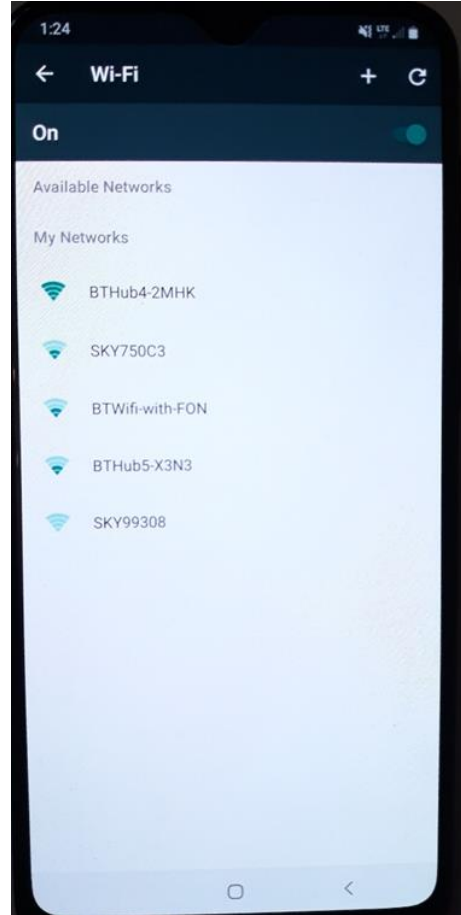
Screen 27



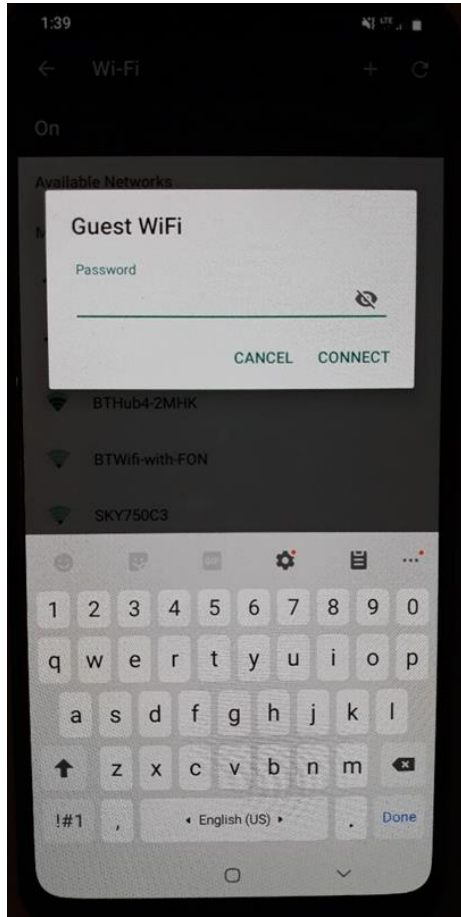
Screen 28



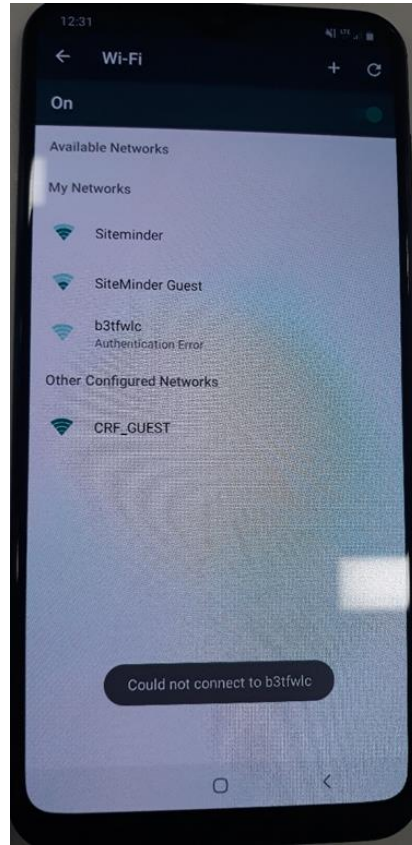
Screen 29



Screen 30

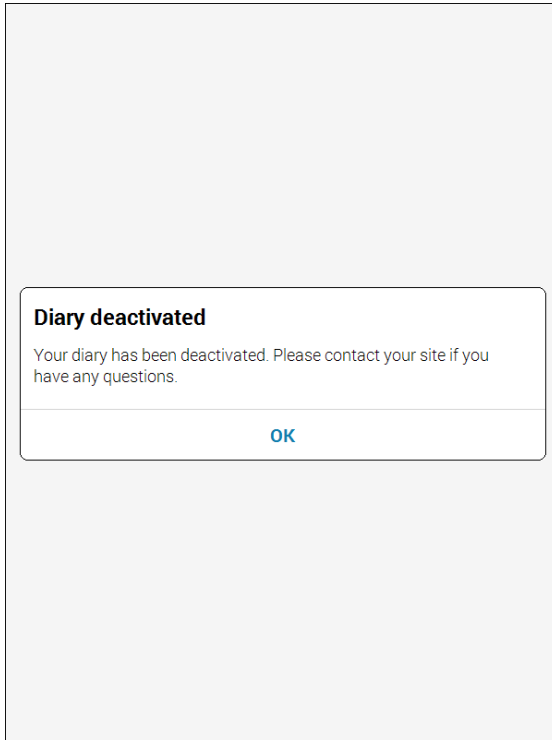


Screen 31



Screen 32

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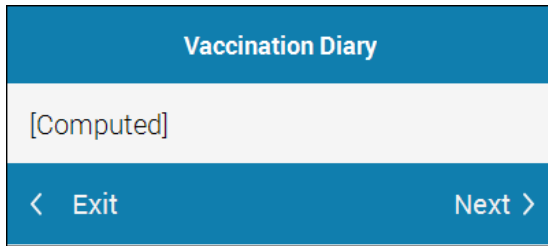


Message 1

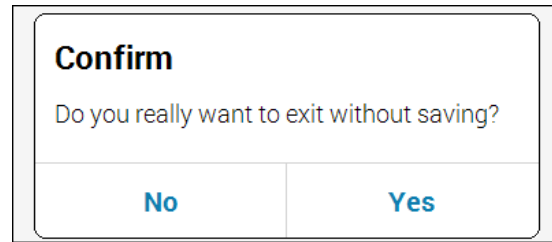
Note: Other messages that could appear on the device include:

- 'Invalid PIN'
- 'Installing study questions'
- 'Securing study questions'
- 'Unsent answers'
- 'There are a lot of unsent study answers. Please make sure your device is connected to the Internet.'
- 'The limit of unsent study answers has been reached. Please connect your device to the Internet to fill in the diary again.'
- 'Oops!'
- 'Something went wrong, please try again or contact the Help desk.'
- 'Unsuccessful sending'
- 'Cannot safely send the study answers, please contact the Help desk.'
- 'Study ended'
- 'You no longer need to fill in the diary. Thank you for your help.'
- 'Updating'
- 'System is updating, please try again later.'
- 'Connection error'
- 'No Internet connection. Please check your Internet connection and try again.'
- 'Time out'
- 'Please check your Internet connection and try again.'
- 'Low storage space'
- 'Your device is running out of available storage. Please free some storage space and try again.'
- 'Error'
- 'Something went wrong, please contact the Help desk or click OK to try again.'

3 Form: Vaccination Diary



Screen 1



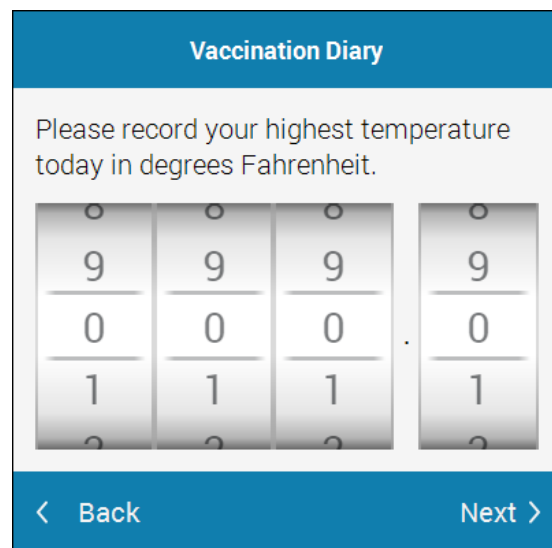
Message 1

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

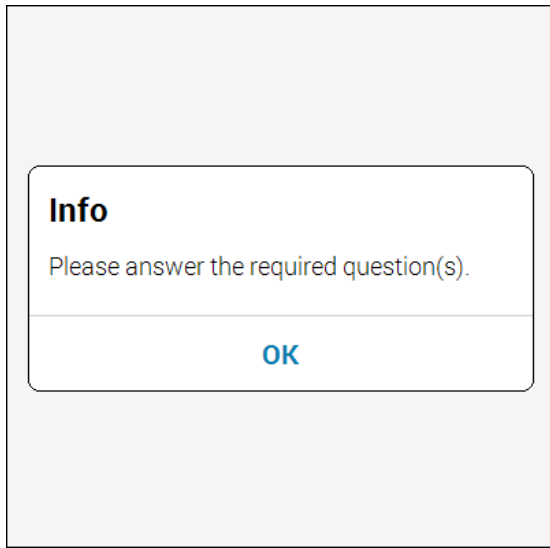
{1} Will display a date

{2} Will display a number of days.

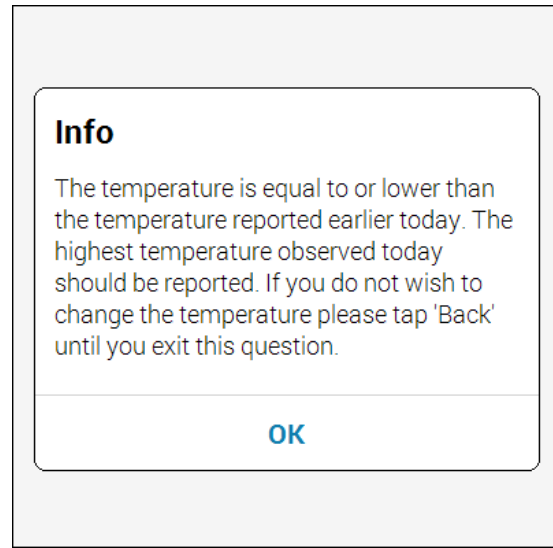
Example: Hello, welcome to the vaccination diary. You will be answering the following questions about how you have been feeling since your vaccination on Mar-27-2020. You will answer these questions for 7 day(s).



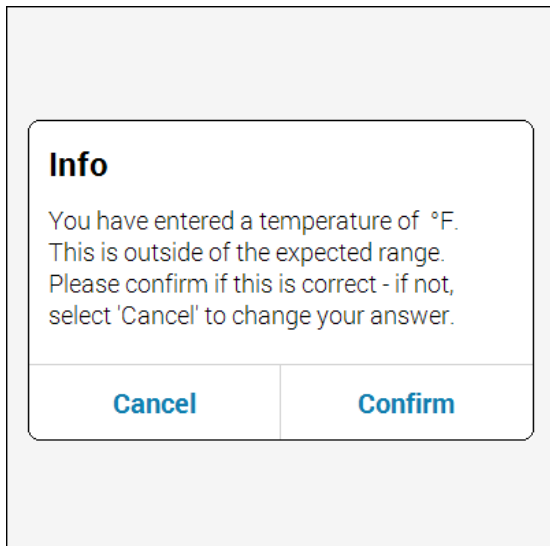
Screen 3



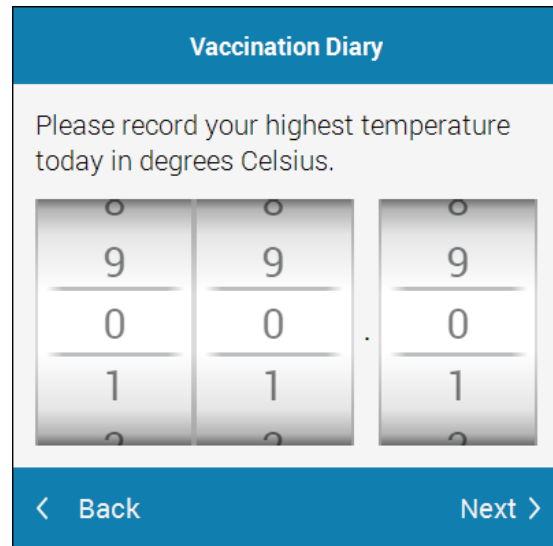
Message 1



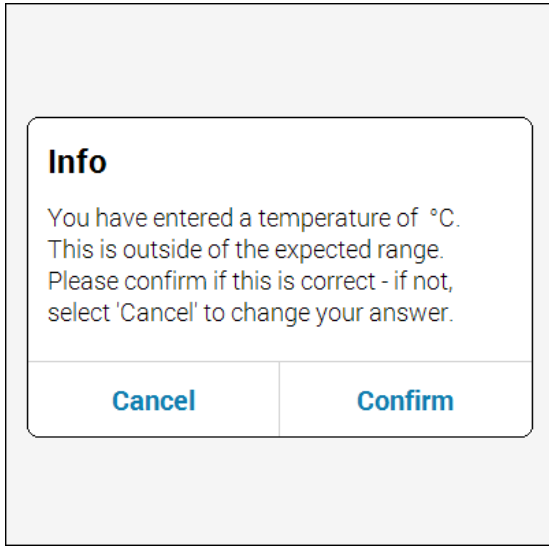
Message 2



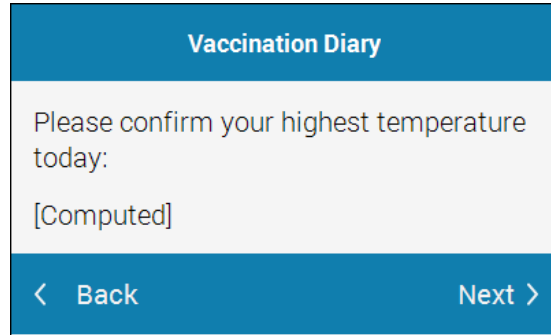
Message 3



Screen 4

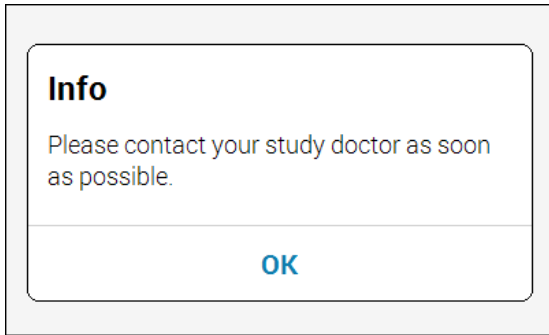


Message 3

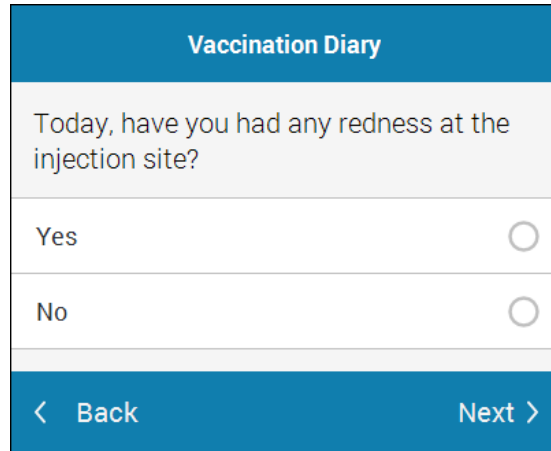


Screen 5

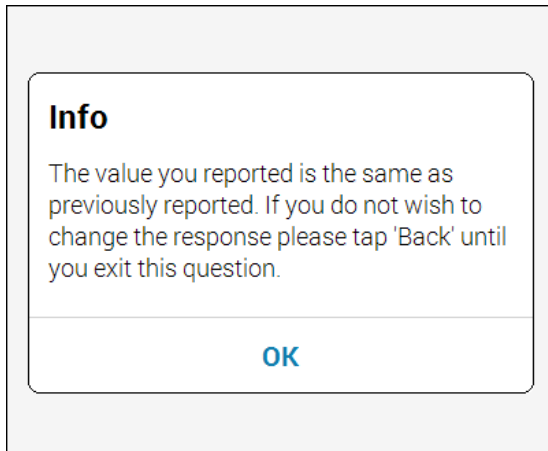
[Computed] will display the temperature selected on Screen 3 or Screen 4



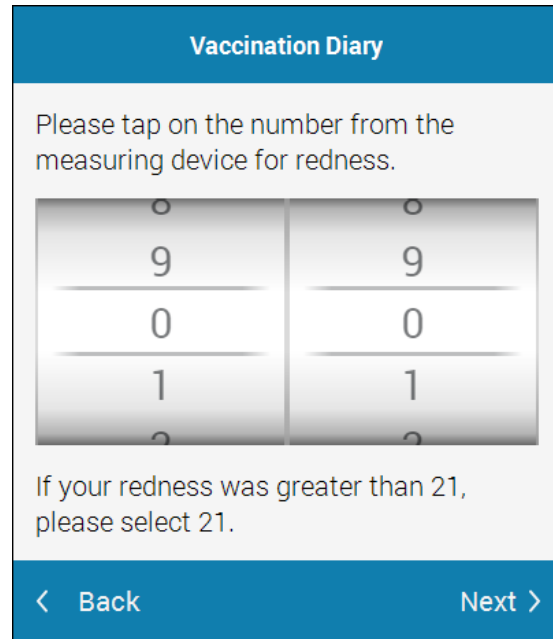
Message 1



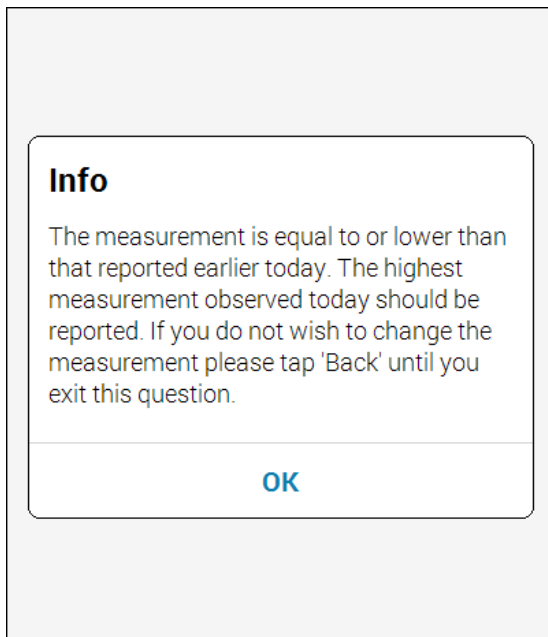
Screen 6



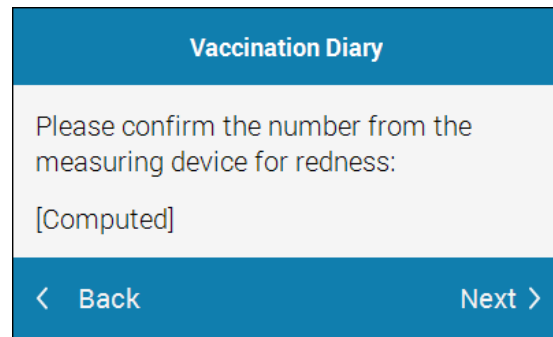
Message 2



Screen 7

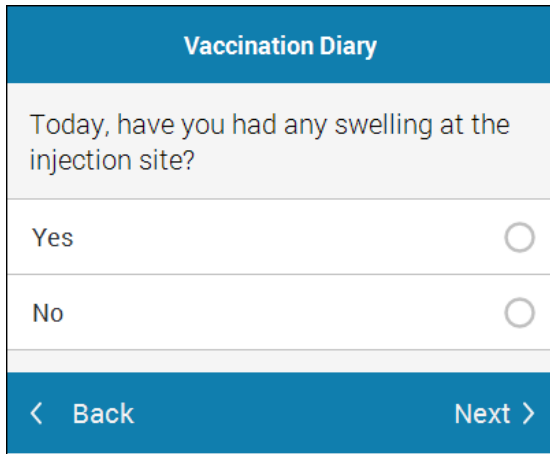


Message 2



Screen 8

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



Vaccination Diary

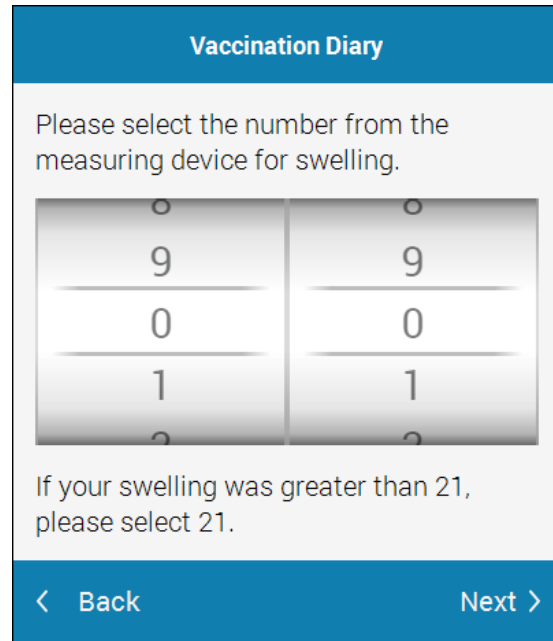
Today, have you had any swelling at the injection site?

Yes

No


< Back Next >

Screen 9



Vaccination Diary

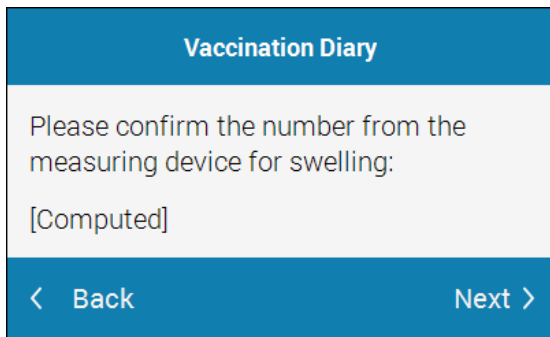
Please select the number from the measuring device for swelling.



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

< Back Next >

Screen 10



Vaccination Diary

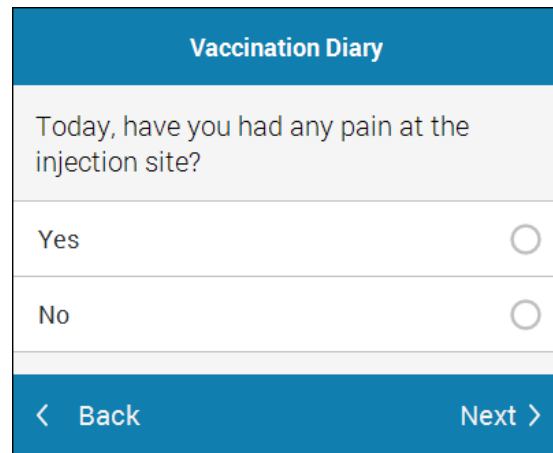
Please confirm the number from the measuring device for swelling:

[Computed]

< Back Next >

Screen 11

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



Vaccination Diary

Today, have you had any pain at the injection site?

Yes

No

< Back Next >

Screen 12

Vaccination Diary

Pain at the injection site definitions:

Mild = Does not interfere with activity

Moderate = Interferes with activity

Severe = Prevents daily activity

< Back Next >

Screen 13

Vaccination Diary

Please indicate whether the pain at the injection site was:

Mild

Moderate

Severe

< Back Next >

Screen 14

Info

Severe = Prevents daily activity. If this is correct tap 'Yes' to go forward or 'No' to change your answer.

No Yes

Message 2

Info

The severity is equal to or lower than the severity reported earlier today. The most severe symptom observed today should be reported. If you do not wish to change the severity please tap 'Back' until you exit this question.

OK

Message 4

Vaccination Diary	
Did you go to the ER or were you hospitalized for this reaction?	
Yes	<input type="radio"/>
No	<input type="radio"/>
< Back Next >	

Screen 15

Vaccination Diary	
Today, have you experienced fatigue (tiredness)?	
Yes	<input type="radio"/>
No	<input type="radio"/>
< Back Next >	

Screen 16

Vaccination Diary	
Fatigue (tiredness) definitions:	
Mild = Does not interfere with activity	
Moderate = Some interference with activity	
Severe = Prevents daily routine activity	
< Back Next >	

Screen 17

Vaccination Diary	
Please indicate whether the fatigue (tiredness) was:	
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
< Back Next >	

Screen 18

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Info
Severe = Prevents daily routine activity. If this is correct tap 'Yes' to go forward or 'No' to change your answer.

No Yes

Message 2

Vaccination Diary

Did you go to the ER or were you hospitalized for this reaction?

Yes

No

< Back Next >

Screen 19

Vaccination Diary

Today, have you experienced headache?

Yes

No

< Back Next >

Screen 20

Vaccination Diary

Headache definitions:

Mild = Does not interfere with activity

Moderate = Some interference with activity

Severe = Prevents daily routine activity

< Back Next >

Screen 21

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Vaccination Diary	
Please indicate whether the headache was:	
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
< Back Next >	

Screen 22

Vaccination Diary	
Did you go to the ER or were you hospitalized for this reaction?	
Yes	<input type="radio"/>
No	<input type="radio"/>
< Back Next >	

Screen 23

Vaccination Diary	
Today, have you experienced vomiting?	
Yes	<input type="radio"/>
No	<input type="radio"/>
< Back Next >	

Screen 24

Vaccination Diary	
Vomiting definitions:	
Mild = 1 to 2 times in 24 hours	
Moderate = More than twice in 24 hours	
Severe = Requires intravenous hydration	
< Back Next >	

Screen 25

Vaccination Diary	
Please indicate whether the vomiting was:	
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
< Back Next >	

Screen 26

Info

Severe = Requires intravenous hydration. If this is correct tap "Yes" to go forward or "No" to change your answer.

[No](#) [Yes](#)

Message 2

Vaccination Diary	
Did you go to the ER or were you hospitalized for this reaction?	
Yes	<input type="radio"/>
No	<input type="radio"/>
< Back Next >	

Screen 27

Vaccination Diary	
Today, have you experienced diarrhea?	
Yes	<input type="radio"/>
No	<input type="radio"/>
< Back Next >	

Screen 28

Vaccination Diary

Diarrhea definitions:

Mild = 2 to 3 loose stools in 24 hours

Moderate = 4 to 5 loose stools in 24 hours

Severe = 6 or more loose stools in 24 hours

< Back Next >

Screen 29

Vaccination Diary

Please indicate whether the diarrhea was:

Mild

Moderate

Severe

< Back Next >

Screen 30

Info

Severe = 6 or more loose stools in 24 hours. If this is correct tap 'Yes' to go forward or 'No' to change your answer.

No **Yes**

Message 2

Vaccination Diary

Did you go to the ER or were you hospitalized for this reaction?

Yes

No

< Back Next >

Screen 31

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Vaccination Diary	
Today, have you experienced chills?	
Yes	<input type="radio"/>
No	<input type="radio"/>
< Back Next >	

Screen 32

Vaccination Diary	
Chills definitions:	
Mild = Does not interfere with activity	
Moderate = Some interference with activity	
Severe = Prevents daily routine activity	
< Back Next >	

Screen 33

Vaccination Diary	
Please indicate whether the chills were:	
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
< Back Next >	

Screen 34

Vaccination Diary	
Did you go to the ER or were you hospitalized for this reaction?	
Yes	<input type="radio"/>
No	<input type="radio"/>
< Back Next >	

Screen 35

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Vaccination Diary	
Today, have you had new or worsened muscle pain (other than at the injection site)?	
Yes	<input type="radio"/>
No	<input type="radio"/>
< Back Next >	

Screen 36

Vaccination Diary	
Muscle pain definitions:	
Mild = No interference with activity	
Moderate = Some interference with activity	
Severe = Prevents daily routine activity	
< Back Next >	

Screen 37

Vaccination Diary	
Please indicate whether the new or worsened muscle pain was:	
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
< Back Next >	

Screen 38

Vaccination Diary	
Did you go to the ER or were you hospitalized for this reaction?	
Yes	<input type="radio"/>
No	<input type="radio"/>
< Back Next >	

Screen 39

Vaccination Diary	
Today, have you had any new or worsened joint pain?	
Yes	<input type="radio"/>
No	<input type="radio"/>
< Back Next >	

Screen 40

Vaccination Diary	
Joint pain definitions:	
Mild = No interference with activity	
Moderate = Some interference with activity	
Severe = Prevents daily routine activity	
< Back Next >	

Screen 41

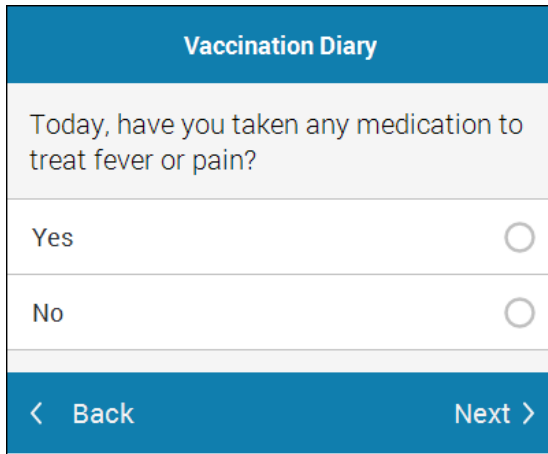
Vaccination Diary	
Please indicate whether the new or worsened joint pain was:	
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
< Back Next >	

Screen 42

Vaccination Diary	
Did you go to the ER or were you hospitalized for this reaction?	
Yes	<input type="radio"/>
No	<input type="radio"/>
< Back Next >	

Screen 43

090177e195746b2f1Approved\Approved On: 06-Nov-2020 14:14 (GMT)



Vaccination Diary

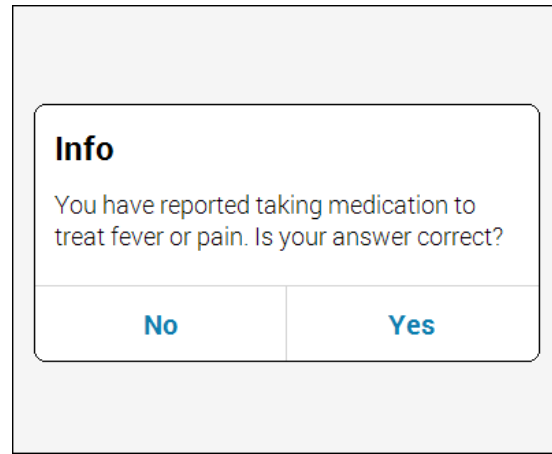
Today, have you taken any medication to treat fever or pain?

Yes

No

< Back Next >

Screen 44

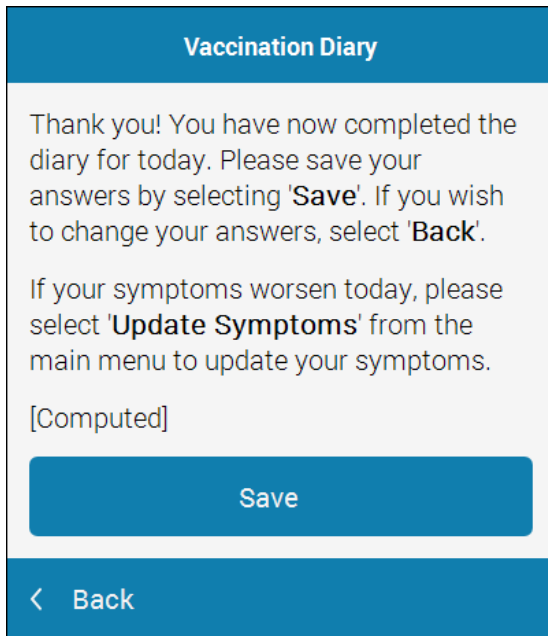


Info

You have reported taking medication to treat fever or pain. Is your answer correct?

No Yes

Message 2



Vaccination Diary

Thank you! You have now completed the diary for today. Please save your answers by selecting **'Save'**. If you wish to change your answers, select **'Back'**.

If your symptoms worsen today, please select **'Update Symptoms'** from the main menu to update your symptoms.

[Computed]

Save

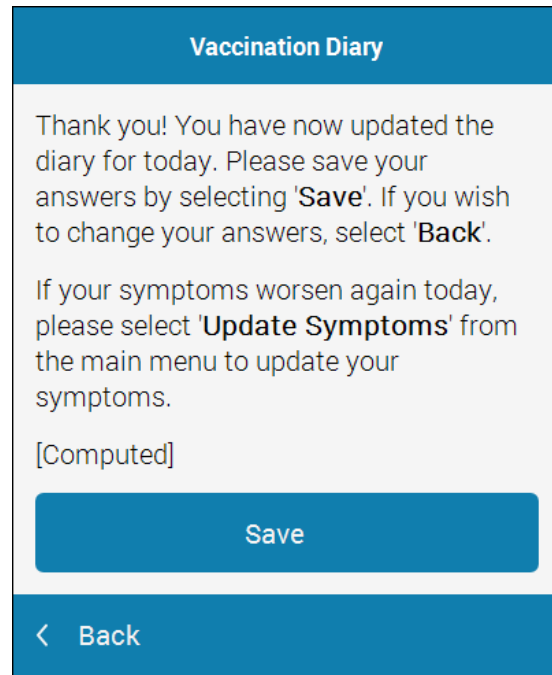
< Back

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).



Vaccination Diary

Thank you! You have now updated the diary for today. Please save your answers by selecting **'Save'**. If you wish to change your answers, select **'Back'**.

If your symptoms worsen again today, please select **'Update Symptoms'** from the main menu to update your symptoms.

[Computed]

Save

< Back

Screen 46

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

Where {1} = a number of days

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

4 Form: COVID-19 Illness Diary

COVID-19 Illness Diary

Have you experienced any of the following?

- A diagnosis of COVID-19;
- Fever;
- New or increased cough;
- New or increased shortness of breath;
- Chills;
- New or increased muscle pain;
- New loss of taste or smell;
- Sore throat;
- Diarrhea;
- Vomiting

Yes

No

< Exit Next >

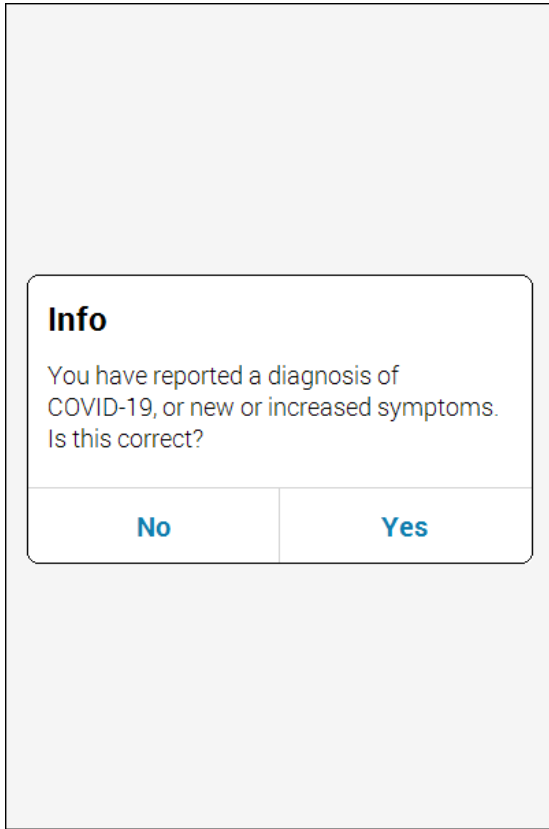
Screen 1

Info

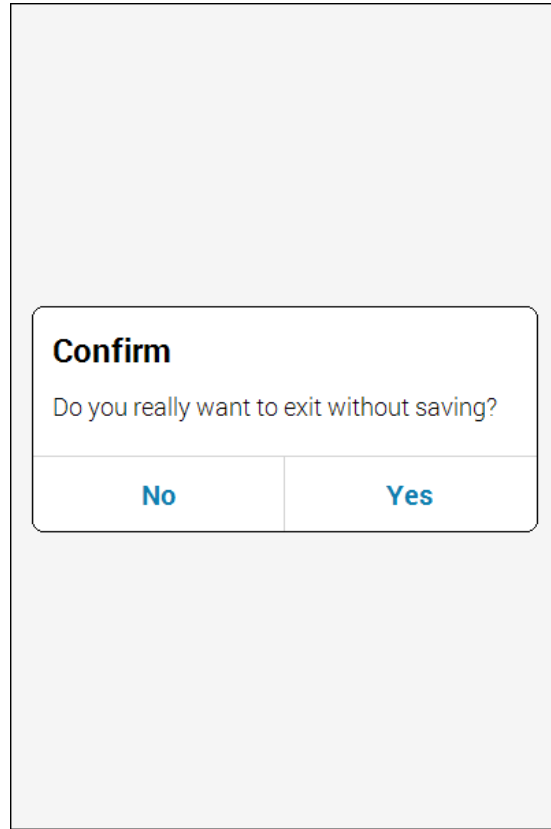
Please answer the required question(s).

OK

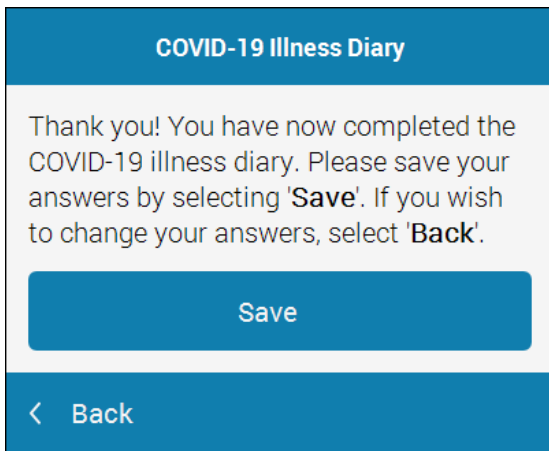
Message 1



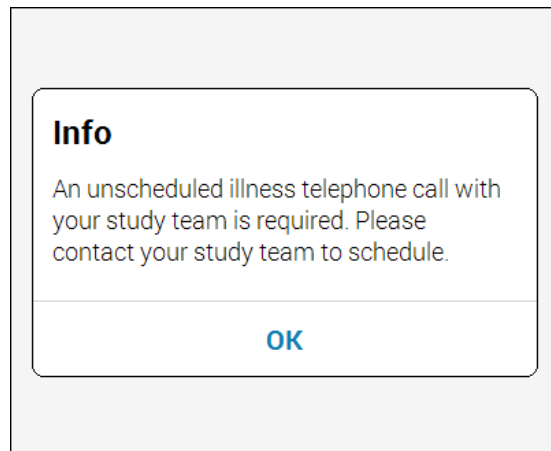
Message 2



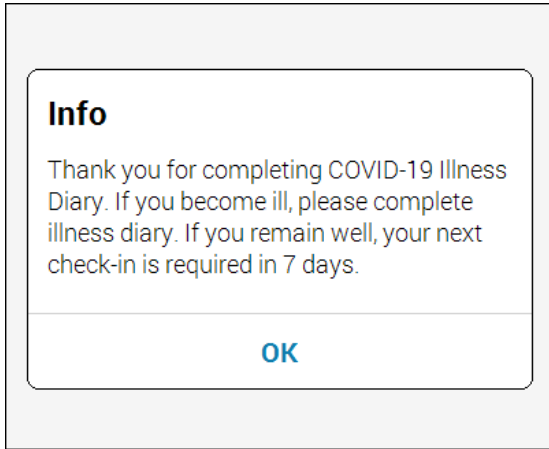
Message 3



Screen 2



Message 1



Message 2

5 Form: Patient main menu

Welcome,

Thank you for taking part in this Study. There are a few things you need to do before you can start filling in your diary.

First you need to set up a security question in case you lose your PIN.

Then you will learn how to complete your diary using a training diary.

Tap '**Set up security question**' to choose your security question and answer.

[Set up security question](#)

[Log out](#)

Screen 1

Log out?

Do you want to log out? You need to complete the security question and the training before you can access the diary.

[No](#) [Yes](#)

Message 1

Thank you,

Your security question and answer have been saved.

Next, tap '**Go to training diary**' to learn how to complete your diary.

[Go to training diary](#)

[Log out](#)

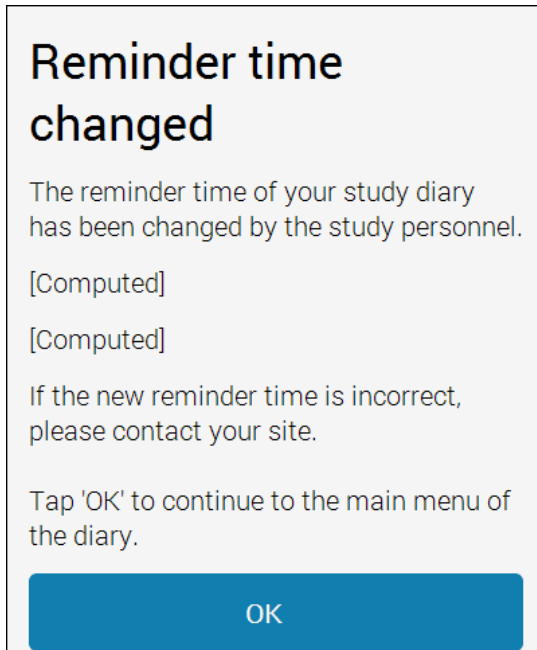
Screen 2

Log out?

Do you want to log out? You need to complete the training before you can access the diary.

[No](#) [Yes](#)

Message 1



Screen 3

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

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



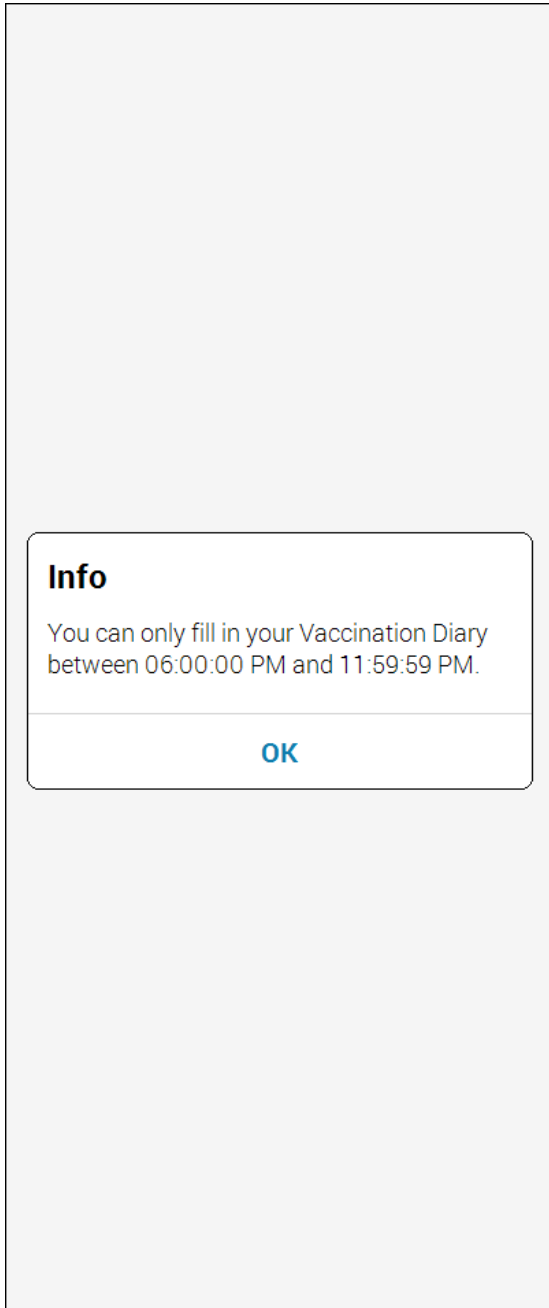
Screen 4

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

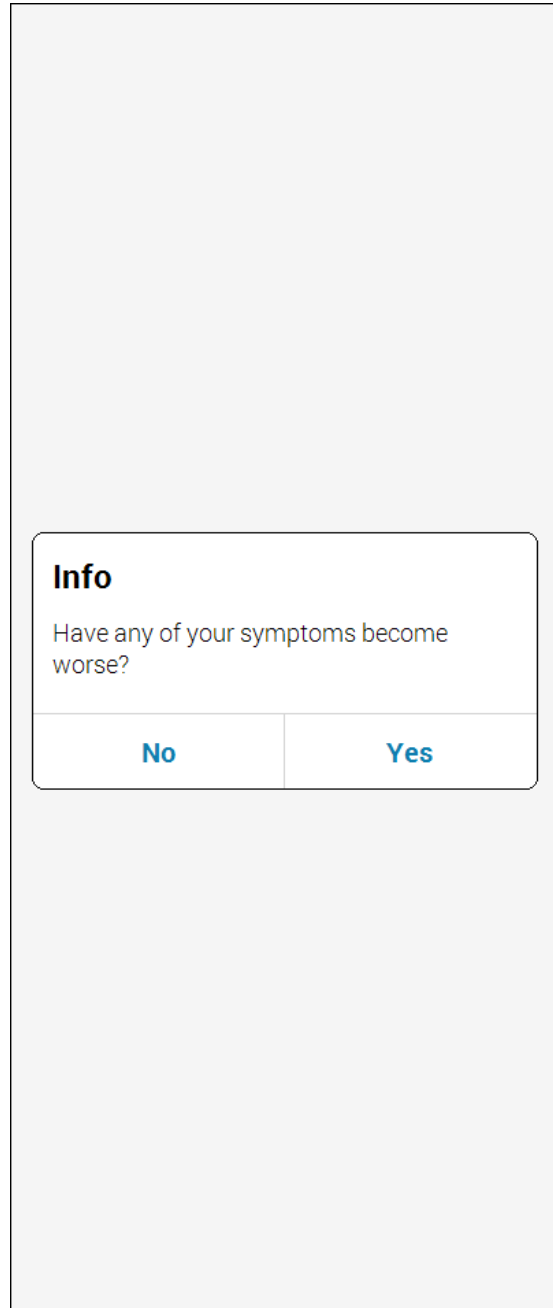
Second [Computed] text below Hello, will either display: "You have completed today's Vaccination Diary.", "You have completed today's Vaccination Diary. Please remember to log in again tomorrow." or "Please fill in your daily Vaccination Diary before midnight."

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

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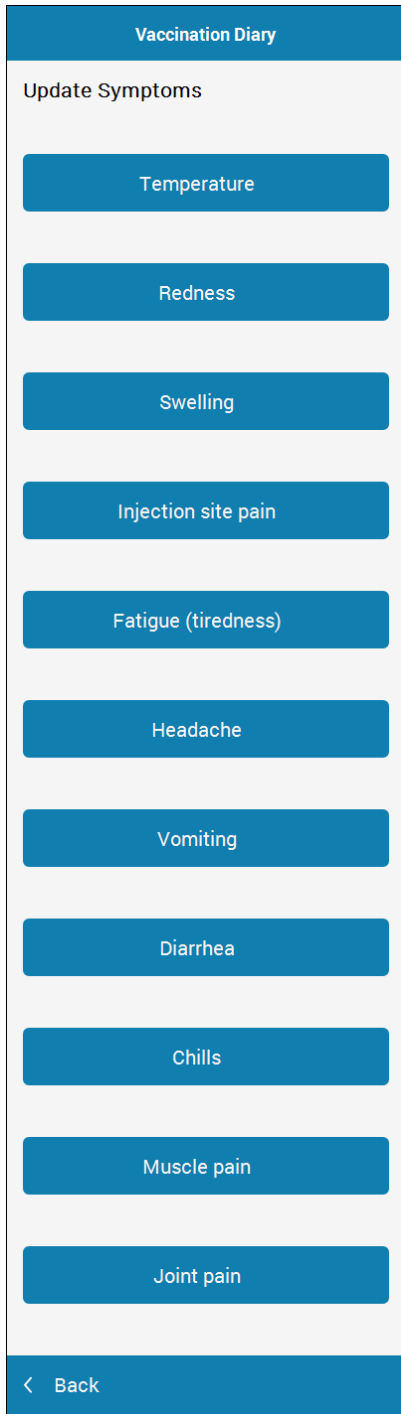
Message 1



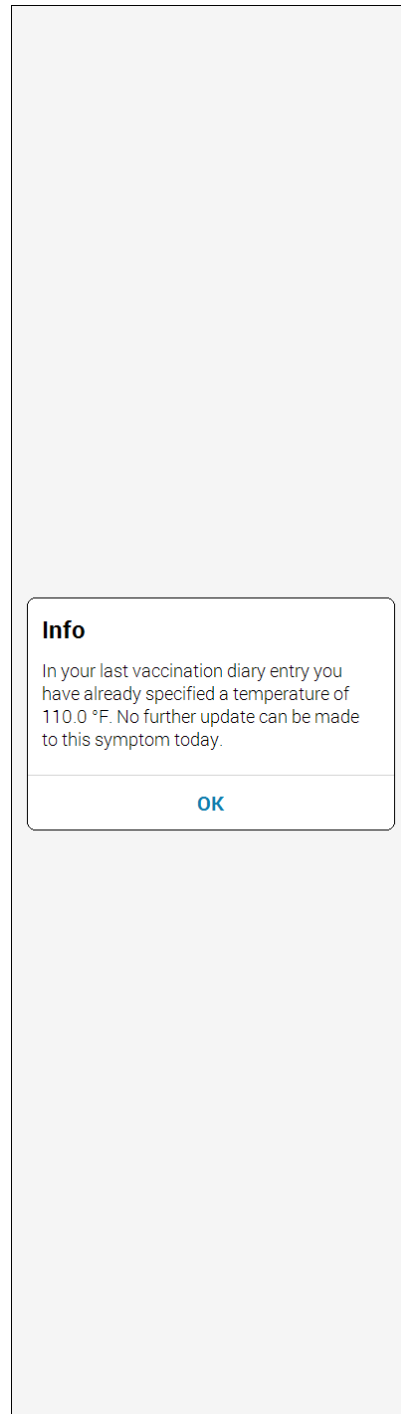
Message 2

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

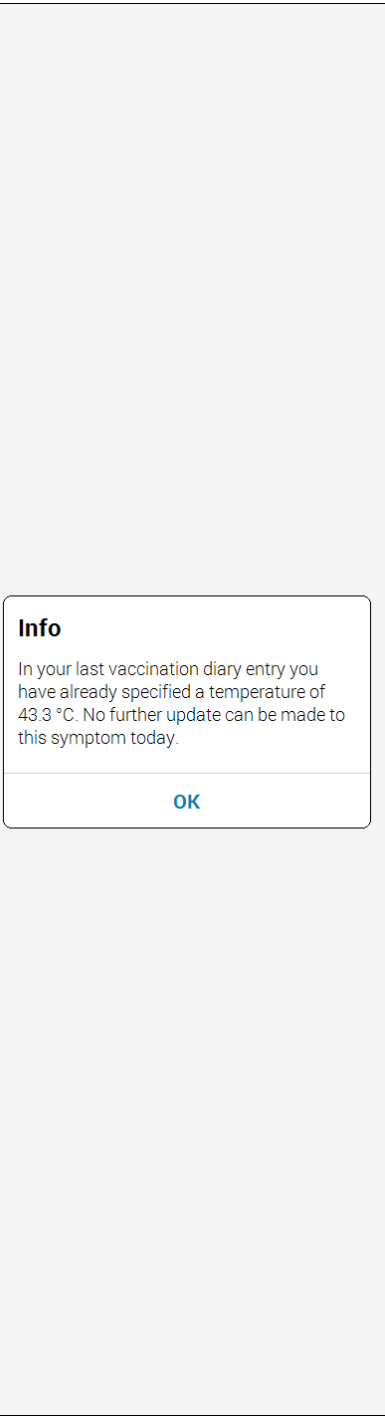
090177e195746b2f\Approved\Approved On: 06-Nov-2020 14:14 (GMT)



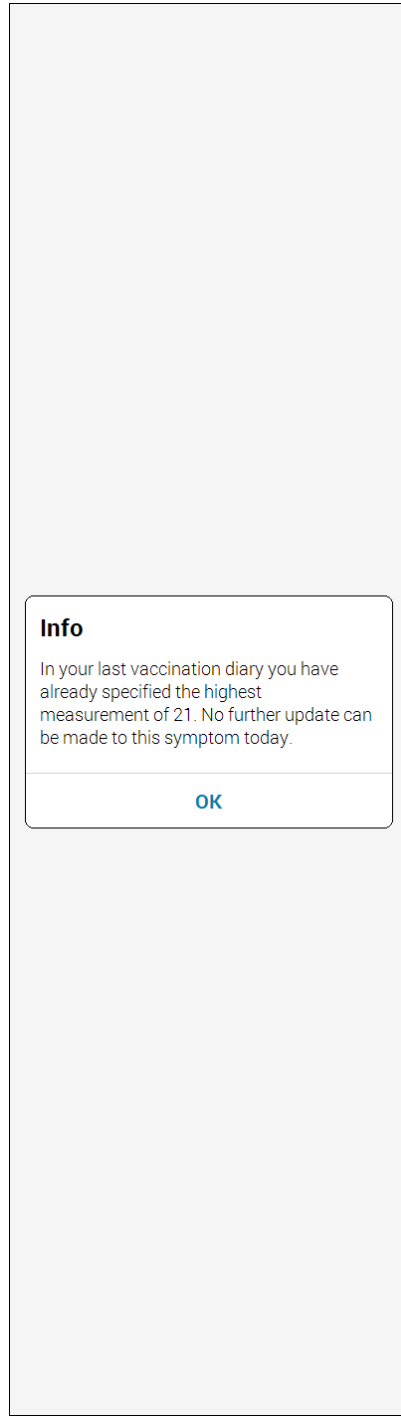
Screen 5



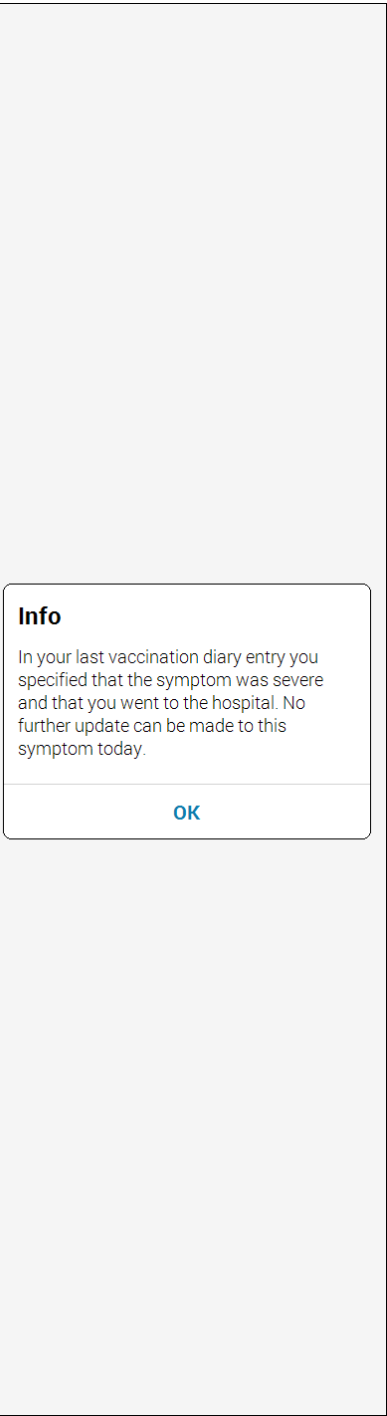
Message 2



Message 3



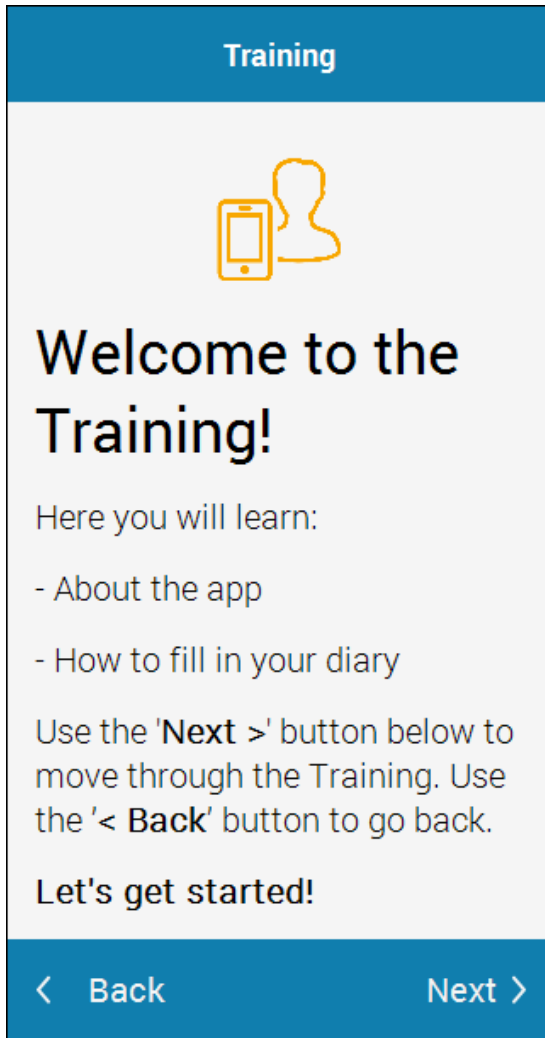
Message 5



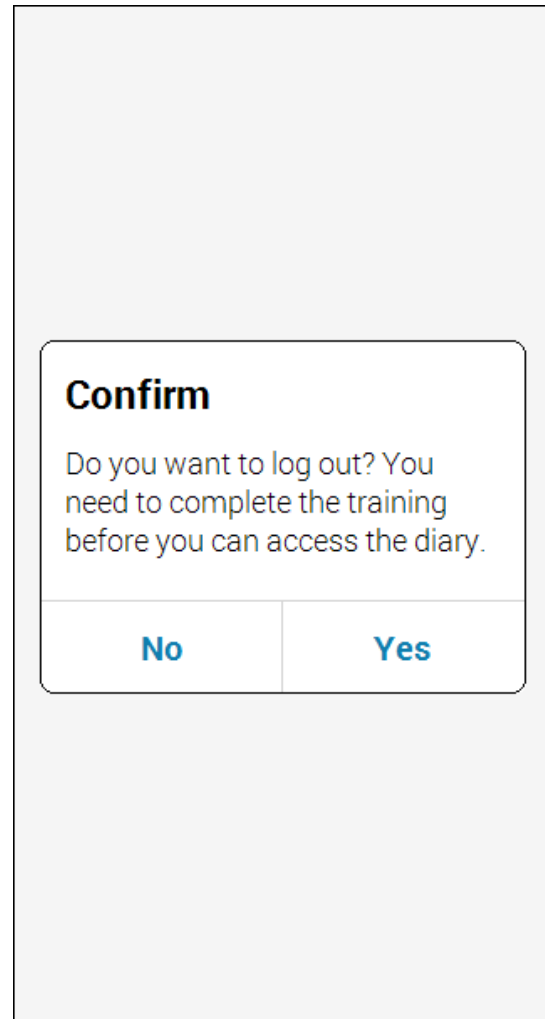
Message 9

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

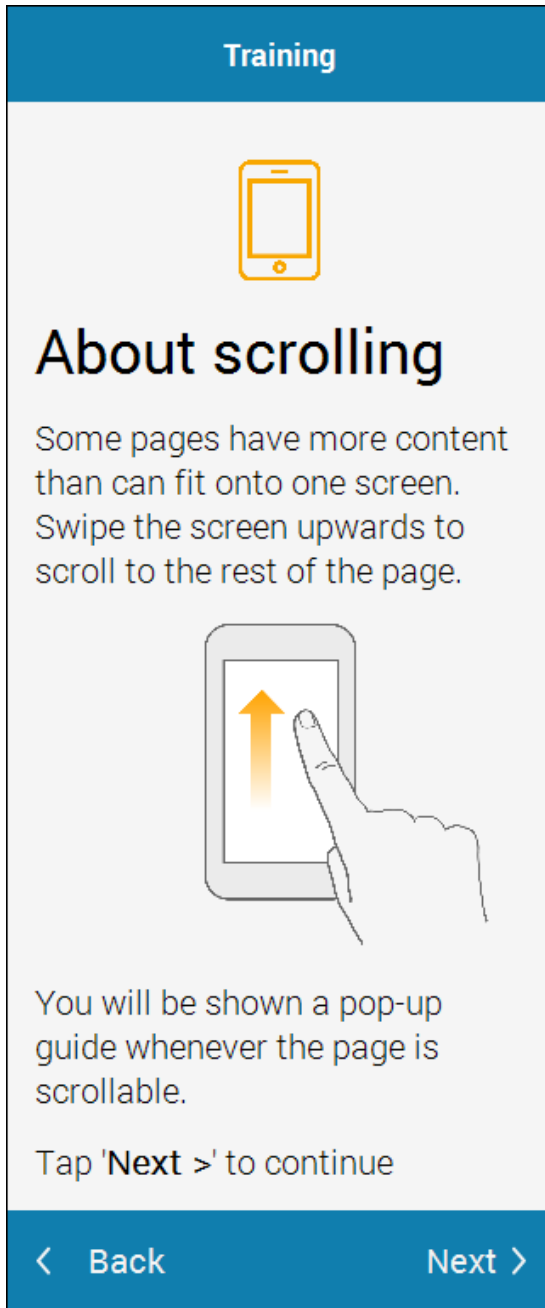
6 Form: Subject training diary



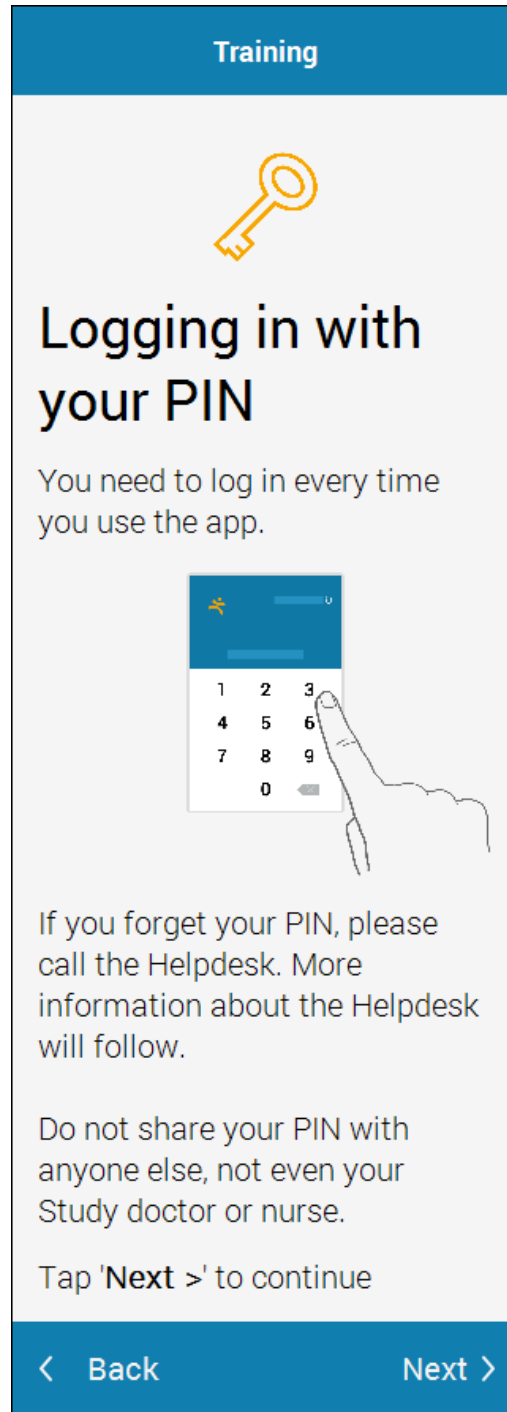
Screen 1



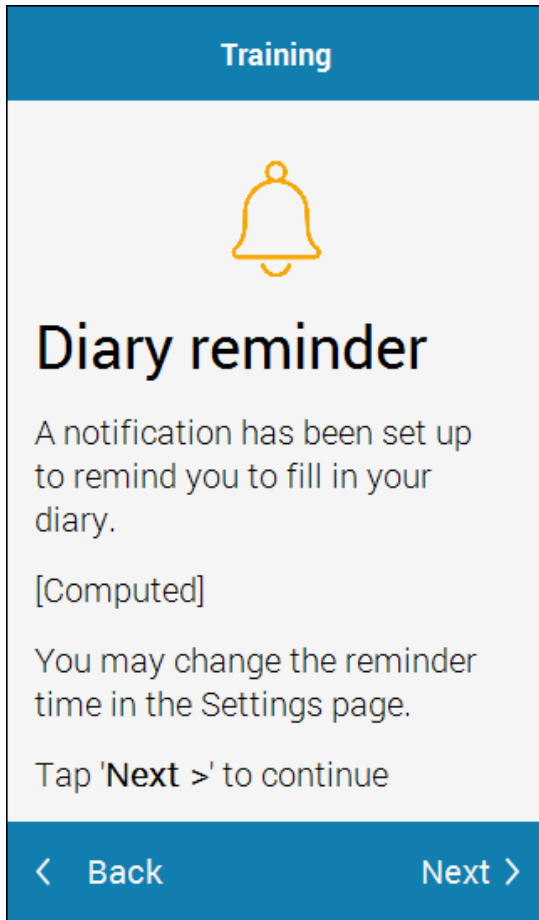
Message 1



Screen 2

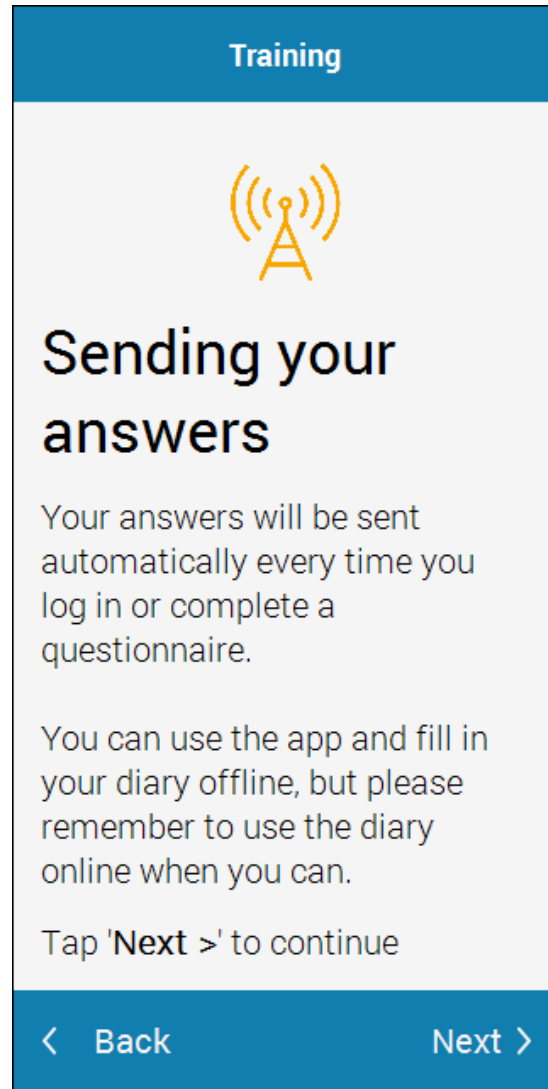


Screen 3




Screen 4

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



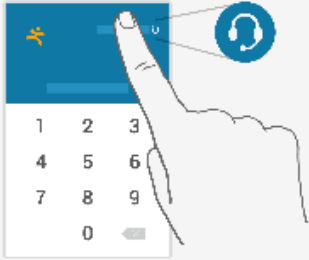
Screen 5

Training



The Helpdesk

We hope you find the app easy to use. If you do have problems, the Helpdesk is always there for you.




You can find the Helpdesk number by tapping the 'Contact info' button on the login screen. The number is also available in your Quick Reference Guide.

Tap 'Next >' to continue

[Back](#) [Next >](#)

Screen 6

Training



Your turn to practice!

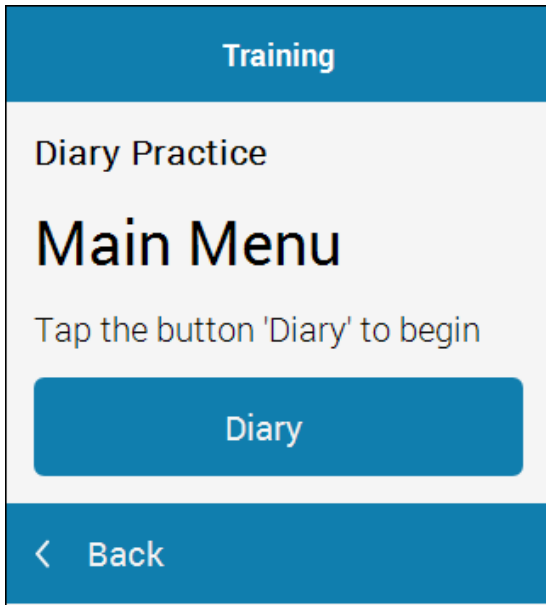
You are about to see a page that we call the 'Main Menu'.

Tap the button 'Diary' to start practicing.

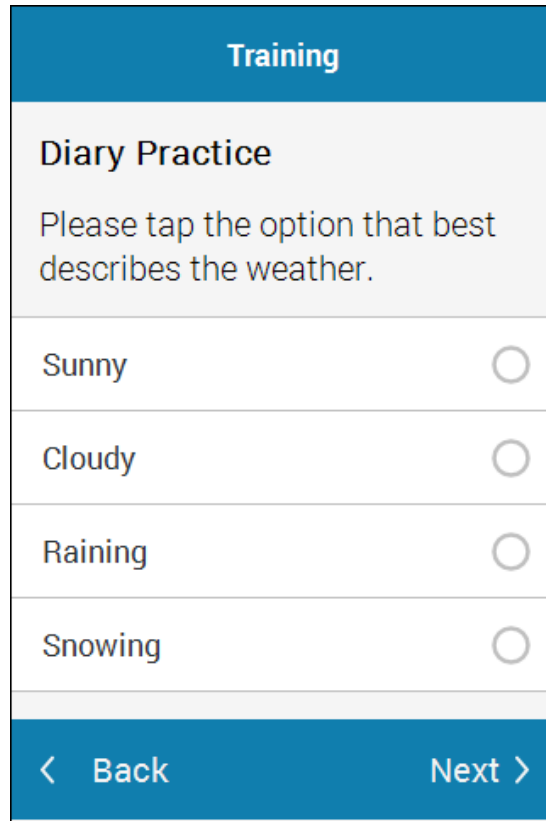
The answers you give during this training session will not be saved.

[Back](#) [Next >](#)

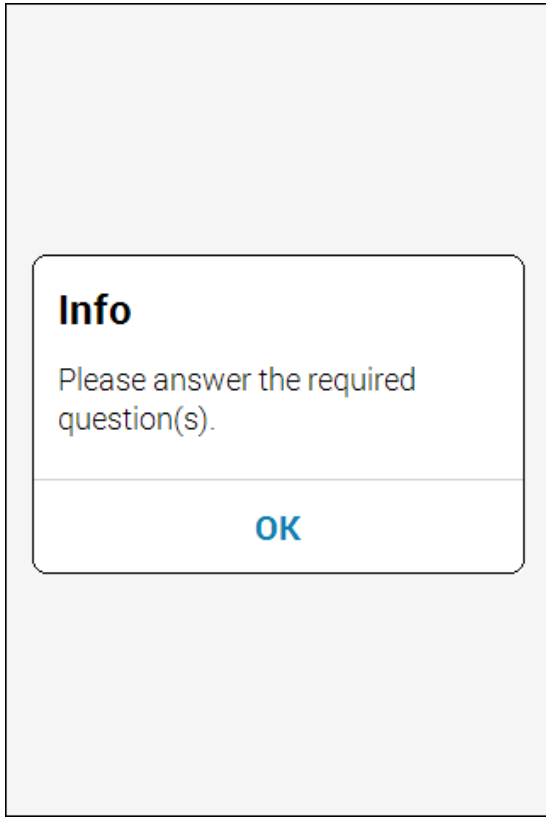
Screen 7



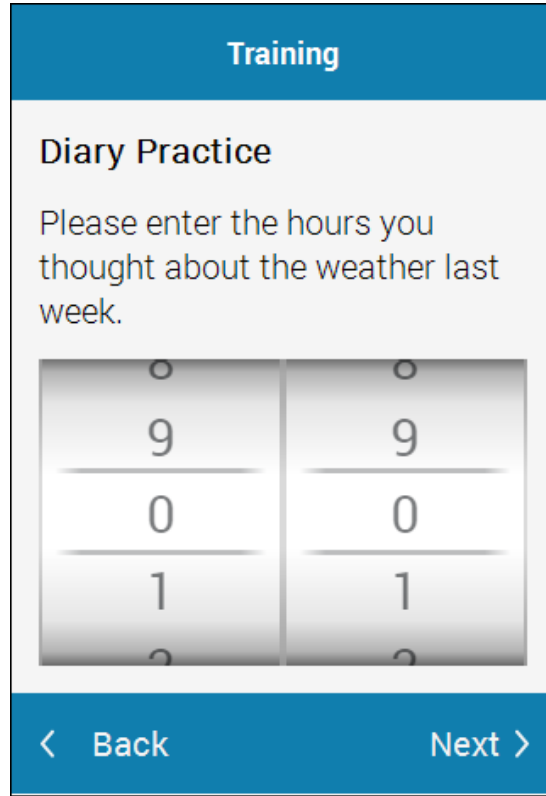
Screen 8



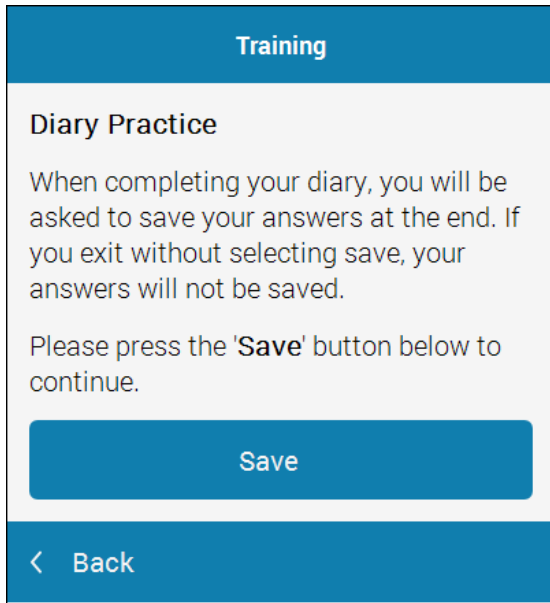
Screen 9



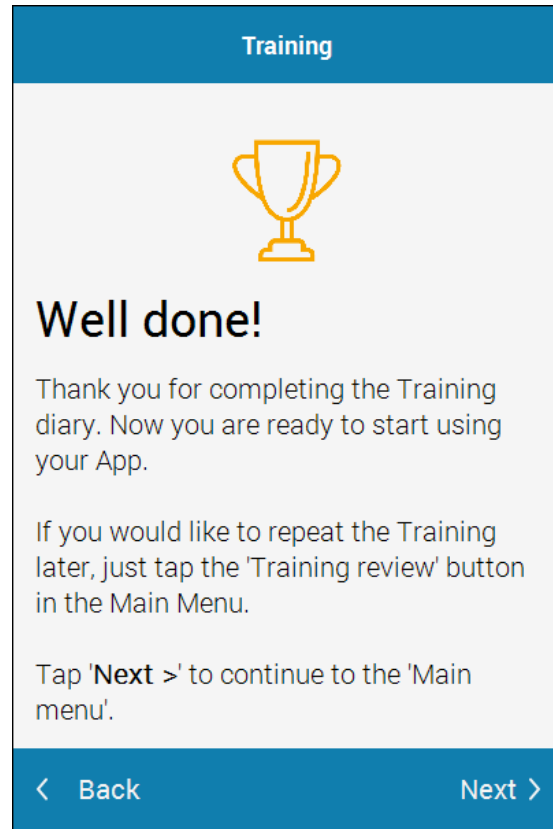
Message 1



Screen 10

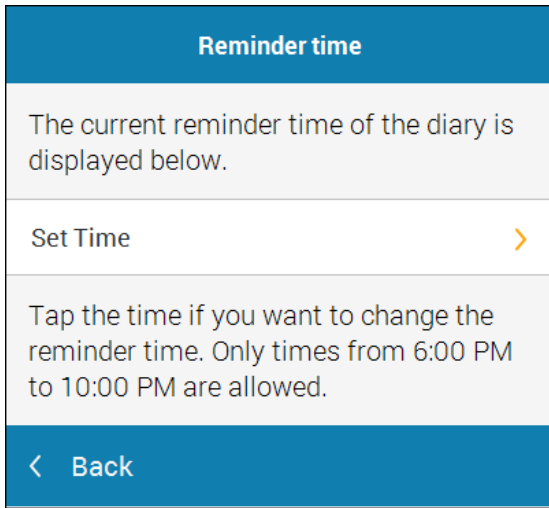


Screen 11

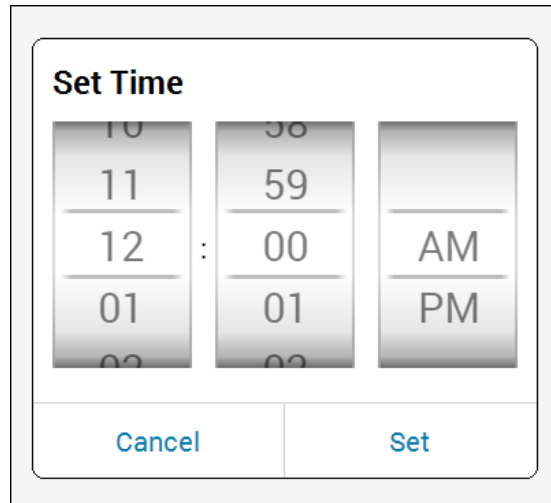


Screen 12

7 Form: Settings



Screen 1



Popup input 1

8 Form: Security question

Security question

Choose your security question. The answer should have only two digits. Your question and answer will be needed if you forget your PIN.

[Computed]

[Computed]

[Computed]

[Computed]

[Computed]

[Computed]

[Computed]

[Computed]

Then tap the 'Next >' button

< Back Next >

Screen 1

Info

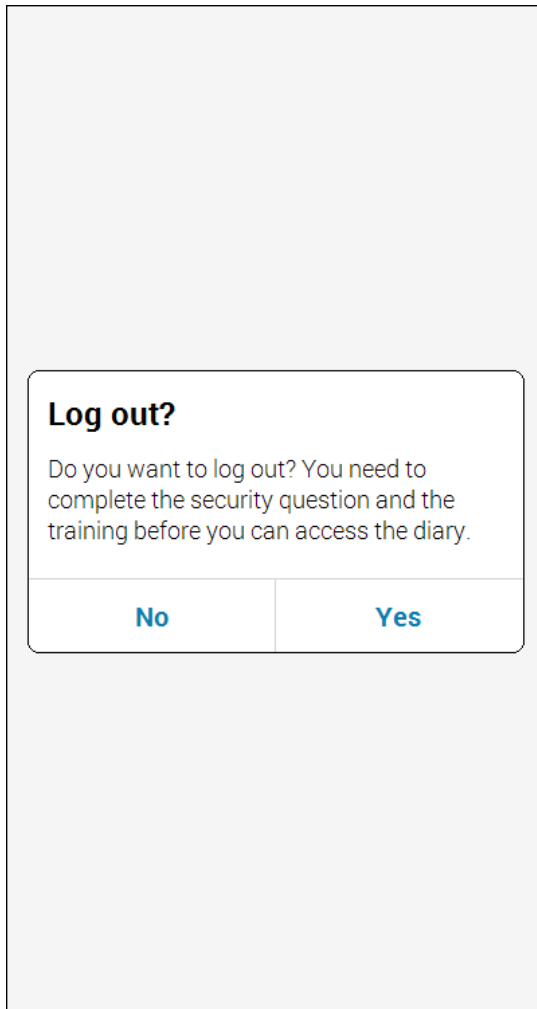
Please select a suitable question.

OK

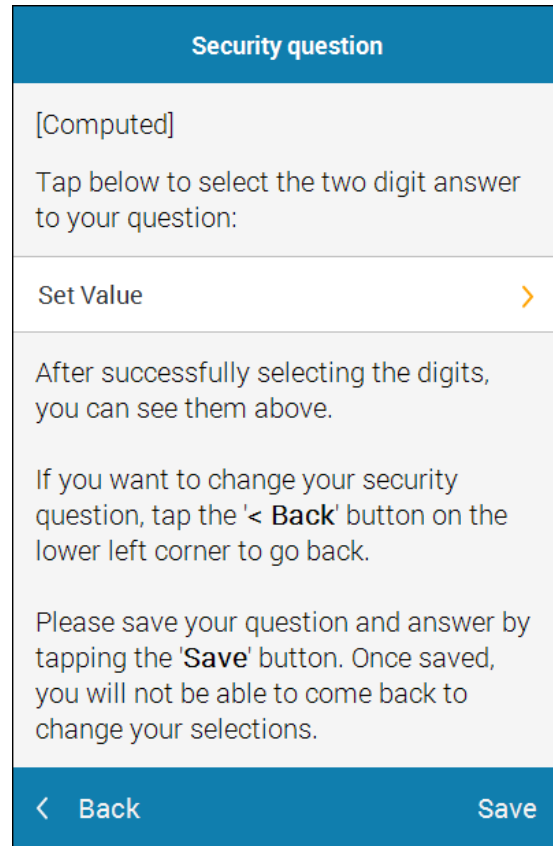
Message 1

[Computed] will show one of the following:

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



Message 2



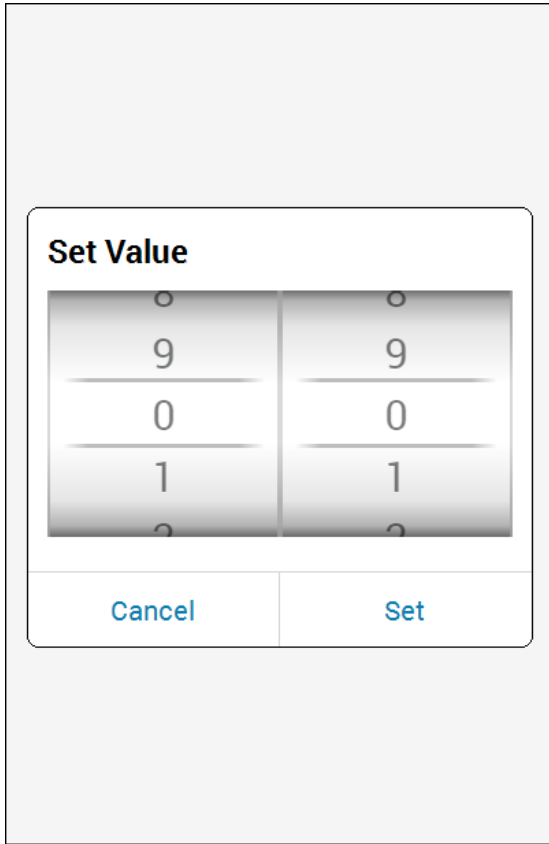
Screen 2

[Computed] will display

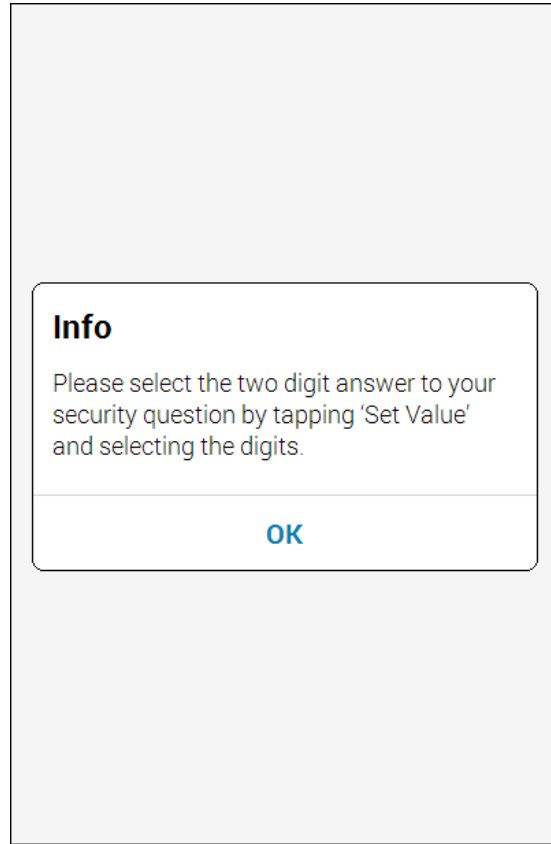
'Your question:

<i>{1}</i>'

{1} will show the question selected on Screen 1



Popup input 1



Message 1

A-1426-0082 / C4591001

App Subject Facing Screen Report

Localized texts are displayed in English (US).

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- 5 Form: Subject training diary..... 42
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- 7 Form: Security question 50

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

Month	January	February	March	April	May	June	July	August	September	October	November	December
Abbr.	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Days	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday					
Abbr.	Mon	Tue	Wed	Thu	Fri	Sat	Sun					

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

1 Notifications / Subject card

Email notification/Subject card to provisioned device subjects:

Welcome to the C4591001 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)

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)

SMS Body for BYOD subjects:

Welcome to the C4591001 Study! To install the TrialMax App, select the link:

[Link]

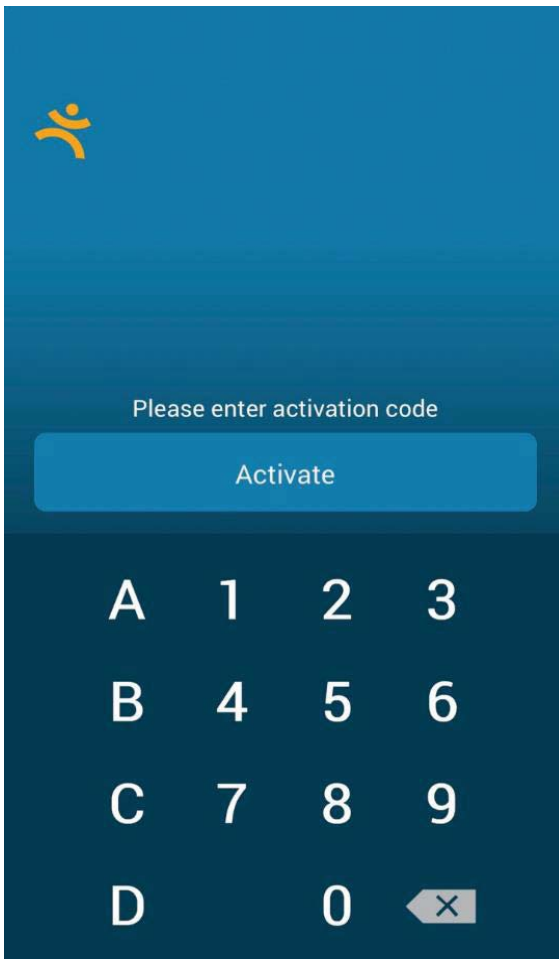
Activate the TrialMax App with code:

[Activation Code]

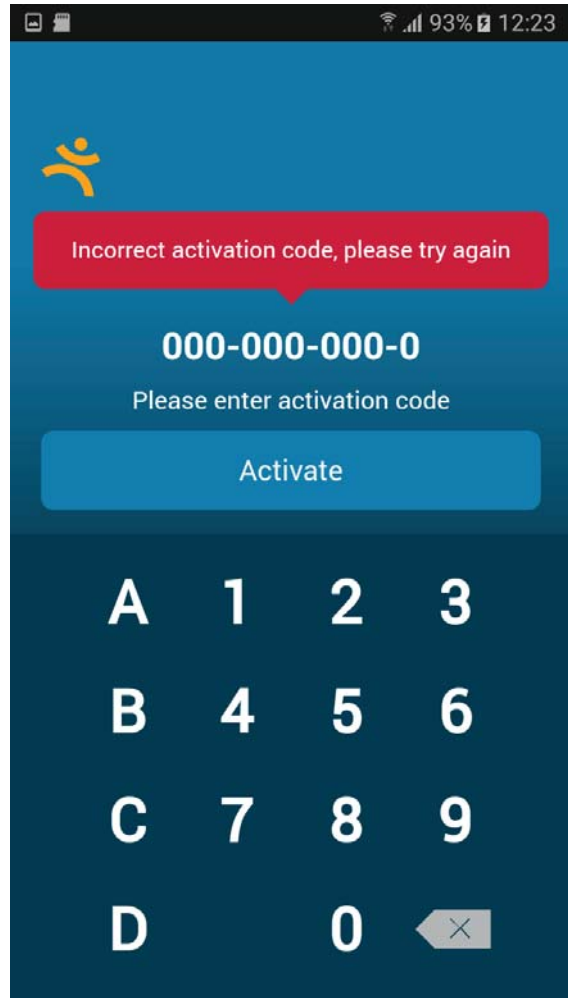
App notification:

Please fill in your vaccination diary!

2 Common



Screen 1

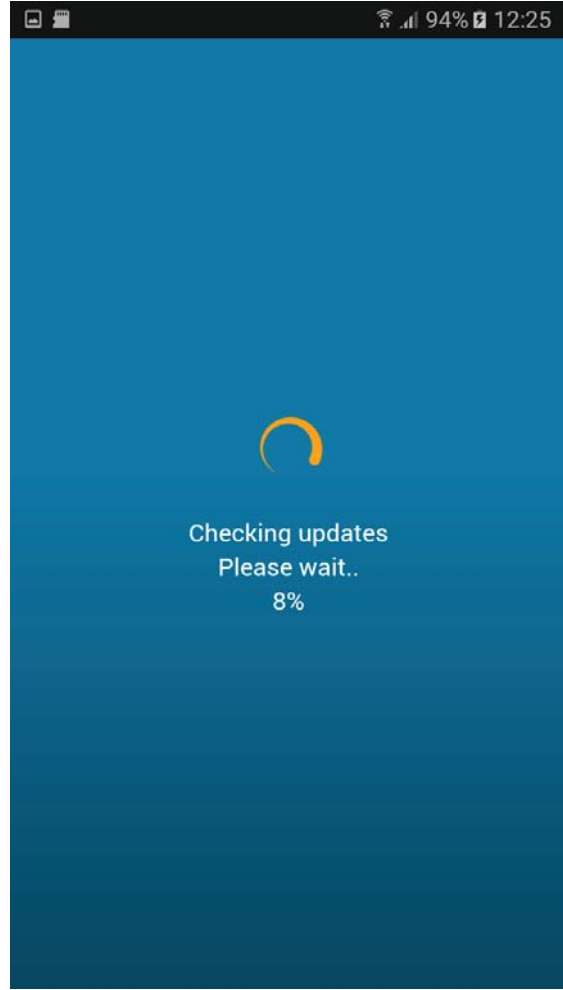


Screen 2

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

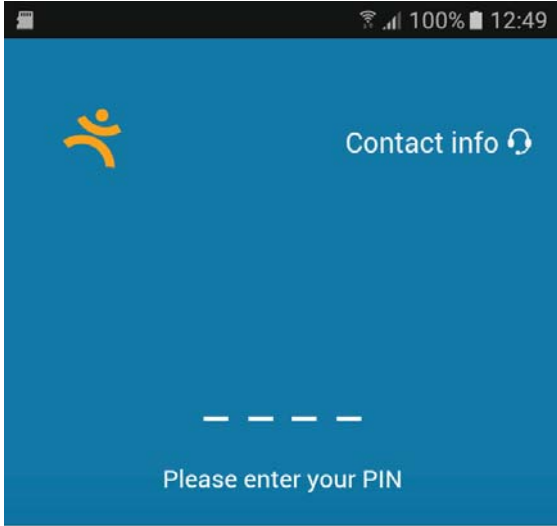


Screen 3

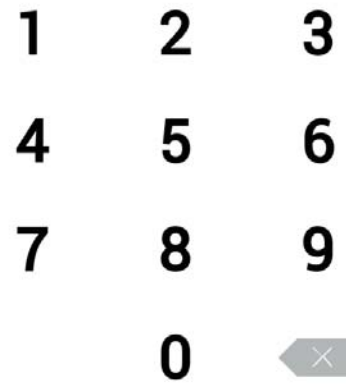
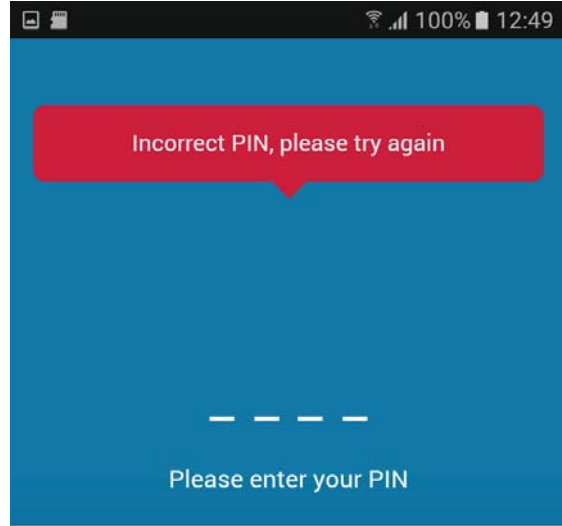


Screen 4

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

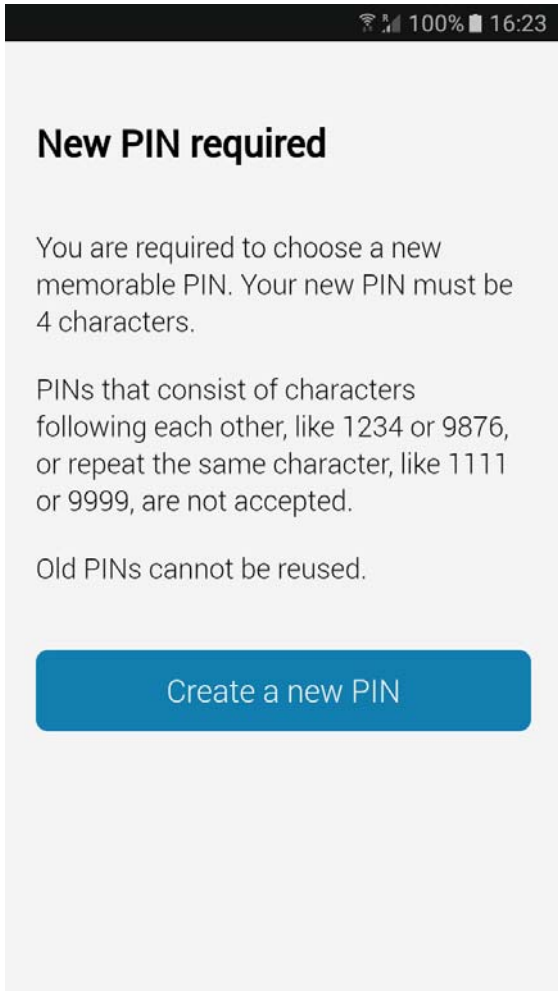


Screen 5

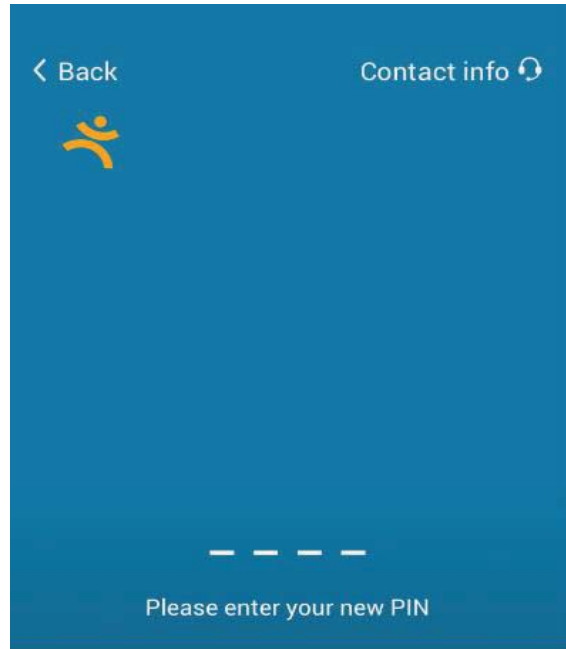


Screen 6

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

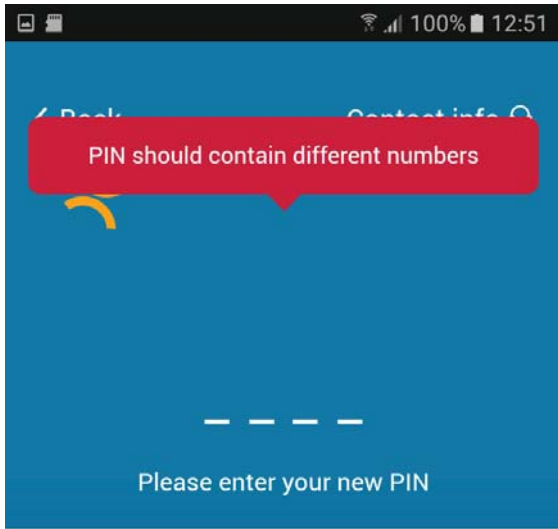


Screen 7

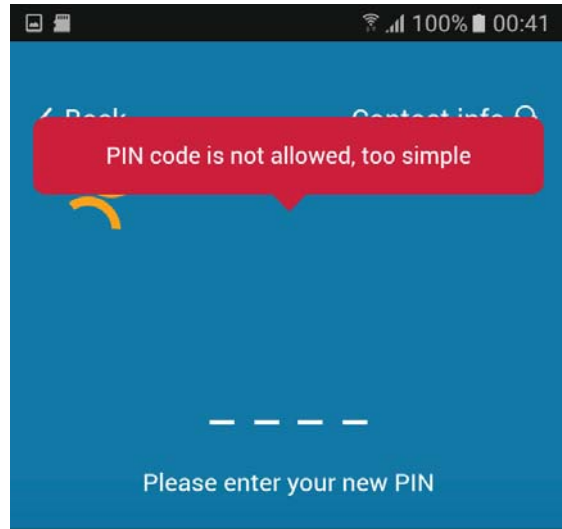


Screen 8

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

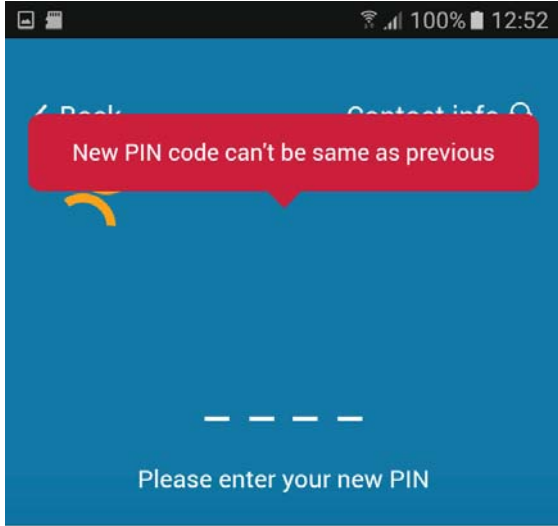


Screen 9

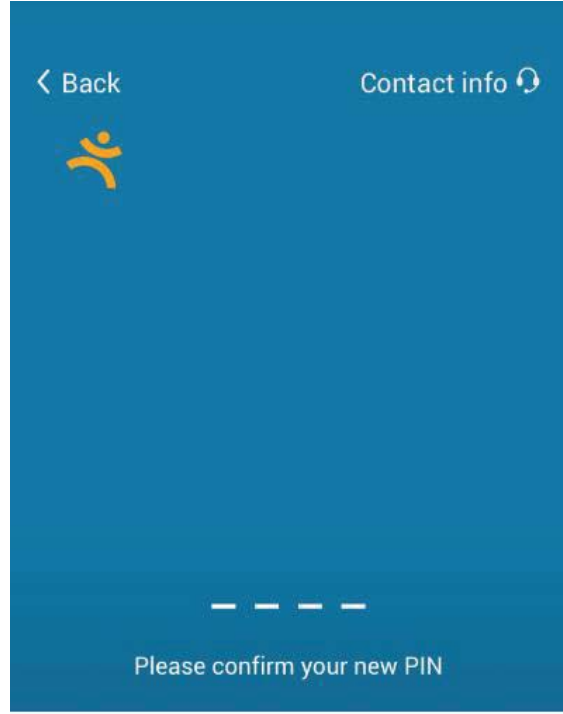


Screen 10

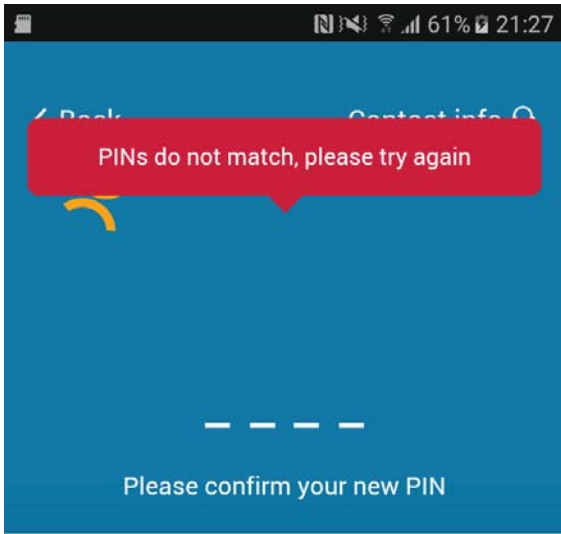
090177e194d02327\Approved\Approved On: 02-Sep-2020 17:58 (GMT)



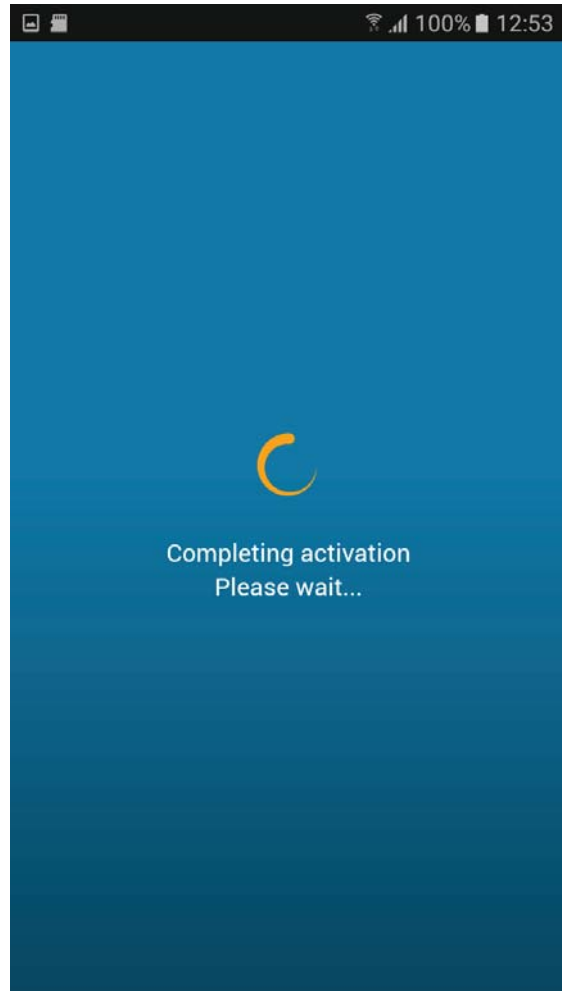
Screen 11



Screen 12

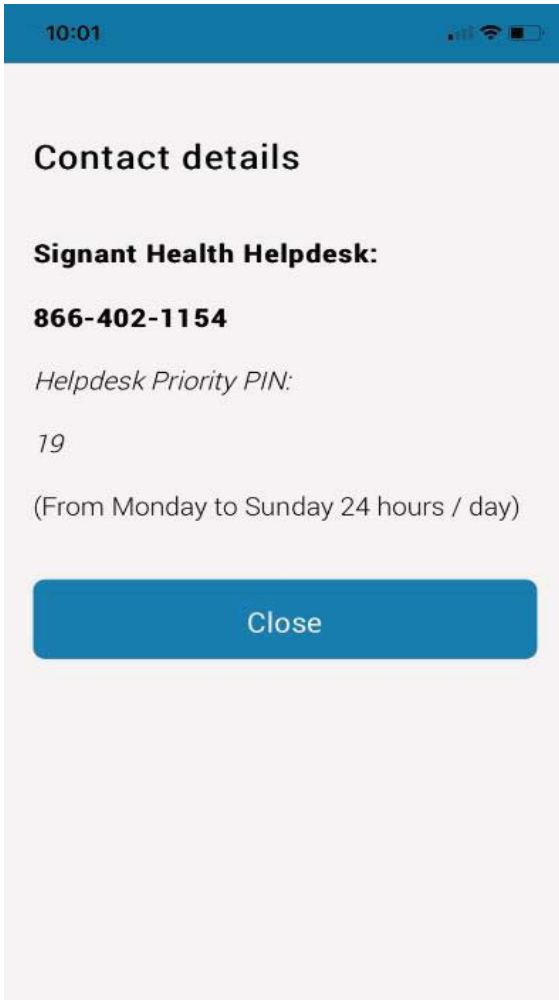


Screen 13

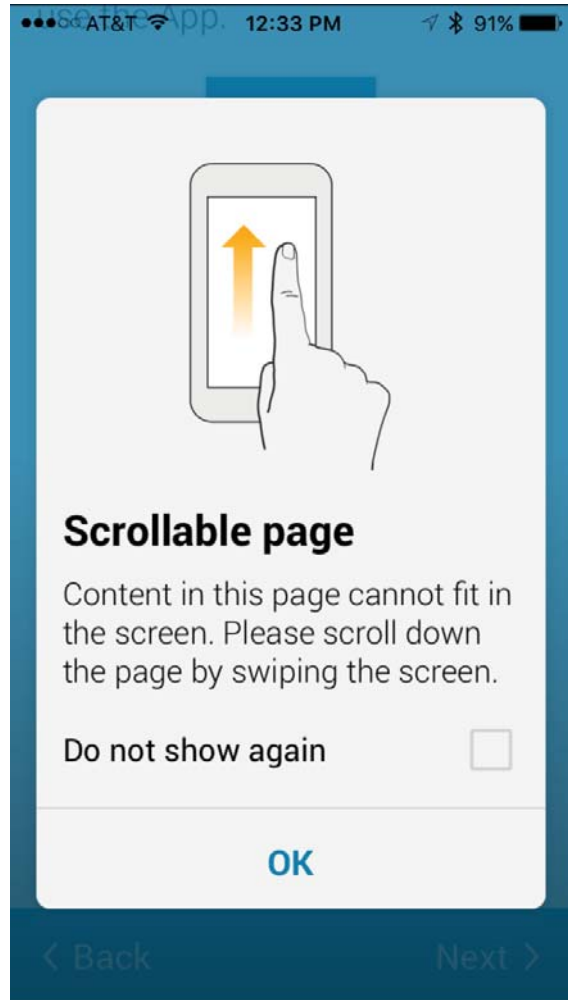


Screen 14

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

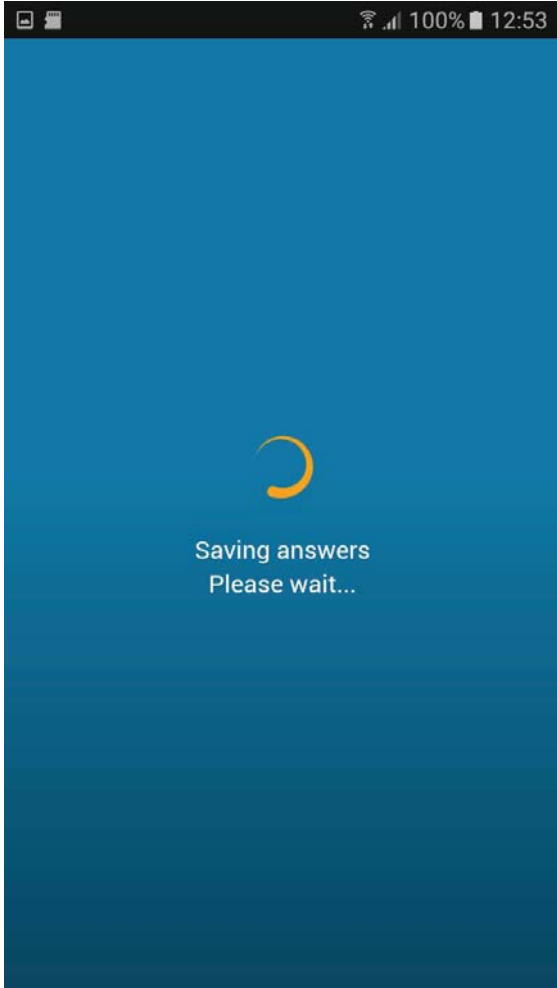


Screen 15

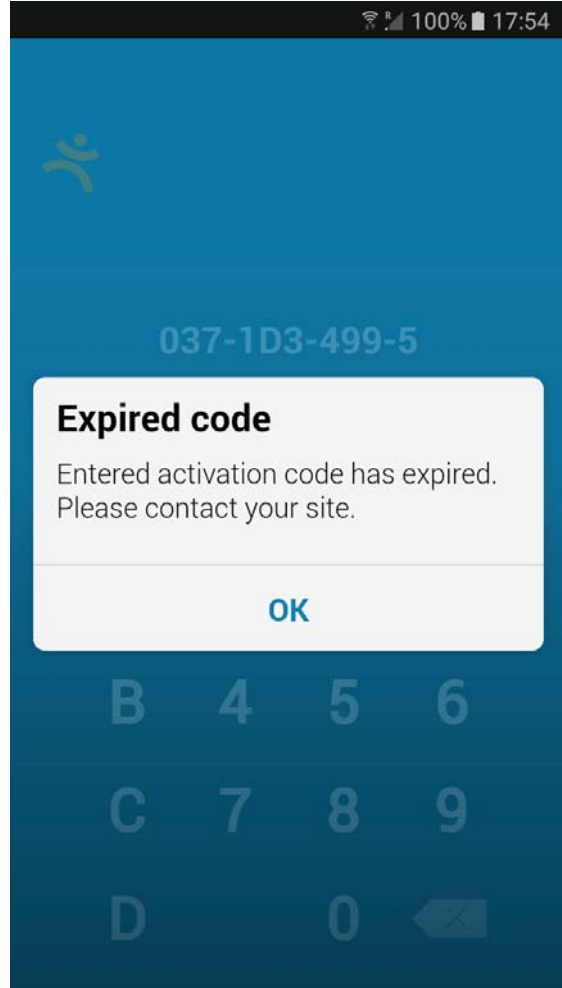


Screen 16

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

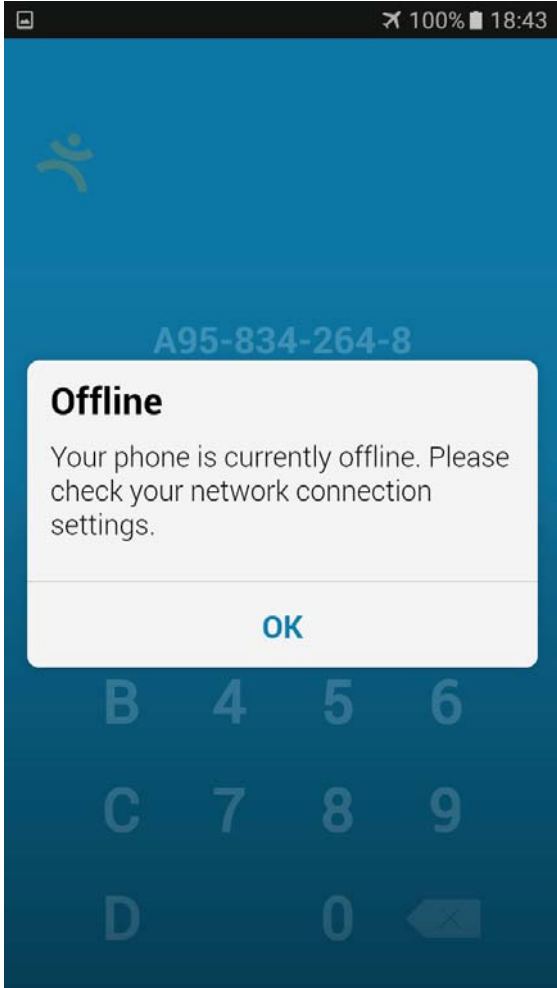


Screen 17

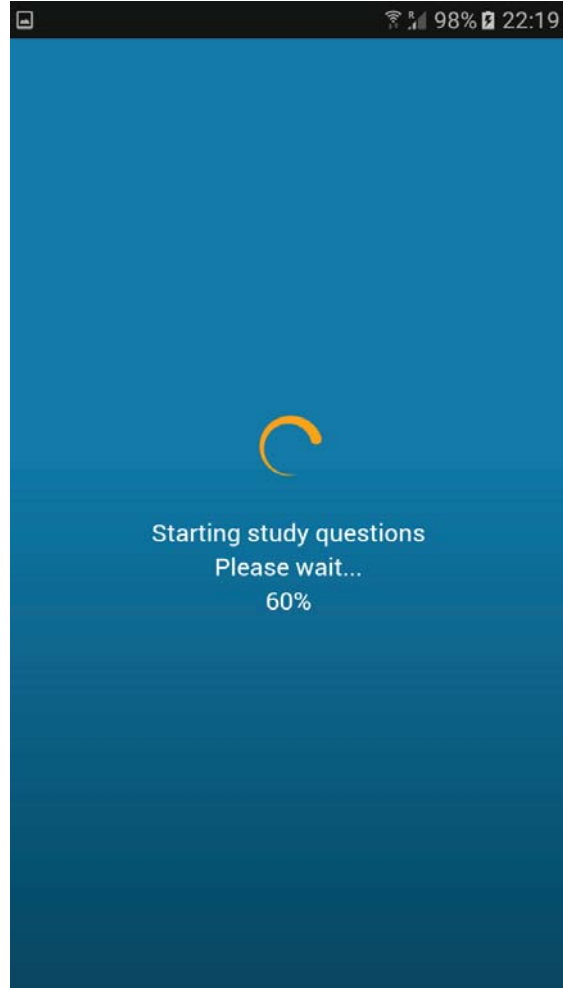


Screen 18

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

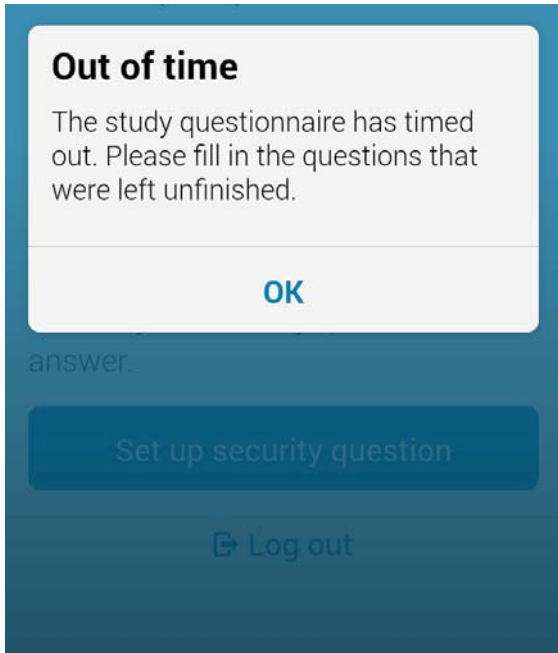


Screen 19

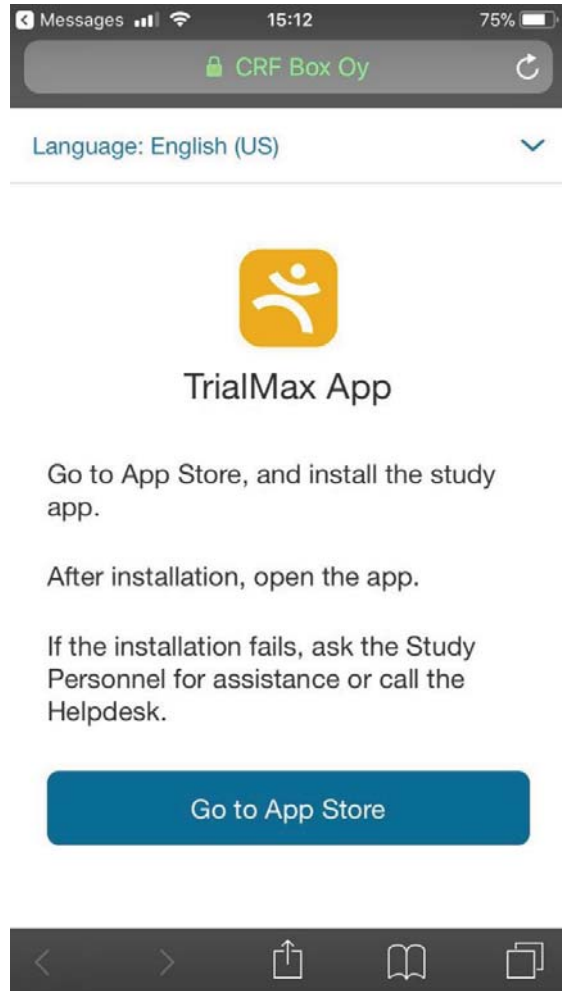


Screen 20

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

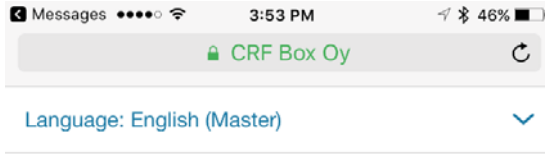


Screen 21



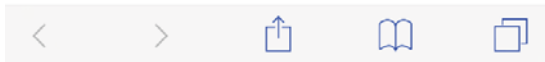
Screen 22

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

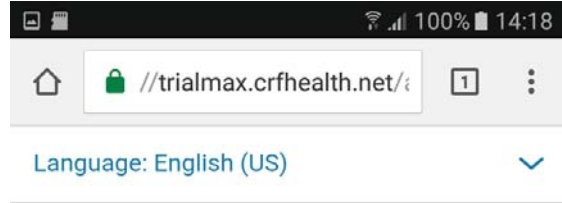


Unfortunately this device cannot run the study app.

Please inform the Study Personnel / contact your site.



Screen 23



TrialMax App

Go to Play Store, and install the study app.

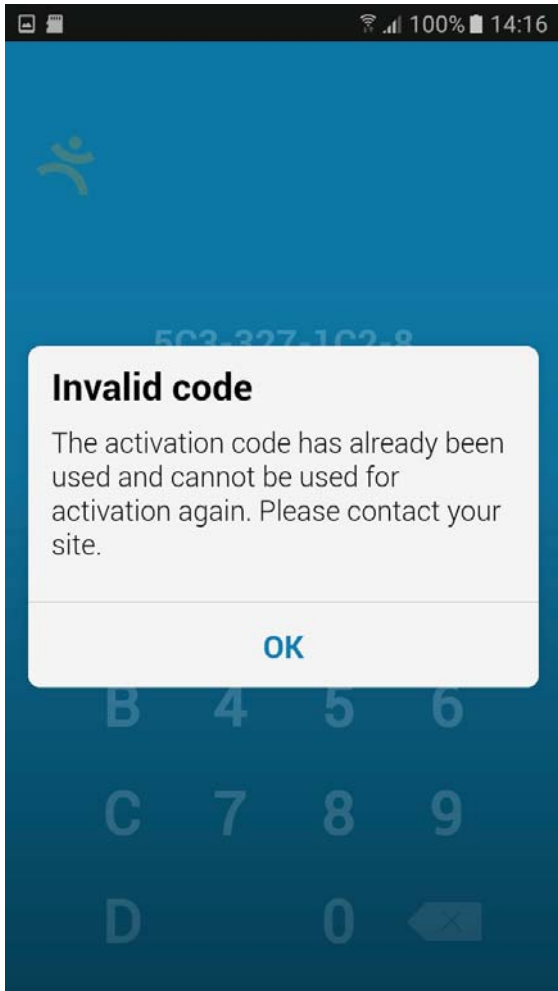
After installation, open the app.

If the installation fails, ask the Study Personnel for assistance or call the Helpdesk.

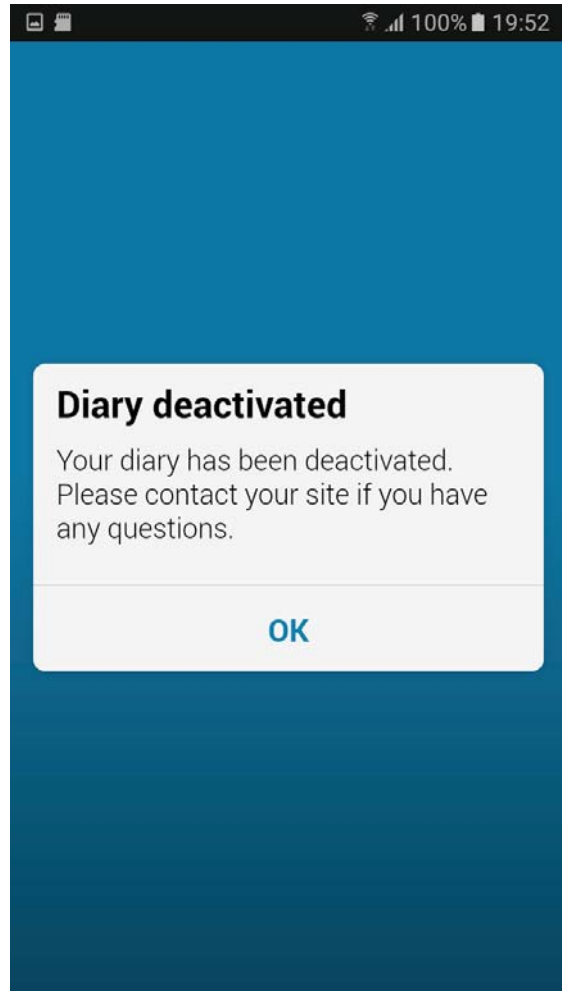


Screen 24

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

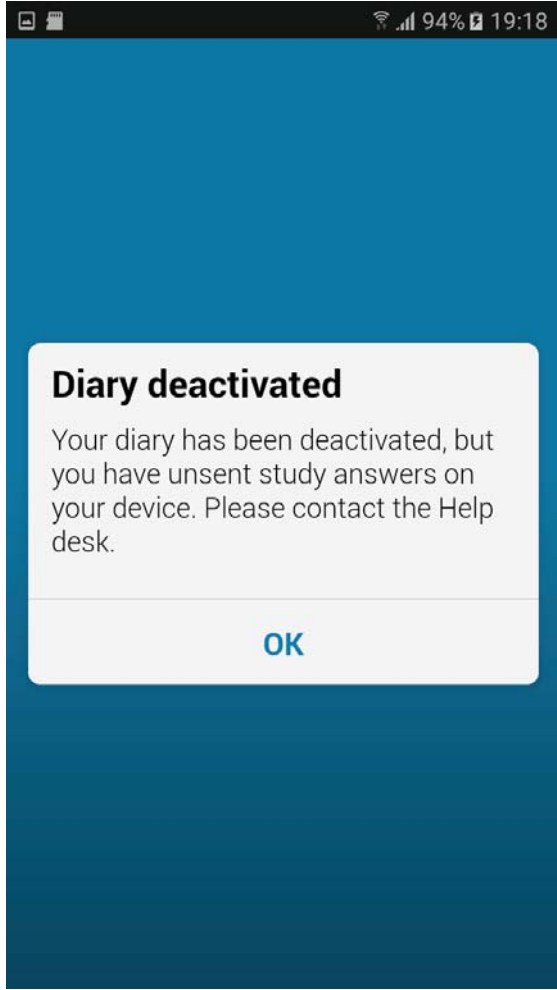


Screen 25



Screen 26

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

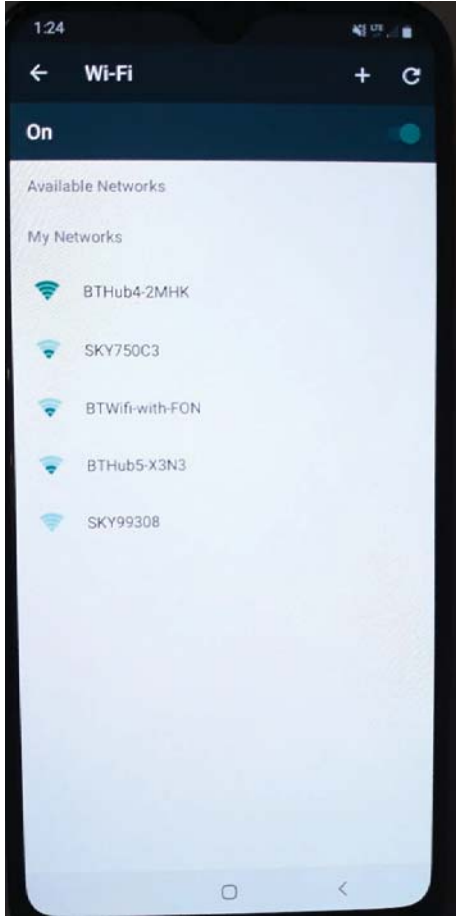


Screen 27

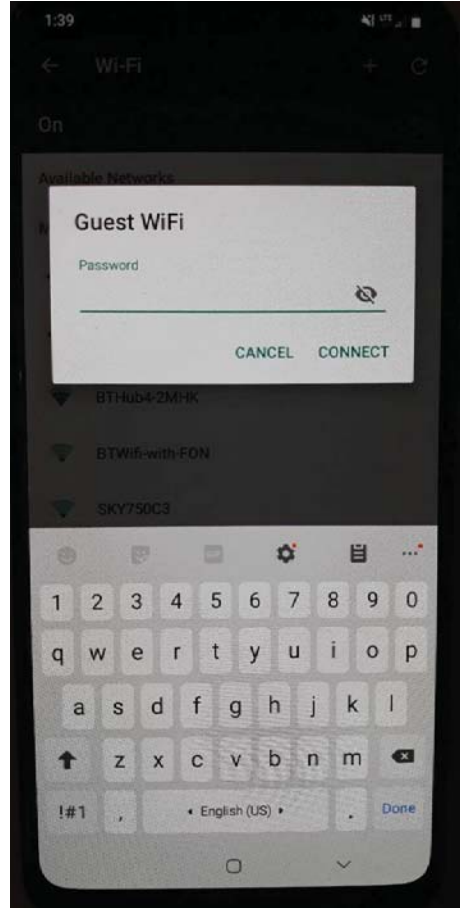


Screen 28

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

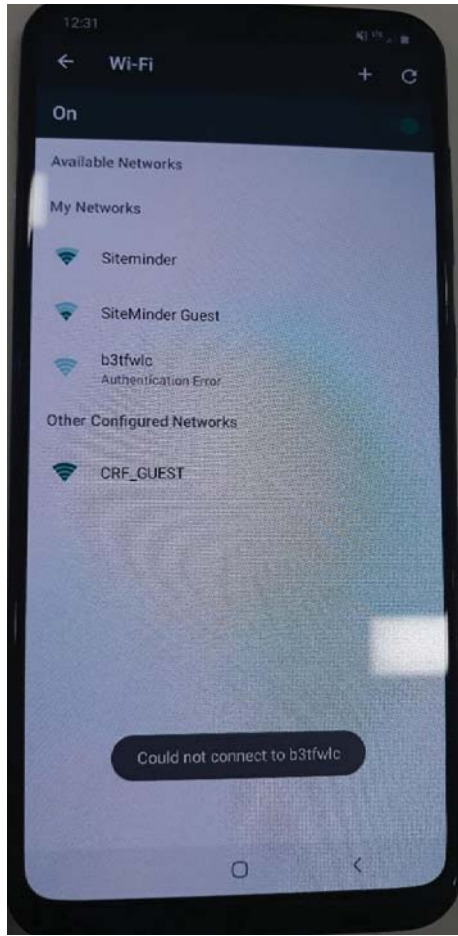


Screen 29

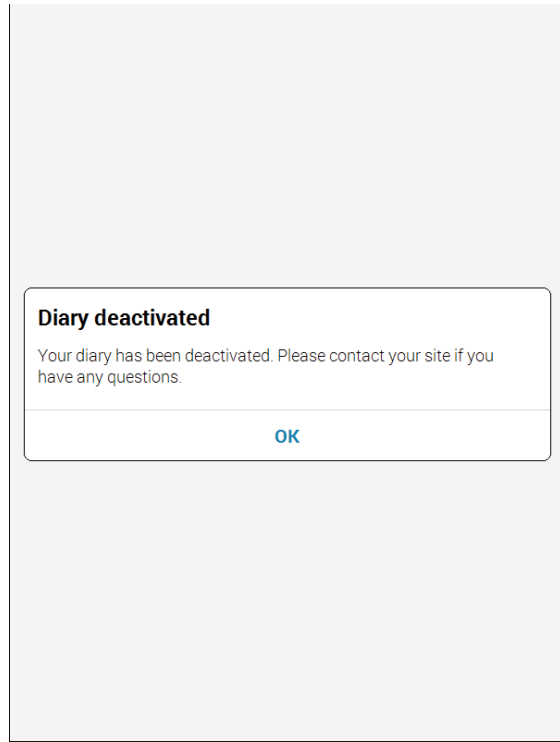


Screen 30

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



Screen 31



Message 1

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

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

'Invalid PIN'

'Installing study questions'

'Securing study questions'

'Unsent answers'

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

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

'Oops!'

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

'Unsuccessful sending'

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

'Study ended'

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

'Updating'

'System is updating, please try again later.'

'Connection error'

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

'Time out'

'Please check your Internet connection and try again.'

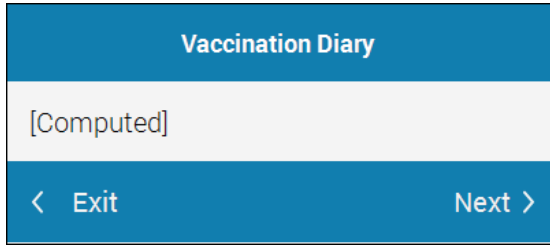
'Low storage space'

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

'Error'

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

3 Form: Vaccination Diary



Screen 1



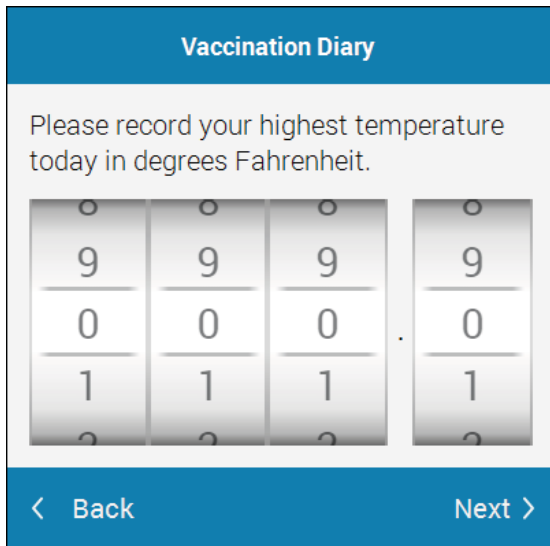
Message 1

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

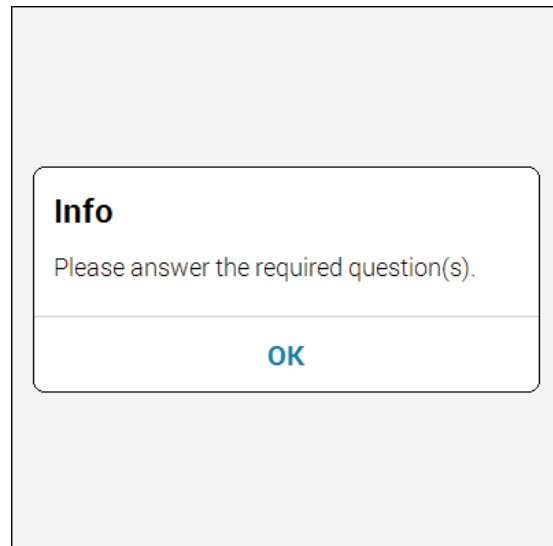
{1} Will display a date

{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).

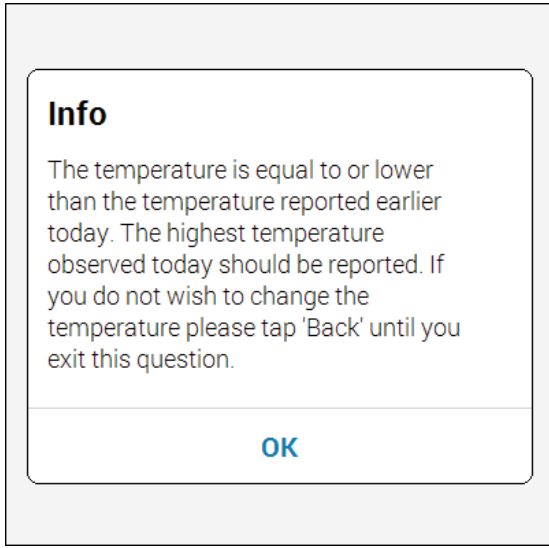


Screen 2

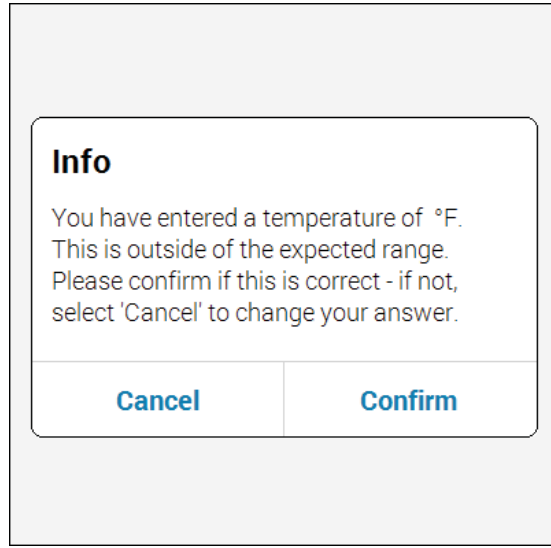


Message 1

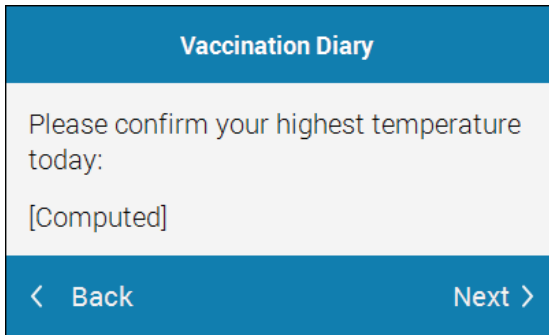
090177e194d02327\Approved\Approved On: 02-Sep-2020 17:58 (GMT)



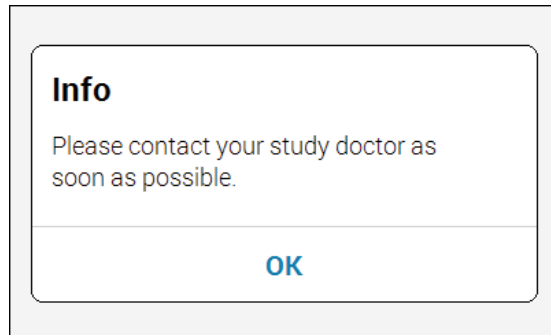
Message 2



Message 3

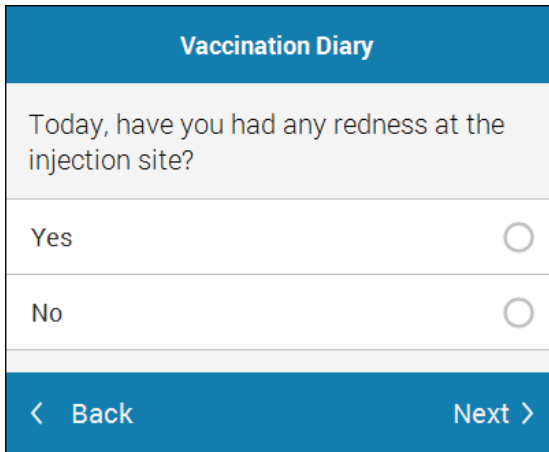


Screen 3

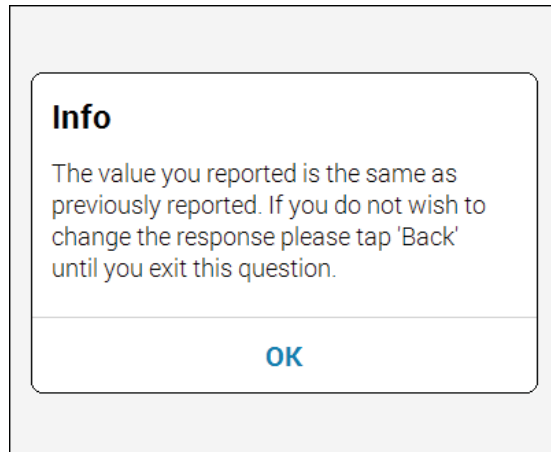


Message 1

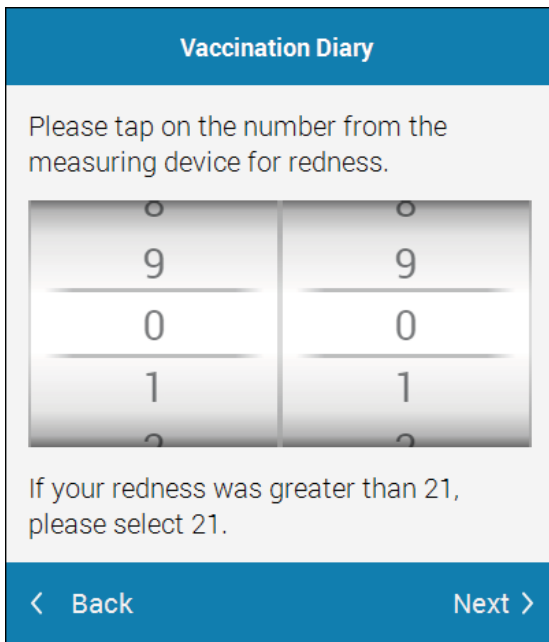
[Computed] will display the temperature selected on Screen 2.



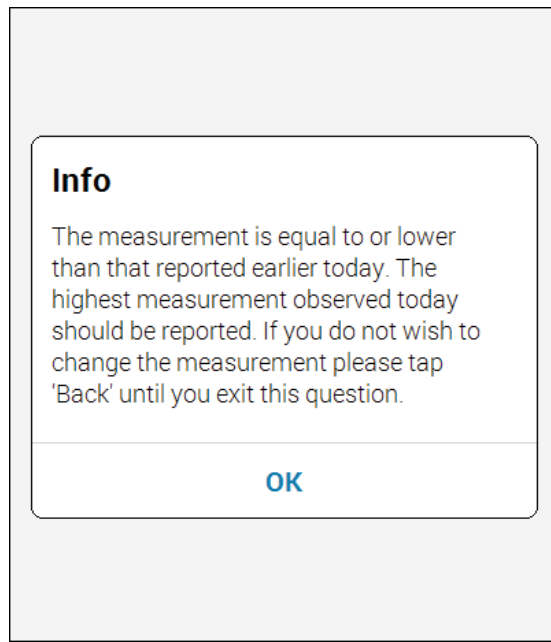
Screen 4



Message 2



Screen 5



Message 2

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

Vaccination Diary

Please confirm the number from the measuring device for redness:

[Computed]

< Back Next >

Screen 6

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

Vaccination Diary

Today, have you had any swelling at the injection site?

Yes

No

< Back Next >

Screen 7

Vaccination Diary

Please select the number from the measuring device for swelling.

9	9
0	0
1	1

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

< Back Next >

Screen 8

Vaccination Diary

Please confirm the number from the measuring device for swelling:

[Computed]

< Back Next >

Screen 9

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

Vaccination Diary	
Today, have you had any pain at the injection site?	
Yes	<input type="radio"/>
No	<input type="radio"/>
< Back Next >	

Screen 10

Vaccination Diary	
Pain at the injection site definitions:	
Mild = Does not interfere with activity	
Moderate = Interferes with activity	
Severe = Prevents daily activity	
< Back Next >	

Screen 11

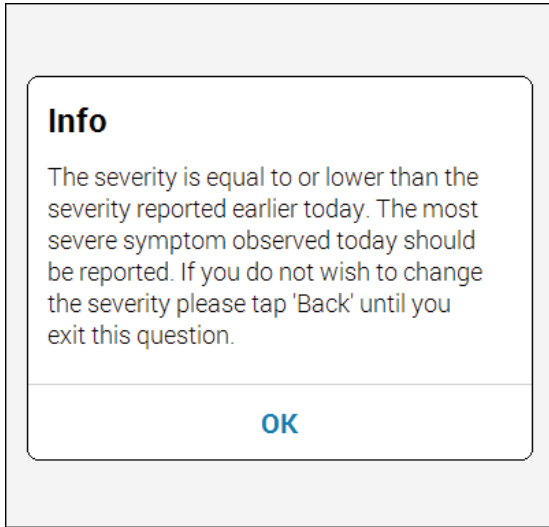
Vaccination Diary	
Please indicate whether the pain at the injection site was:	
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
< Back Next >	

Screen 12

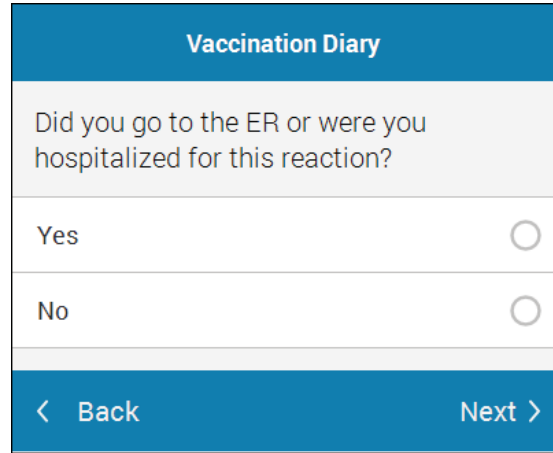
<p>Info</p> <p>Severe = Prevents daily activity. If this is correct tap 'Yes' to go forward or 'No' to change your answer.</p>	
No	Yes

Message 2

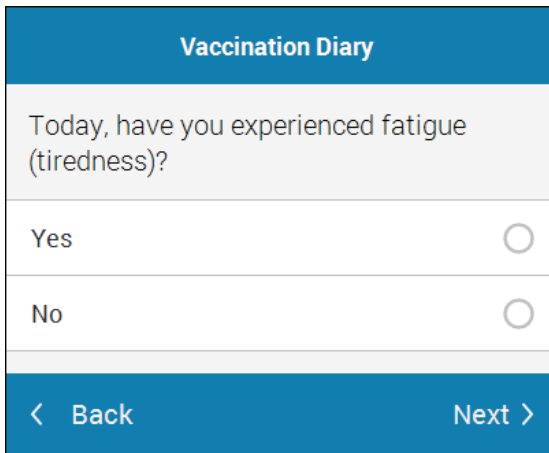
090177e194d02327\Approved\Approved On: 02-Sep-2020 17:58 (GMT)



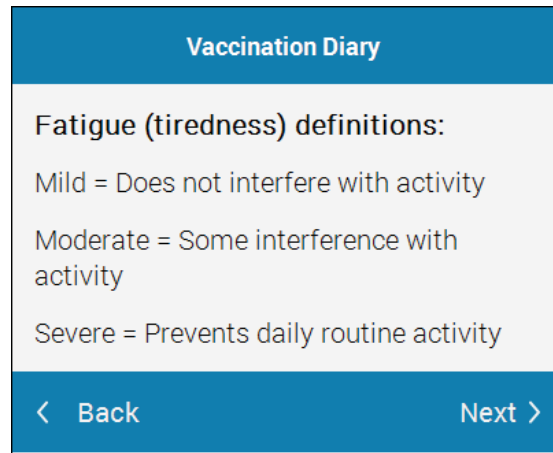
Message 4



Screen 13



Screen 14



Screen 15

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

Vaccination Diary	
Please indicate whether the fatigue (tiredness) was:	
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
< Back Next >	

Screen 16

Info

Severe = Prevents daily routine activity. If this is correct tap 'Yes' to go forward or 'No' to change your answer.

[No](#) [Yes](#)

Message 2

Vaccination Diary	
Did you go to the ER or were you hospitalized for this reaction?	
Yes	<input type="radio"/>
No	<input type="radio"/>
< Back Next >	

Screen 17

Vaccination Diary	
Today, have you experienced headache?	
Yes	<input type="radio"/>
No	<input type="radio"/>
< Back Next >	

Screen 18

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

Vaccination Diary	
Headache definitions:	
Mild = Does not interfere with activity	
Moderate = Some interference with activity	
Severe = Prevents daily routine activity	
< Back	Next >

Screen 19

Vaccination Diary	
Please indicate whether the headache was:	
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
< Back	Next >

Screen 20

Vaccination Diary	
Did you go to the ER or were you hospitalized for this reaction?	
Yes	<input type="radio"/>
No	<input type="radio"/>
< Back	Next >

Screen 21

Vaccination Diary	
Today, have you experienced vomiting?	
Yes	<input type="radio"/>
No	<input type="radio"/>
< Back	Next >

Screen 23

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

Vaccination Diary	
Vomiting definitions:	
Mild = 1 to 2 times in 24 hours	
Moderate = More than twice in 24 hours	
Severe = Requires intravenous hydration	
< Back	Next >

Screen 23

Vaccination Diary	
Please indicate whether the vomiting was:	
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
< Back	Next >

Screen 24

<p>Info</p> <p>Severe = Requires intravenous hydration. If this is correct tap 'Yes' to go forward or 'No' to change your answer.</p>	
No	Yes

Message 2

Vaccination Diary	
Did you go to the ER or were you hospitalized for this reaction?	
Yes	<input type="radio"/>
No	<input type="radio"/>
< Back	Next >

Screen 25

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

Vaccination Diary

Today, have you experienced diarrhea?

Yes

No

< Back Next >

Screen 26

Vaccination Diary

Diarrhea definitions:

Mild = 2 to 3 loose stools in 24 hours

Moderate = 4 to 5 loose stools in 24 hours

Severe = 6 or more loose stools in 24 hours

< Back Next >

Screen 27

Vaccination Diary

Please indicate whether the diarrhea was:

Mild

Moderate

Severe

< Back Next >

Screen 28

Info

Severe = 6 or more loose stools in 24 hours. If this is correct tap 'Yes' to go forward or 'No' to change your answer.

No Yes

Message 2

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

Vaccination Diary	
Did you go to the ER or were you hospitalized for this reaction?	
Yes	<input type="radio"/>
No	<input type="radio"/>
< Back Next >	

Screen 29

Vaccination Diary	
Today, have you experienced chills?	
Yes	<input type="radio"/>
No	<input type="radio"/>
< Back Next >	

Screen 30

Vaccination Diary	
Chills definitions:	
Mild = Does not interfere with activity	
Moderate = Some interference with activity	
Severe = Prevents daily routine activity	
< Back Next >	

Screen 31

Vaccination Diary	
Please indicate whether the chills were:	
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
< Back Next >	

Screen 32

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

Vaccination Diary	
Did you go to the ER or were you hospitalized for this reaction?	
Yes	<input type="radio"/>
No	<input type="radio"/>
< Back Next >	

Screen 33

Vaccination Diary	
Today, have you had new or worsened muscle pain (other than at the injection site)?	
Yes	<input type="radio"/>
No	<input type="radio"/>
< Back Next >	

Screen 34

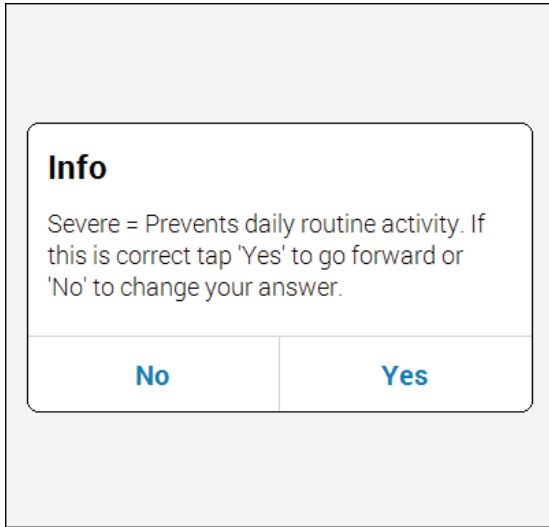
Vaccination Diary	
Muscle pain definitions:	
Mild = No interference with activity	
Moderate = Some interference with activity	
Severe = Prevents daily routine activity	
< Back Next >	

Screen 35

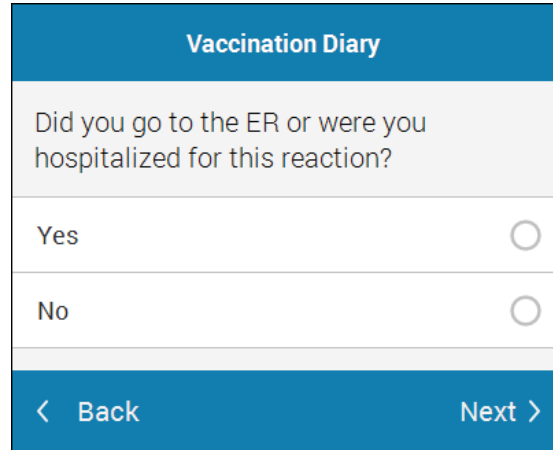
Vaccination Diary	
Please indicate whether the new or worsened muscle pain was:	
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
< Back Next >	

Screen 36

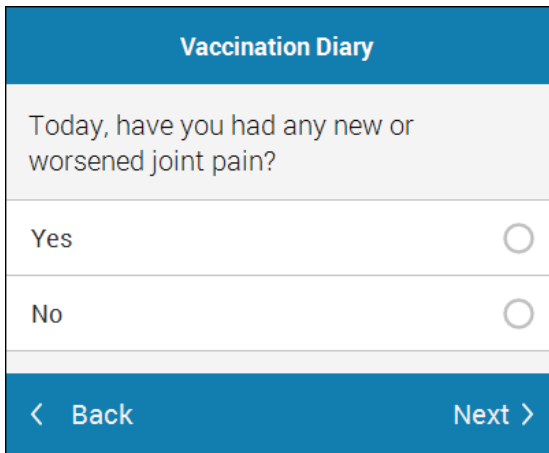
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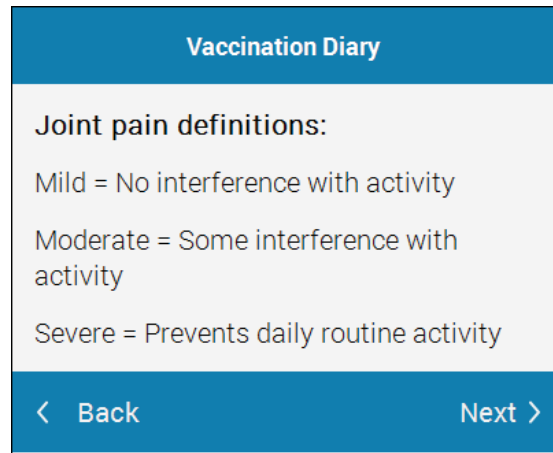
Message 2



Screen 37



Screen 38



Screen 39

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Vaccination Diary	
Please indicate whether the new or worsened joint pain was:	
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
< Back Next >	

Screen 40

Vaccination Diary	
Did you go to the ER or were you hospitalized for this reaction?	
Yes	<input type="radio"/>
No	<input type="radio"/>
< Back Next >	

Screen 41

Vaccination Diary	
Today, have you taken any medication to treat fever or pain?	
Yes	<input type="radio"/>
No	<input type="radio"/>
< Back Next >	

Screen 42

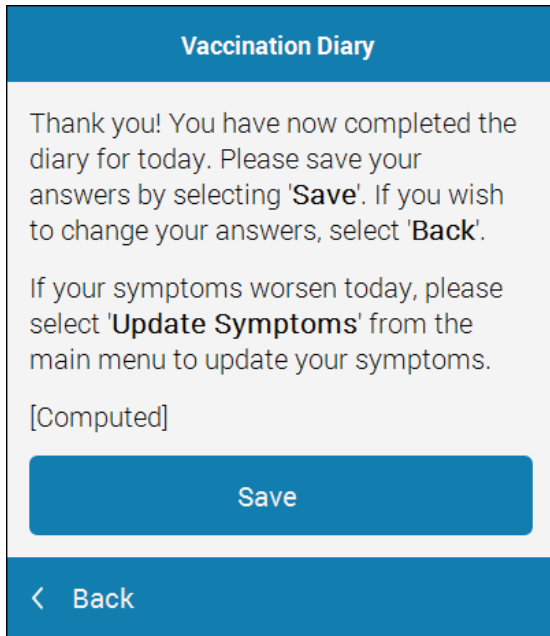
Info

You have reported taking medication to treat fever or pain. Is your answer correct?

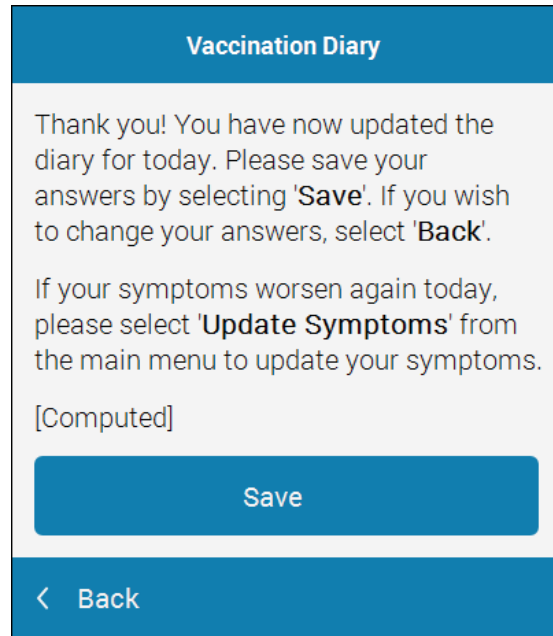
[No](#) [Yes](#)

Message 2

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Screen 43



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).

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

Where {1} = a number of days

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

4 Form: Patient Main Menu

Welcome,


Thank you for taking part in this Study. There are a few things you need to do before you can start filling in your daily diary.

First you need to set up a security question in case you lose your PIN.

Then you will learn how to complete your daily diary using a training diary.

Tap **'Set up security question'** to choose your security question and answer.

Set up security question

 **Log out**

Screen 1

Log out?

Do you want to log out? You need to complete the security question and the training before you can access the daily diary.

No **Yes**


Message 1

Thank you,

Your security question and answer have been saved.

Next, tap **'Go to training diary'** to learn how to complete your daily diary.

Go to training diary

 **Log out**

Screen 2

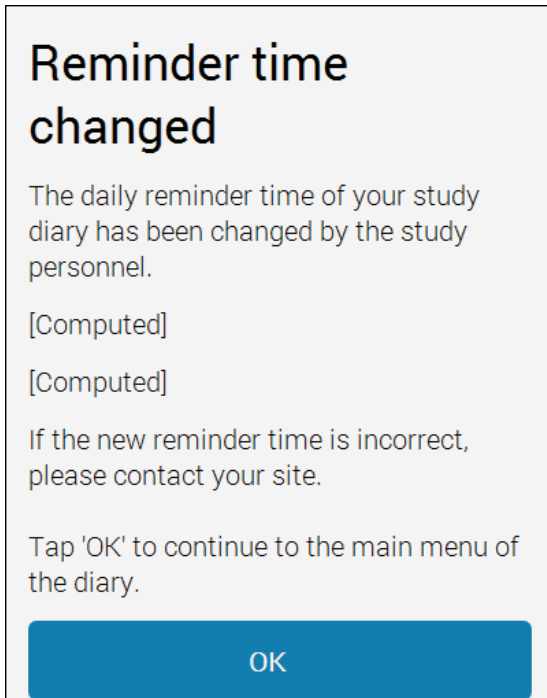
Log out?

Do you want to log out? You need to complete the training before you can access the daily diary.

No **Yes**

Message 1

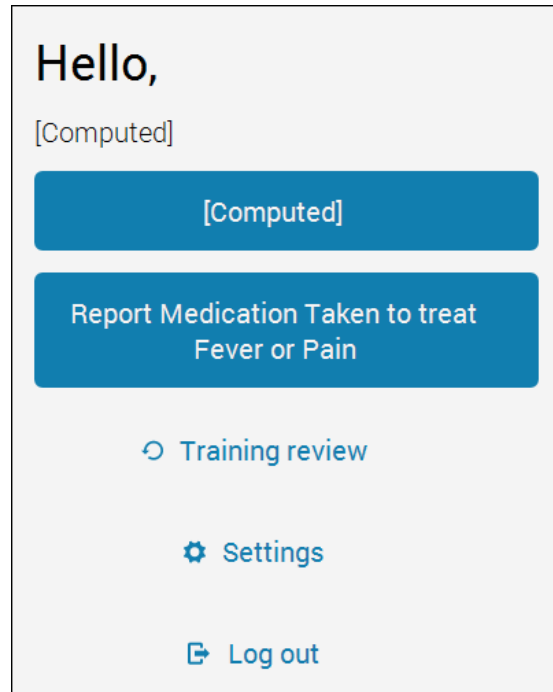
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Screen 3

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

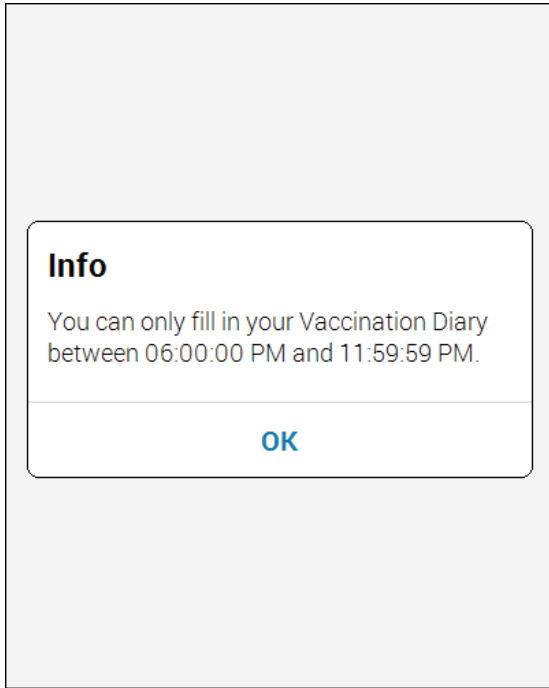
Second [Computed] will show 'New reminder time: {1}' where {1} will be the new reminder time



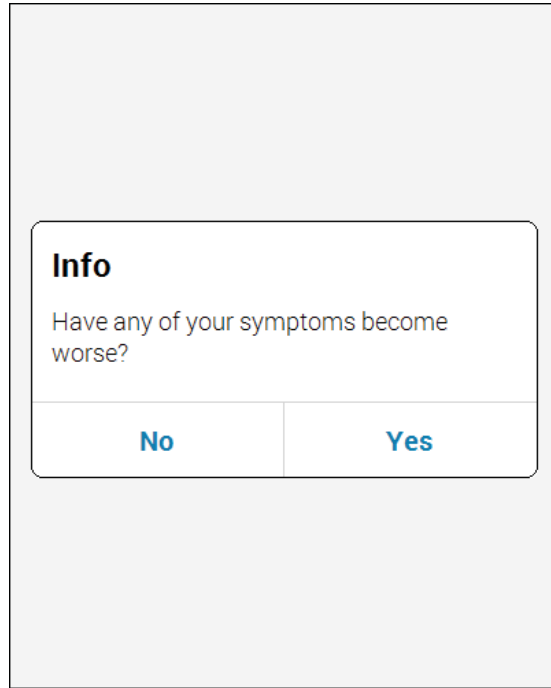
Screen 4

[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

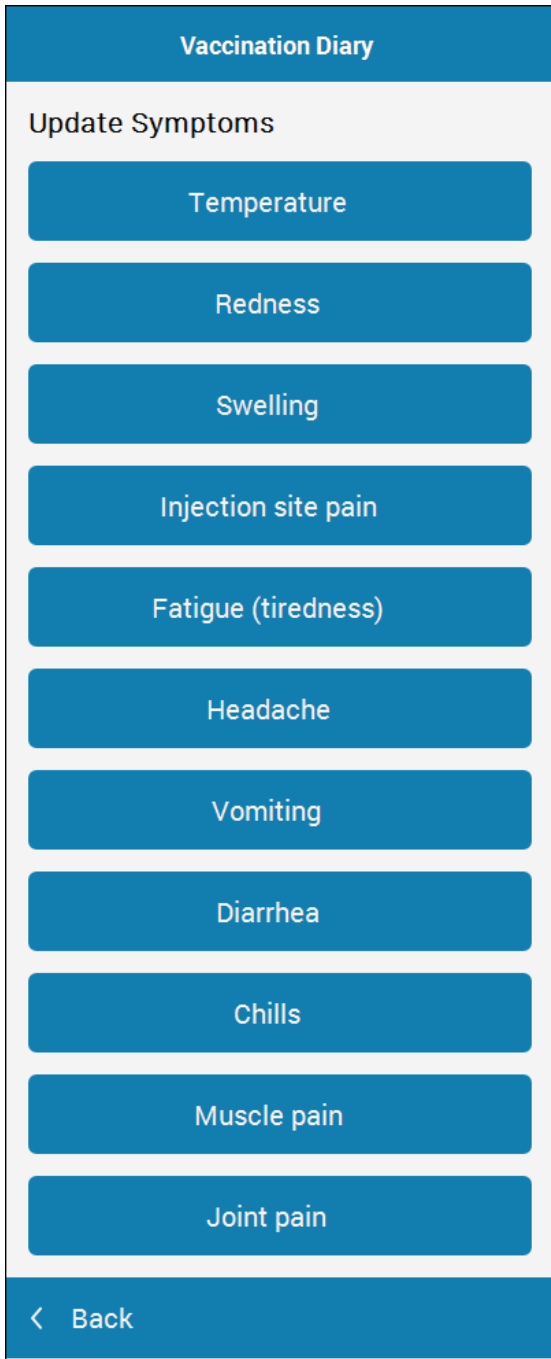


Message 2

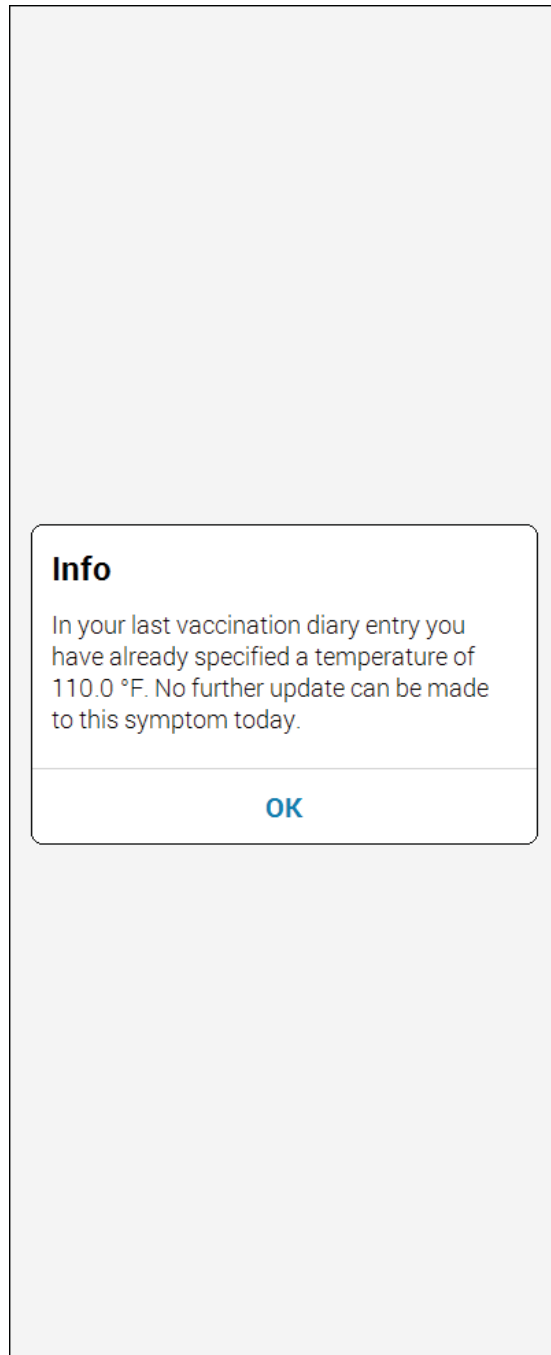
Device text will format out the leading 0's and seconds. Actual popup will read "6:00 PM and 11:59 PM"

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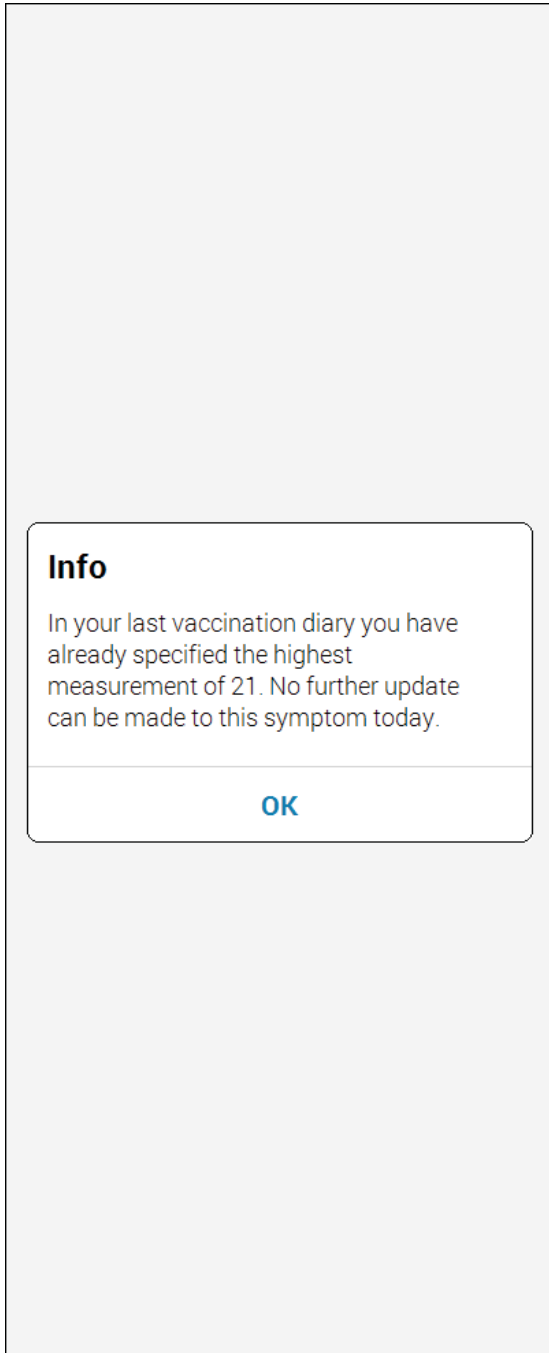


Screen 5

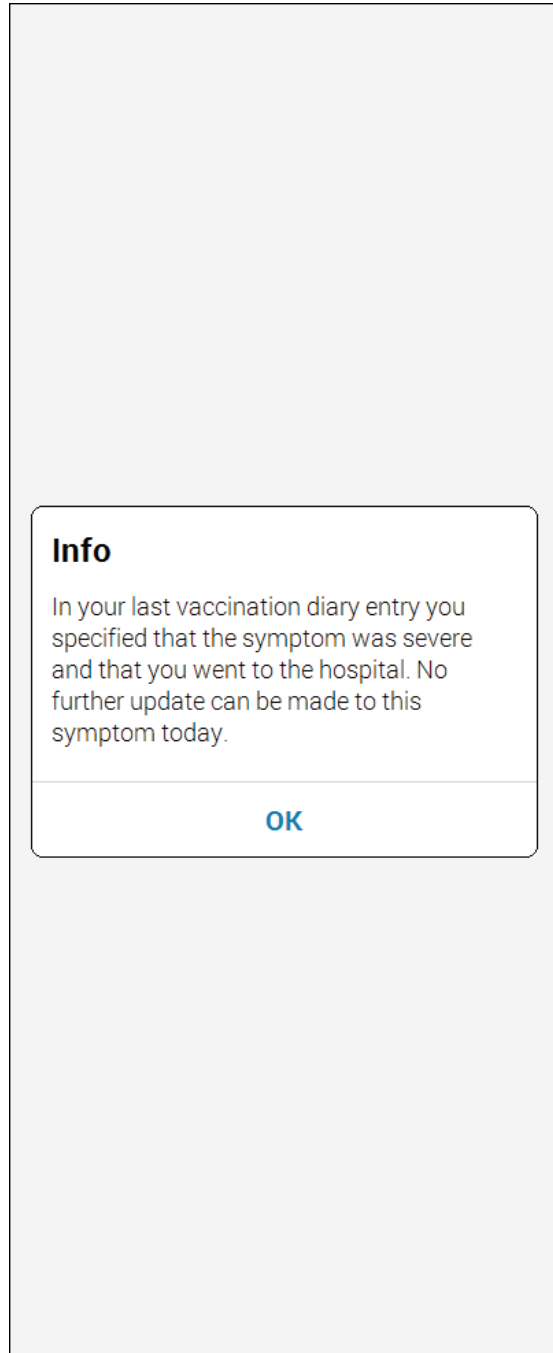


Message 2

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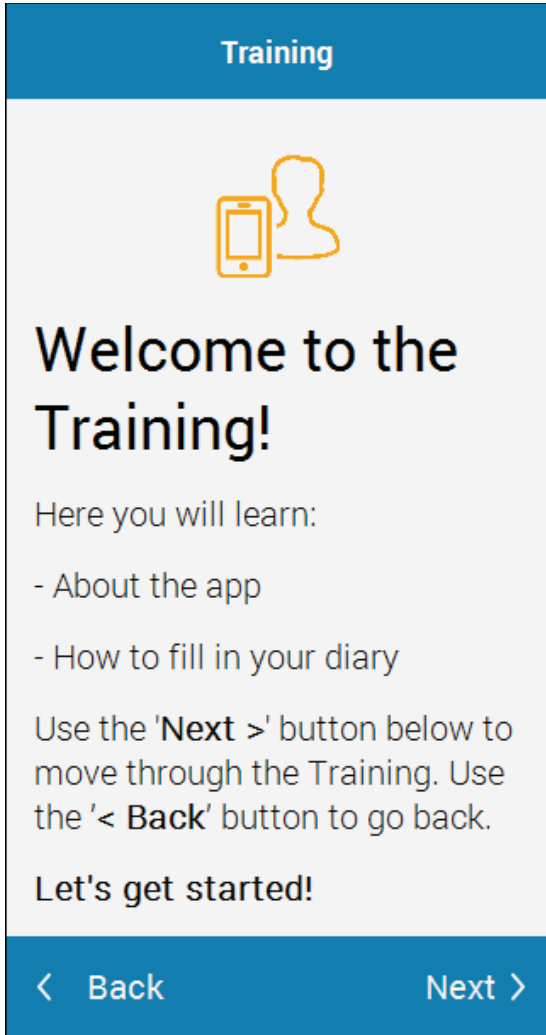


Message 4

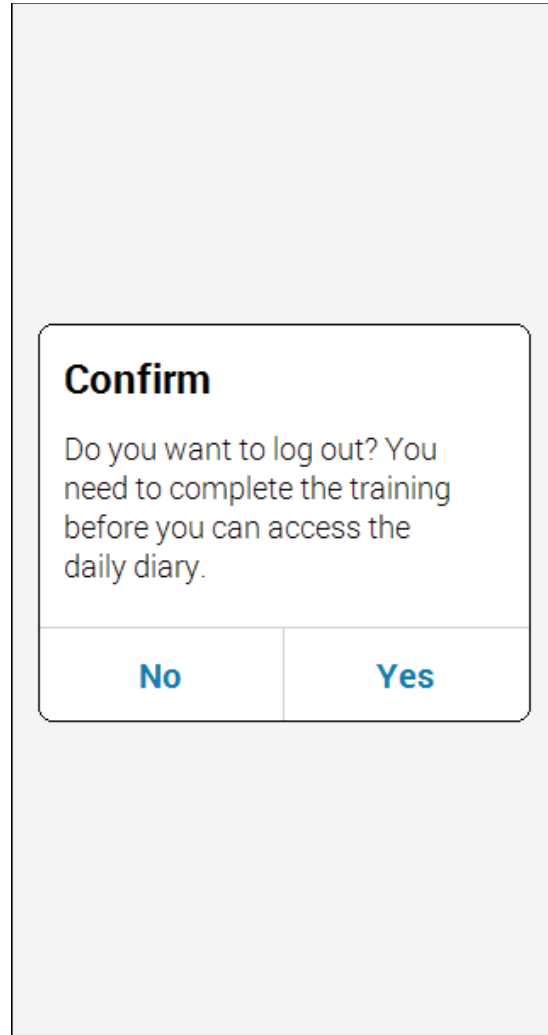


Message 8

5 Form: Subject training diary



Screen 1




Message 1

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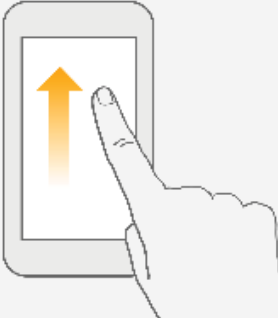
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Training



About scrolling

Some pages have more content than can fit onto one screen. Swipe the screen upwards to scroll to the rest of the page.




You will be shown a pop-up guide whenever the page is scrollable.

Tap **'Next >'** to continue

< Back **Next >**


Screen 2

Training



Logging in with your PIN

You need to log in every time you use the app.



If you forget your PIN, please call the Helpdesk. More information about the Helpdesk will follow.

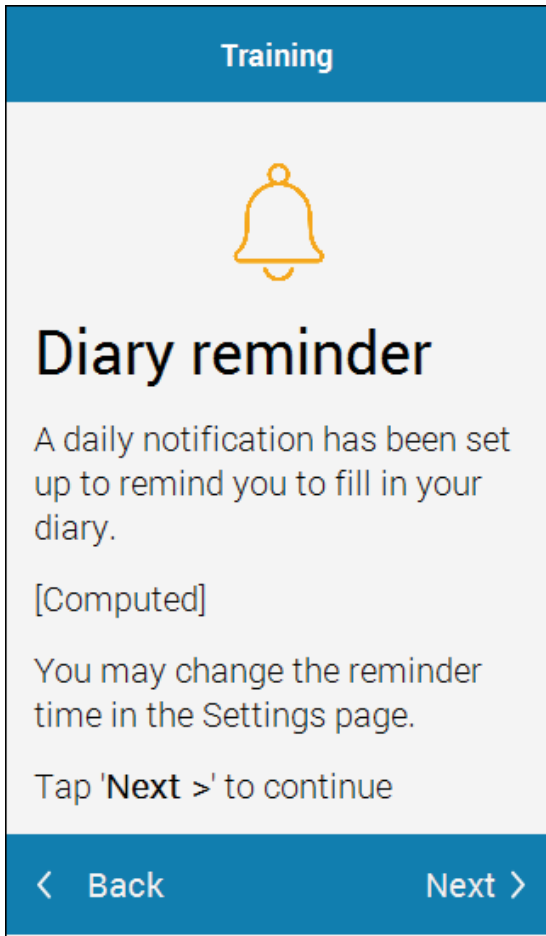
Do not share your PIN with anyone else, not even your Study doctor or nurse.

Tap **'Next >'** to continue

< Back **Next >**

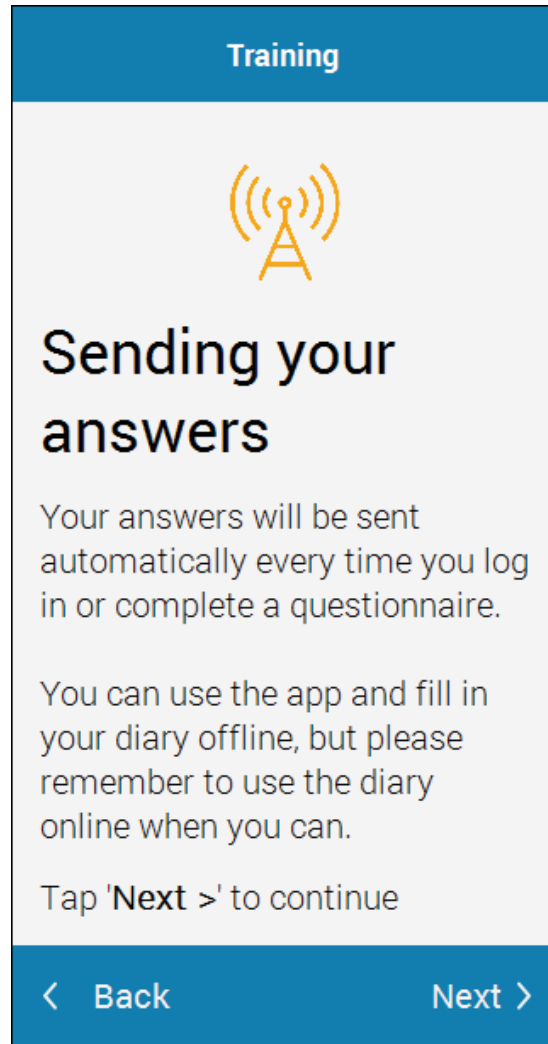
Screen 3

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Screen 4


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



Screen 5

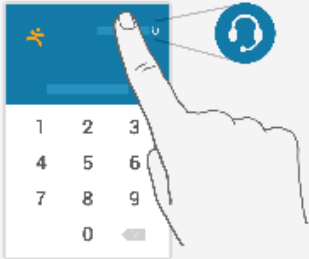
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Training



The Helpdesk

We hope you find the app easy to use. If you do have problems, the Helpdesk is always there for you.




You can find the Helpdesk number by tapping the 'Contact info' button on the login screen. The number is also available in your Quick Reference Guide.

Tap **'Next >'** to continue

< Back **Next >**

Screen 6

Training



Your turn to practice!

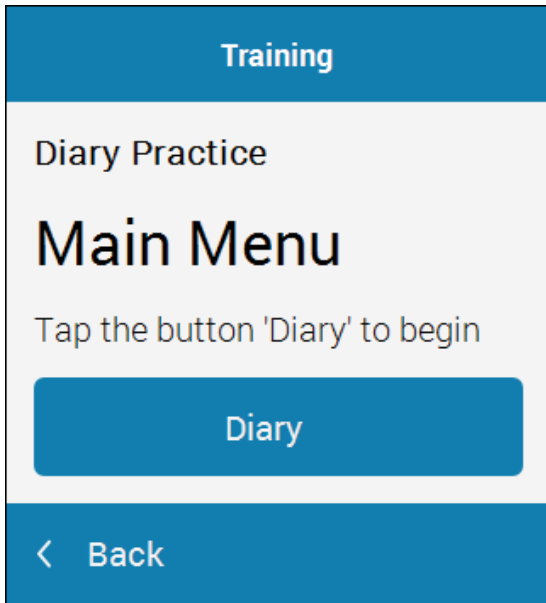
You are about to see a page that we call the 'Main Menu'.

Tap the button 'Diary' to start practicing.

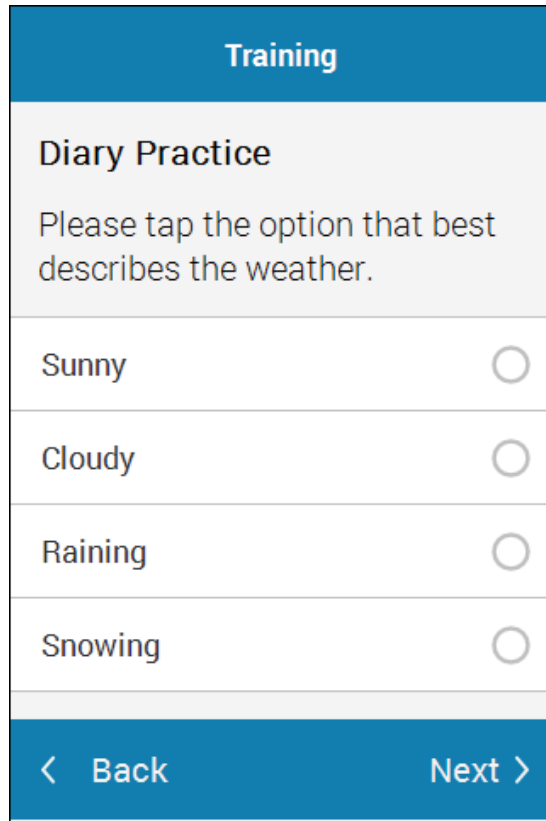
The answers you give during this training session will not be saved.

< Back **Next >**

Screen 7

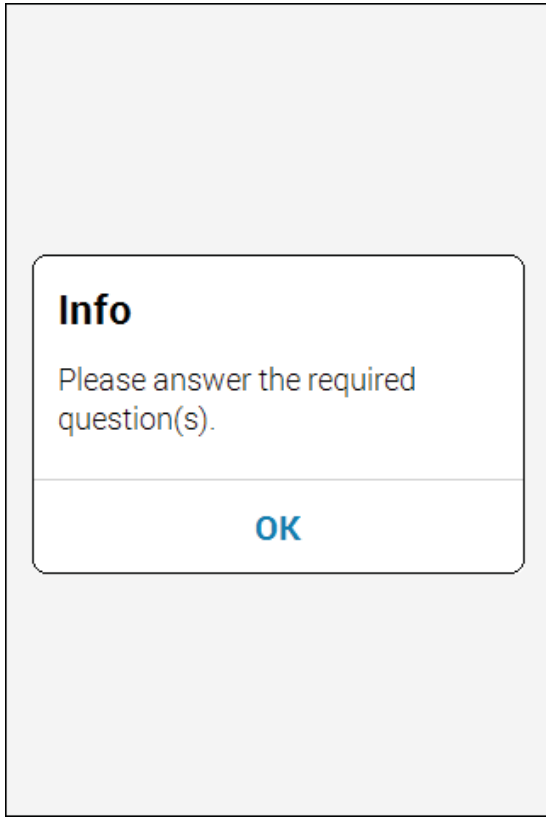


Screen 8

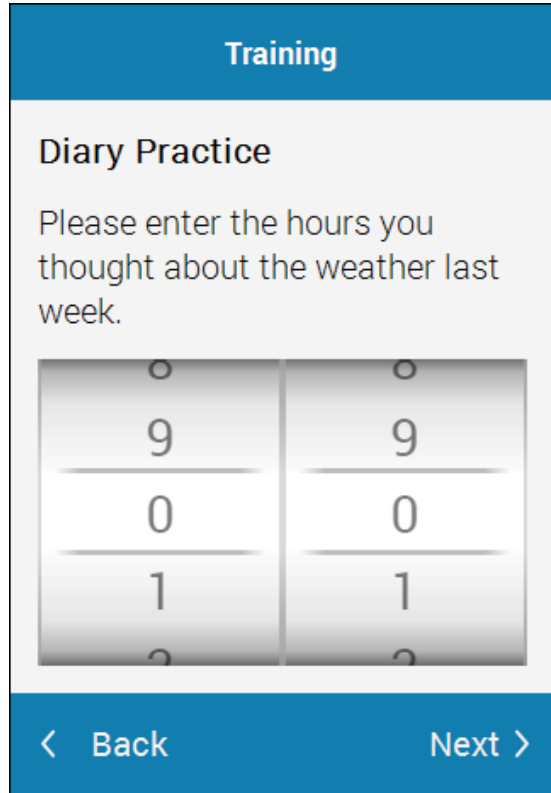


Screen 9

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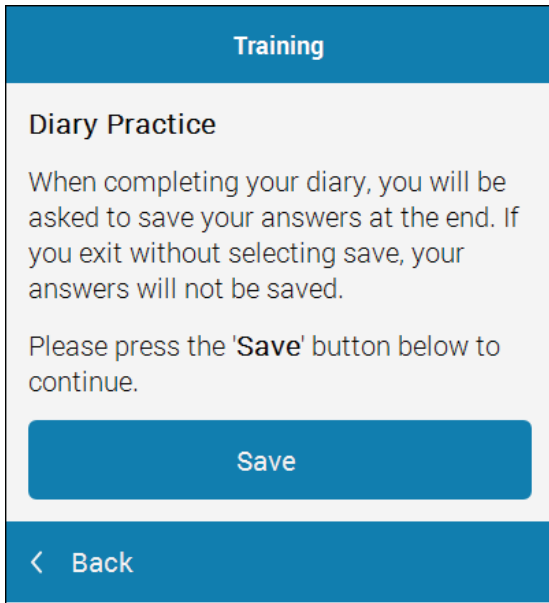


Message 1

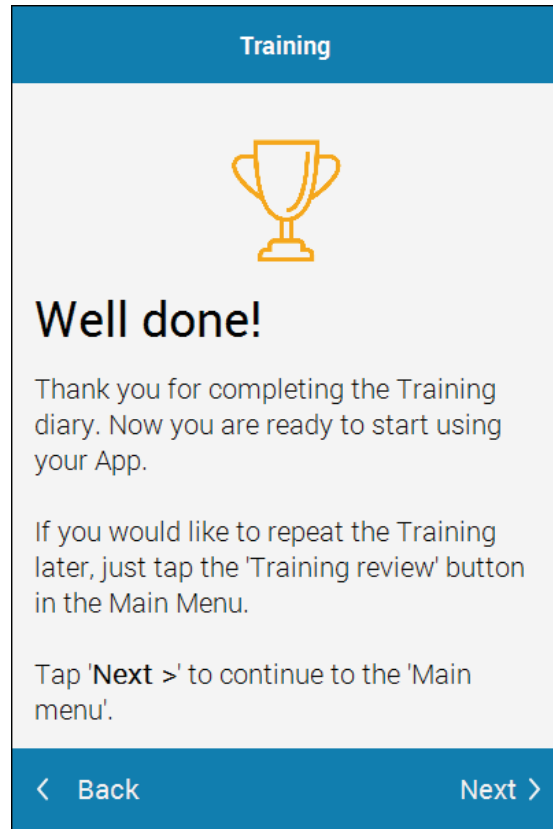


Screen 10

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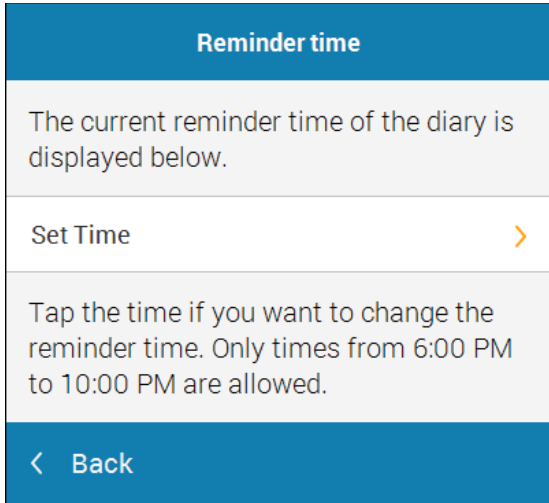
Screen 11



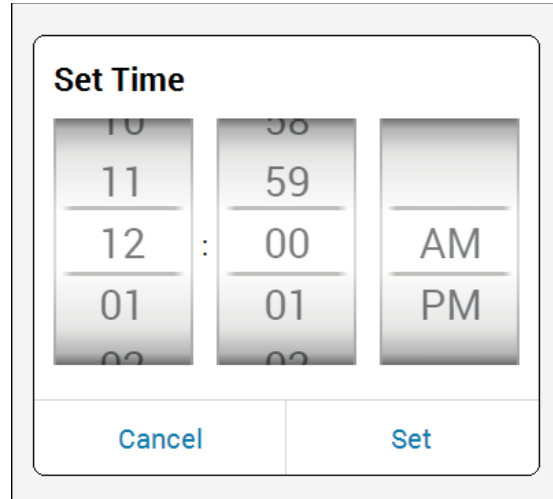
Screen 12

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6 Form: Settings



Screen 1



Popup input 1

7 Form: Security question

Screen 1

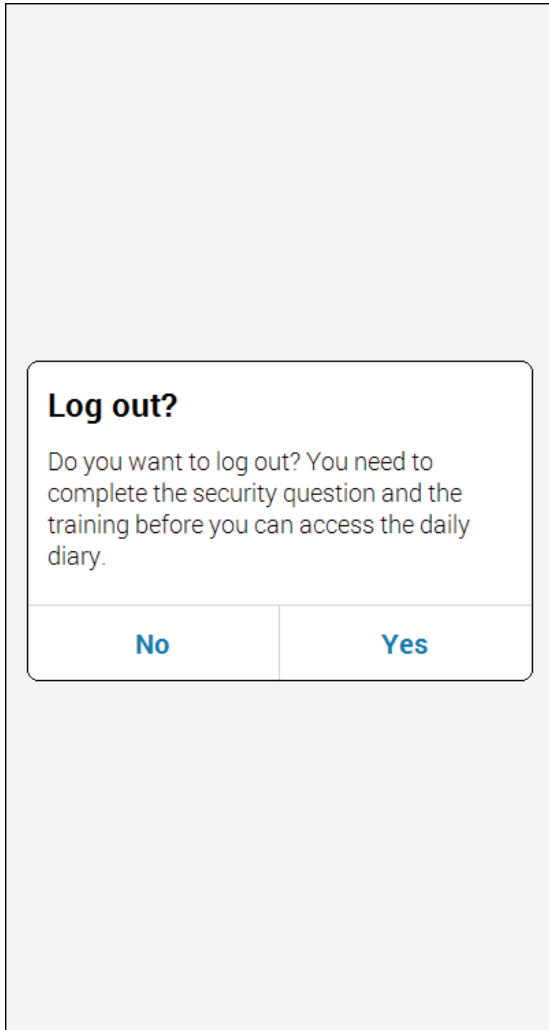
Message 1

[Computed] will show one of the following:

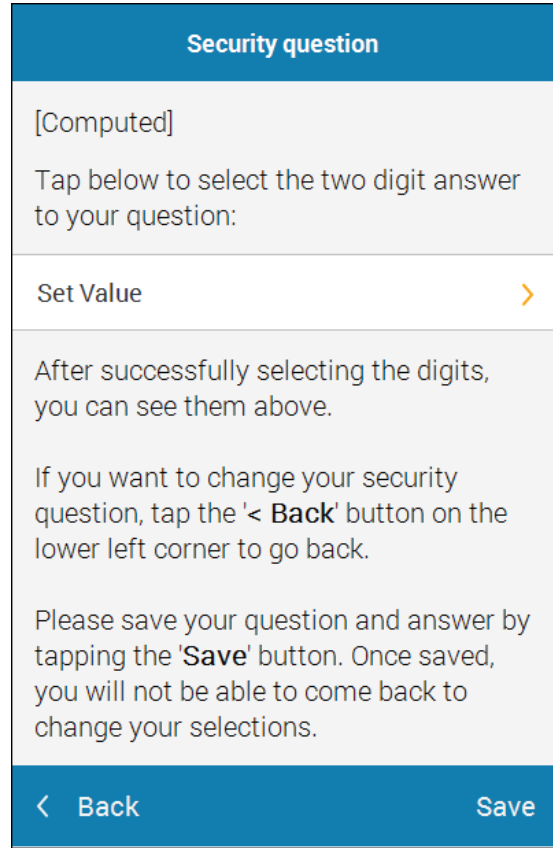
- 'Your oldest sibling's birth year (YY)'
- 'Your mother's birth year (YY)'
- 'Last two digits of your childhood phone number'
- 'Day of the month of your father's birthday'
- 'Day of the month of your mother's birthday'
- 'Childhood home door number (2 digits only)'
- 'How old were you when you passed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

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Message 2



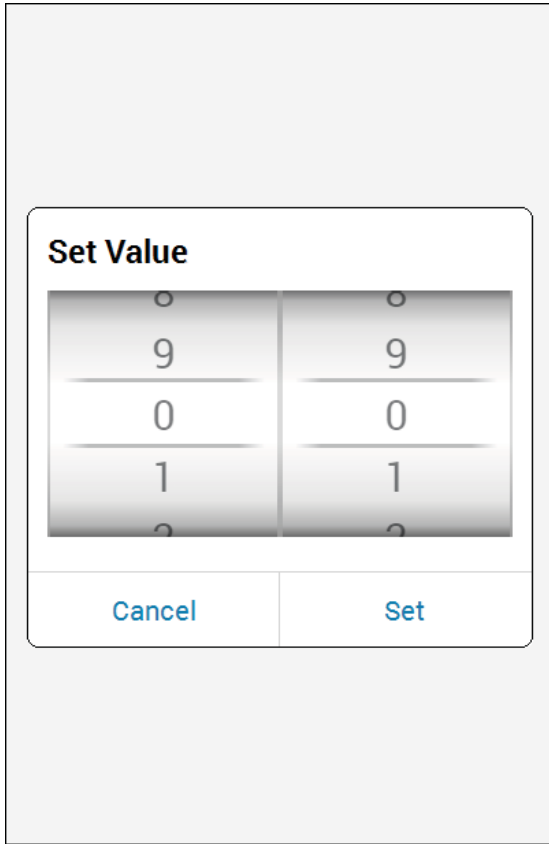
Screen 2

[Computed] will display

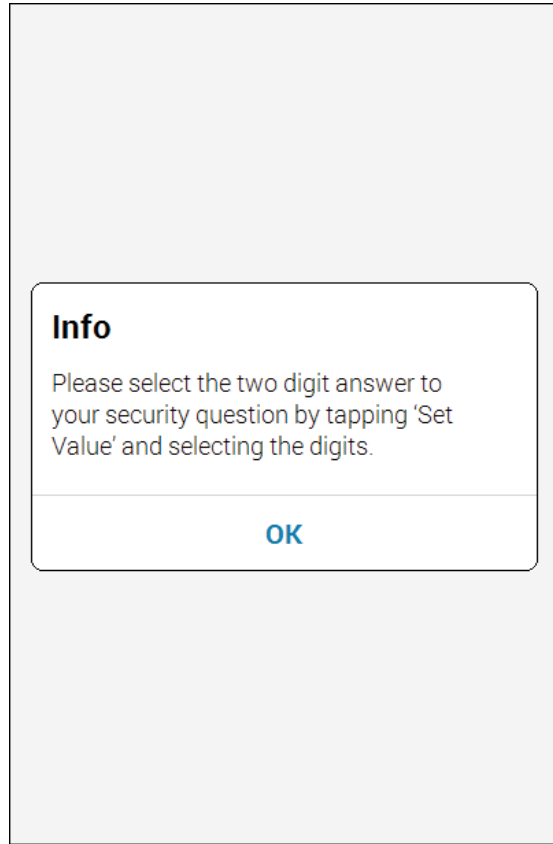
'Your question:

<i>{1}</i>'

{1} will show the question selected on Screen 1



Popup input 1



Message 1

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SCREEN REPORT APPROVAL

Content for Approval					
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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:	<small>DocuSigned by:</small> Kathleen Snyder <small>23F5428A29294D3...</small>

03-Apr-2020 | 21:11 EDT

SIGNANT HEALTH

Approval	
Name: Brittany Hayes	Signature:
Title: Project Manager II	<small>DocuSigned by:</small> Brittany Hayes <small>C4D491375B6548E...</small>

03-Apr-2020 | 21:10 EDT

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