



SHAPE Mobile Application Quick Overview

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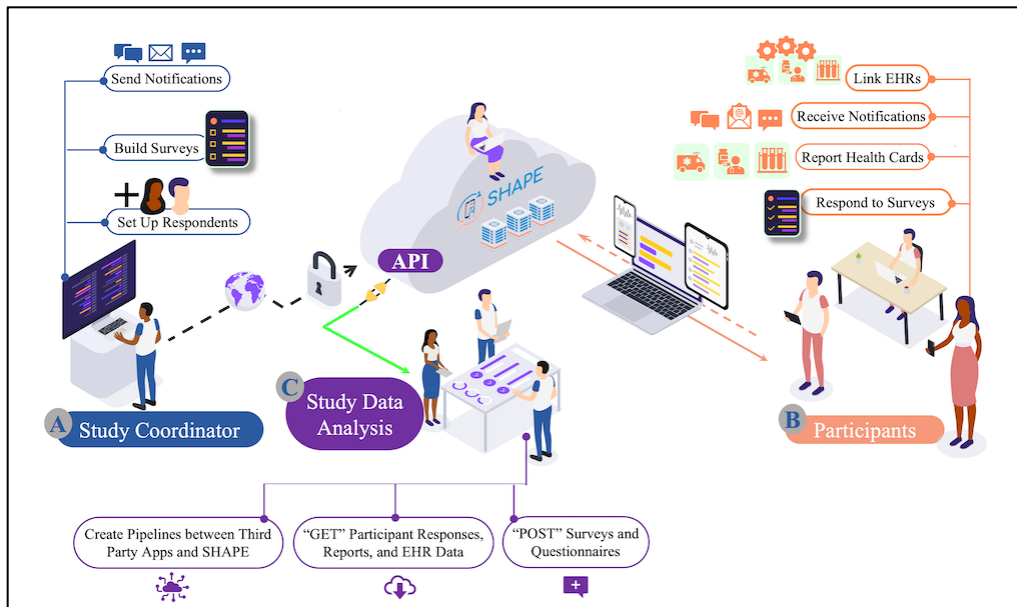
Architecture

FDA's Survey of Health and Patient Experience (SHAPE) Application is a mobile application that is available on Apple App Store, Google Play Store, and the web. Surveys can be configured and shared with users through a backend administrator application where the study administrators curate surveys for the SHAPE App to display to participants. User, survey, response, and metadata information is stored in Google Firebase and Storage.

The SHAPE Platform consists of:

- SHAPE Mobile Application (code is currently open sourced)
 - o Framework: React/Node.js 10
 - o Features include:
 - Surveys
 - Questionnaires
 - Self-Report Diaries
 - Message Center
 - Profile
 - EHR Integration
- SHAPE Administrator Application
 - o Framework: React/Node.js 10
 - o Features include:
 - Web-based configuration portal for survey administrators
 - Survey Skip Logic
 - Message Center for email, SMS and in-app notification communications
 - Automated functionality to send notifications, as well as add users to follow-up questionnaires based on the completion of a previous questionnaire or responses to a question
 - Response dashboards
 - Study population curation center
 - Question development portal
 - Single Line Text, Radio Button, Date Time, Checkbox, Dropdown, Slider, Text Area, Range, Information Only type questions
- SHAPE API
 - o Framework: React/Express/Node.js 10
- Secure Storage Environment
 - o Google Firebase
 - o Google Authentication
 - o Google Cloud Firestore
 - o Google Storage
 - o Google Functions
 - o Google Hosting

Figure 1. SHAPE Platform



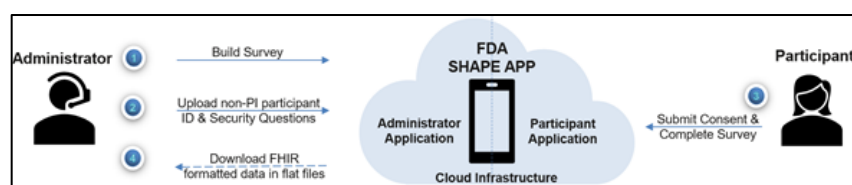
Application Overview

Figure 2 illustrates the overall survey development and deployment process. The SHAPE Platform is hosted in a cloud environment and consists of two separate applications: the SHAPE Admin application and the SHAPE App (the participant side mobile application).

The administrator builds a survey through the SHAPE Admin interface and the mobile (participant side) application presents the surveys and questionnaires to the application users. There are two types of surveys – private and public. The private surveys are limited to patients that are invited to participate. For private studies, participants are assigned to surveys by the administrator in the SHAPE Admin App, then once invited participants can register their account with the SHAPE App using the unique ID code provided to them.

The public surveys allow administrators to create surveys that can be open to anyone interested in joining. Once a survey is developed and deployed, respondents can access the application, consent to the study, and complete the survey all using the SHAPE App. The responses provided by the participants can be reviewed and accessed by the administrators in the SHAPE Admin App. Participants can also receive messages from the administrators via the SHAPE App's message center.

Figure 2. Overall SHAPE Participant Process



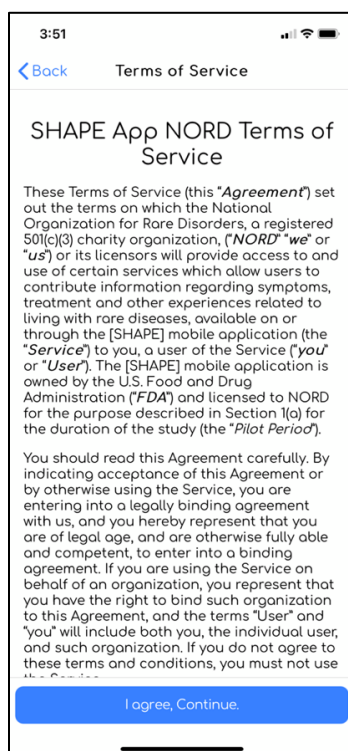
Throughout this document, we will reference Surveys vs. Questionnaires and Respondents vs. Participants:

- A survey represents the data collected for a particular study and consists of questionnaires. The questions are created within the questionnaires.
- A respondent is an individual invited to use the SHAPE app and is responsible for entering data into the application. The respondent may be responsible for entering data for one or more study participants (e.g., multiple children). Each participant is a study subject. A respondent can have one or more participants associated with it, however each participant can be associated with only one respondent.

Enrollment and Consent

Every first-time SHAPE App user is presented and must accept the application's Terms of Service agreement. The Terms of Service is specific to the organization they're listed as a participant in their survey. To agree, the respondent must select the "I agree, Continue." Button.

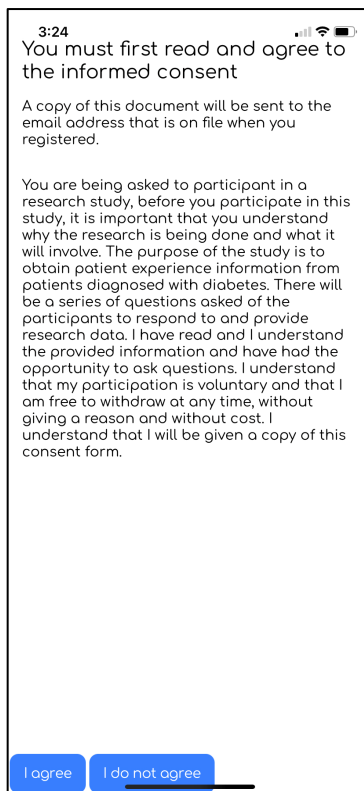
Figure 3. SHAPE Terms of Service



As surveys and questionnaires get "opened" by the survey administrators, those that the respondent is assigned to will be displayed within the SHAPE App, as available. The Informed Consent is developed and provided to SHAPE via the SHAPE Admin app by the survey administrator. The Informed Consent text will be displayed and all

respondents must read and agree before they're able to open, view, and respond to the survey and questionnaires.

Figure 4. Survey Informed Consent



3:24

You must first read and agree to the informed consent

A copy of this document will be sent to the email address that is on file when you registered.

You are being asked to participate in a research study, before you participate in this study, it is important that you understand why the research is being done and what it will involve. The purpose of the study is to obtain patient experience information from patients diagnosed with diabetes. There will be a series of questions asked of the participants to respond to and provide research data. I have read and I understand the provided information and have had the opportunity to ask questions. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason and without cost. I understand that I will be given a copy of this consent form.

I agree I do not agree

Once the respondent has agreed to the Informed Consent, they will receive a copy of the consent in the inbox of their provided registration email and then be shown any open surveys that apply.

Figure 5. Emailed Informed Consent



SA SHAPE Application
shapeapplication@gmail.com

Date:
27-07-2021 15:24:14

Subject: Informed Consent for Survey: Diabetes Patient Survey

You are being asked to participate in a research study, before you participate in this study, it is important that you understand why the research is being done and what it will involve. The purpose of the study is to obtain patient experience information from patients diagnosed with diabetes. There will be a series of questions asked of the participants to respond to and provide research data. I have read and I understand the provided information and have had the opportunity to ask questions. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason and without cost. I understand that I will be given a copy of this consent form.

Available Question Types

Single Line Text

3:25 Questionnaire

Answering on behalf of Karen

What is your primary physician's name?

This question is required. Type your physician's full name (first and last)

Karen

Question 1 of 10

Save & Complete Later

Next

Radio Button

1:45 Questionnaire

< Back

Answering on behalf of Karen

What type of diabetes have you been diagnosed with?

This question is required. Select your diagnosis

Type 1 ☐

Type 2 ☐

Prediabetes ☒

Gestational ☐

Question 3 of 7

Save & Complete Later

Next

Checkbox

3:26 Questionnaire

< Back

Answering on behalf of Karen

Select all the diagnostic tests you've undergone in the last 6 months

Select all that apply

A1C Blood Test ☐

Glucose Tolerance Test ☒

Fasting Blood Sugar Test ☒

Glucose Screening Test ☐

Random Blood Sugar Test ☐

Question 5 of 10

Save & Complete Later

Next

Date Time

Questionnaire

Answering on behalf of Captain

date equals 7/7/2022 should skip

Required question: custom required message

Instructions: answer

Date

07/22/2022 clear

Question 5 of 7

Save and Exit

< Back Next >

Dropdown

11:13 Questionnaire

Answering on behalf of Karen

Select your state of residence

This question is required. Select your state

AZ

AR

CA

CO

CT

DE

Cancel OK

Question 1 of 6

Save & Complete Later

Next

Slider

3:26 Questionnaire

< Back

Answering on behalf of Karen

Provide your latest A1C test result

Select the approximate number

Lower: 0 Upper: 15 Step: 5

5

Question 7 of 10

Save & Complete Later

Next

Range

11:13 Questionnaire

Answering on behalf of Karen

Enter your current weight

Only number values are valid, min value: 50 max value: 300

This question is required. Enter your current weight to the nearest pound

115

Question 2 of 6

Save & Complete Later

Next

Text Area

3:26 Questionnaire

Answering on behalf of Karen

Provide additional information around your diagnosis

Provide information around what led to your diagnosis and the medical treatment plan

My diagnosis was three years ago and our medical treatment plan is to begin medication and reevaluate in two years

Question 4 of 10

Save & Complete Later

Next

reevaluate re-evaluate reevaluated

q w e r t y u i o p

a s d f g h j k l

z x c v b n m

123 space return

😊 🎤

Information Only

11:14 Questionnaire

Answering on behalf of Karen

Diabetes Resources



The following sites have great resources for any diabetic patients

ADA - American Diabetes Association
DiabetesEducator.org
Centers for Disease Control & Prevention (CDC)
Diabetes - Academy for Nutrition and Dietetics

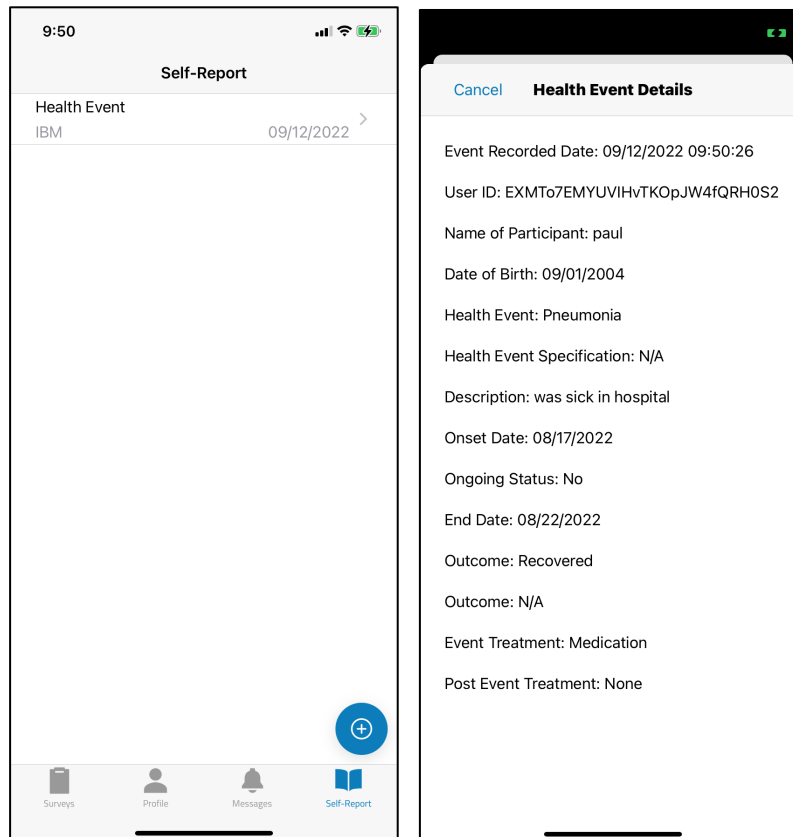
Question 6 of 6

Save and Complete

Self-Report Diaries

Participants are able to submit a self-report diary entry within any survey they are part of. A self-report is a non-dynamic mini questionnaire that is targeted at obtaining health event specific data from respondents. Once a respondent has successfully submitted a self-report the receipt and submitted information can be reviewed in the self-report tab home.

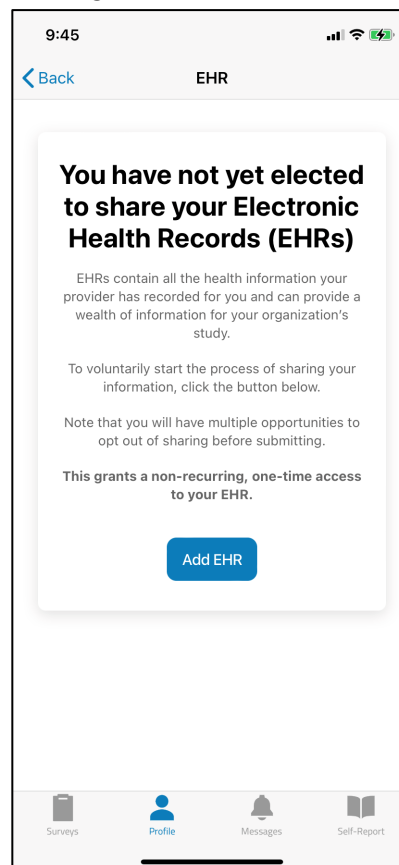
Figure 6. Self-Report Home and Entry



EHR One-Time Data Pull Integration

SHAPE App respondents can complete a data pull of their Electronic Health Record (EHR). This process is completed by a series of in-app selections in conjunction with a third-party secure cloud-based FHIR EHR platform. The participants are directed outside of the SHAPE app to log into their EHR vendors using their vendor credentials and then allow a one-time data pull of their records into the SHAPE app environment.

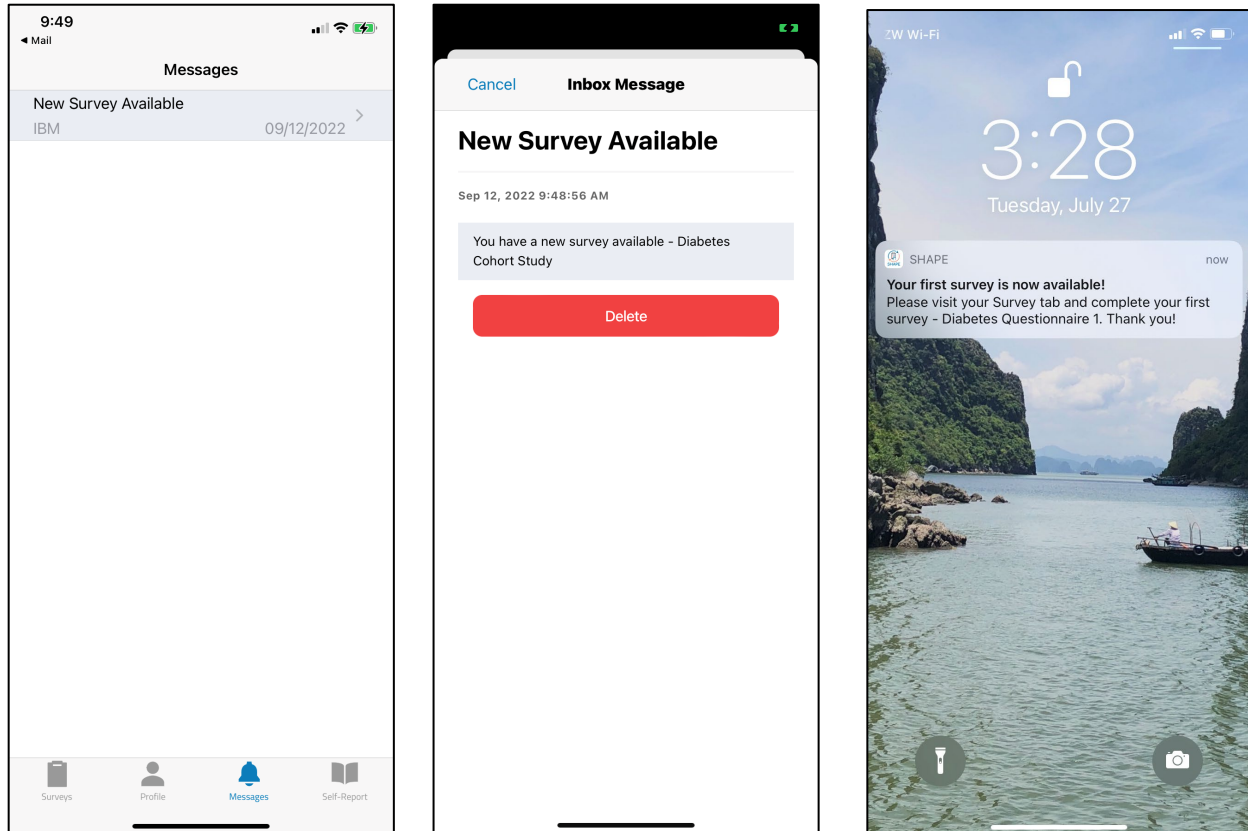
Figure 7. EHR Home



Communications

The SHAPE app administrators have the ability to send messages through three channels: text messages, emails, and in-app messages. If the respondent enables push notifications, the application can connect to the device's native notification center and send notifications to the user on their home screen.

Figure 8. SHAPE Messages and Push Notification



Current Capabilities

Capability	Details
Participant Enrollment	For private studies, study administrators control who can create accounts and participate in studies through unique participant IDs and security question validation.
Open Enrollment	For public studies, any interested user can download SHAPE and participate in the study via streamlined registration process.
Consent Record Keeping	Consent agreement is stored in a secure storage and emailed to participants.
Survey/Questionnaire Duplication	Survey administrators can duplicate previously developed surveys or questionnaires for easy deployment.
Skip Logic (gender, age, response)	Survey questions can have skip logic rules included that would branch/select what question is presented next to the respondent. This logic can be based on the respondent's gender, age, or response to the current question.
Data Validation (range, numeric, required, optional)	- Restrict open text responses to specific numbers, letters, or special characters - Enforce an integer range - Enforce dates in the future or part - Enforce only one selection for radio buttons - Configure an error message when a respondent attempts to pass a required question
Communication to User (in-app, email, SMS)	Survey administrator can send a message to the respondent via an in-app message, email message, or SMS.
Push Notifications	Study administrators can opt to send push notifications to participants through their device's notification center.
Automatic Scheduled Jobs Services	Study administrators can set up automated questionnaire/self-report reminder messages, as well as add users to follow-up questionnaires based on the joining or completion of a previous questionnaire.
Ability to display image	Allows the survey administrator to present a JPEG image on an information only card.
Ability for patients to modify completed responses	Allows the respondents to open questionnaires they have previously submitted to and edit their responses.
Ability to access the mobile app via a web browser	Allows the respondent to be able to open SHAPE and log in using their credentials on a web browser.

Ability to partition access to questionnaires within survey	Survey administrators can subsection a larger survey population pool into smaller populations for specific questionnaires.
Ability to submit adhoc Self-Report Entries	Respondents can submit diary entries for health events and clinical visits at any time.
Ability to integrate to EHR for a one-time data pull	Respondents can log into their EHR vendor's portal and agree to one-time data pulling their records into the SHAPE environment.

Branding

Utilizing the FDA SHAPE App platform requires branding work so that the application is easily recognizable by participants. The SHAPE App branding consists of your organization's logo, the color scheme, the new app logo, and the home screen image. Branding is not included in the look and feel of the questions or health events within the app.