



SHAPE Administrator Application Quick Overview

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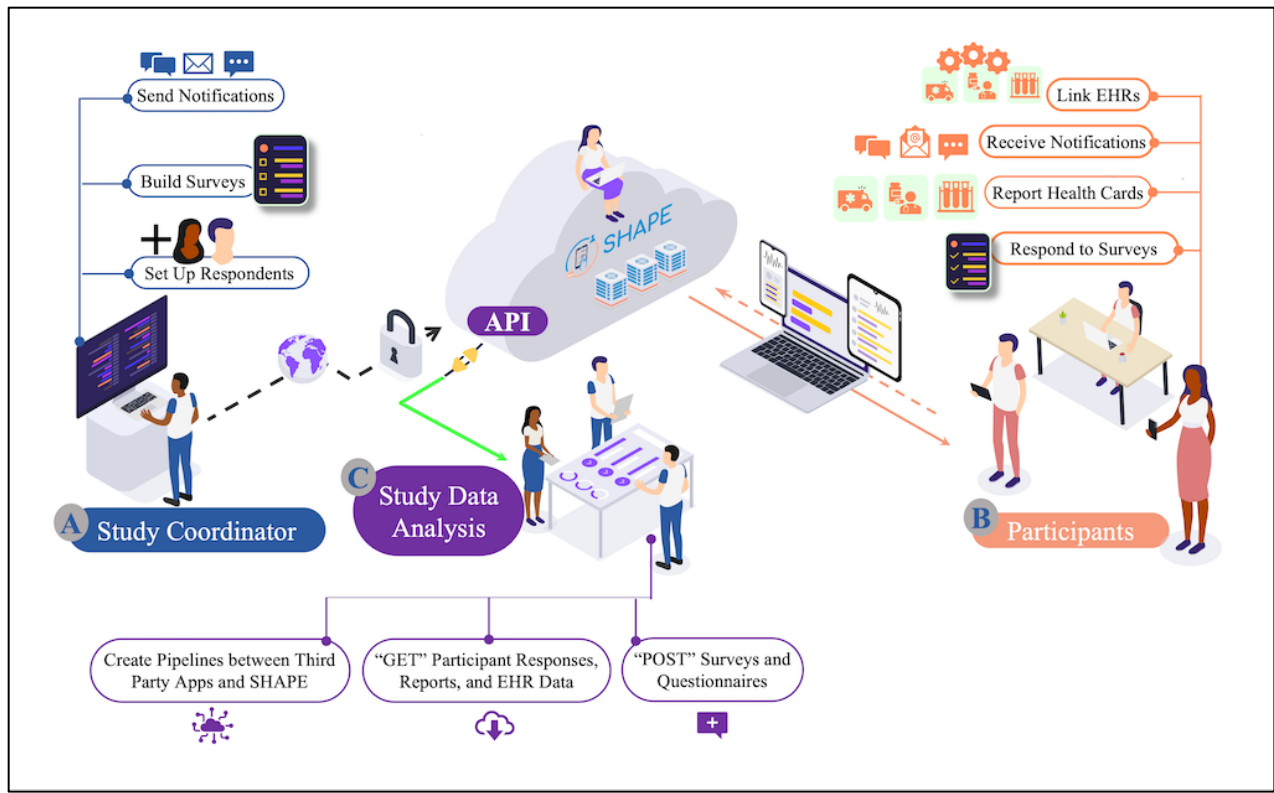
Architecture

FDA's Survey of Health and Patient Experience (SHAPE) Application is a mobile application that is available in the Apple App Store, Google Play Store, and on the web. The SHAPE Application has been designed and developed as a flexible and scalable application for the design and deployment of patient experience surveys. The SHAPE Administrator Application is where study administrators can configure and share surveys with SHAPE App users. User, survey, response, and metadata information is stored in Google's Cloud Firestore database and Cloud Storage.

The SHAPE Platform (Figure 1) consists of:

- SHAPE Mobile Application (code is currently open sourced)
 - o Framework: React, Ionic and Node.js
 - o Features include:
 - Surveys
 - Questionnaires
 - Self-Report Diaries
 - Message Center
 - Profile
 - EHR Integration
- SHAPE Administrator Application
 - o Framework: React, Ionic and Node.js
 - 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 and Node.js
- 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



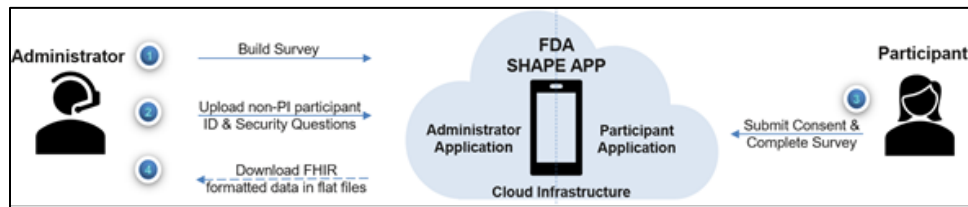
Application Overview

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. There are two types of surveys – private and public. The private surveys are limited to patients that are invited to participate. The administrator has the option to upload a CSV file containing unique, non-personally identifiable (PI) codes for multiple respondents at once or manually enter this information through the administrator application, individually. The administrator shares a unique code with each participant outside of the application. The respondent will then use the unique code provided to register with the SHAPE application.

The public surveys allow administrators to create surveys that can be open to anyone interested in joining. Once the survey is developed and deployed, respondents can access the application, consent to the study, and complete the survey. The administrator can use the SHAPE Admin application to track each respondent's completion status and download the gathered data in both FHIR-formatted JSON and traditional JSON files.

Figure 2. Overall Administrator 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.

Multi-tenancy

The SHAPE Admin app supports multi-tenancy which allows multiple organizations to utilize SHAPE to deploy their studies while controlling access and restricting their workspaces. When a new organization joins SHAPE, there will be the creation of their own organization workspace that cannot be accessed by the other SHAPE organization members.

Each organization will see their organization name in the upper right-hand corner of the SHAPE Admin home page, listed after the administrator's name. When participants go to register with the SHAPE App, they will need to select their appropriate organization to successfully register and gain access to their surveys.

Figure 3. Administrator Home Page



Survey Creation

The administrator creates a survey, which is comprised of questionnaires. Each questionnaire is a discrete set of questions. The surveys allow the administrator to collect longitudinal data. Upon logging into the application, the administrator is directed to the home page, where existing surveys are displayed, and new surveys can be created.

The following information is required to create a new survey:

- Title of Survey
- Subtitle
- Description
- Informed Consent. The informed consent is attached to a survey and can be different for each survey. The survey informed consent is inherited by the questionnaires created within the survey.

The administrator can assign the following statuses to surveys at any given time throughout the lifecycle of the study:

- *Open*. Change the survey status to 'open' and make it visible to respondents. They will then be able to view and respond to questions. When the administrator opens the survey, the 'Status' field will change to "Open." Once the survey is "Open," administrators cannot edit survey details (e.g., name, description), but can still add questionnaires, respondents, and other items. Please note that there needs to be at least one active questionnaire to initially open the survey.
- *Close*. Change the survey status to 'close' and no longer allow the survey to be visible to the respondents. The collected data can now be downloaded.
- *Edit*. Enables the 'Survey Name', 'Subtitle', 'Description', and 'Informed Consent' fields to be editable. When done editing, select the 'SAVE' button in the button menu on the top right section of the interface.
- *Archive*. Removes the survey from the administrator's view. The data is only accessible directly from the database (i.e., a database administrator would need to retrieve anything related to this survey once it is archived).
- *Schedule*. Launches the scheduled jobs wizard that allows administrators to create and schedule certain administrator activity jobs. (Refer to [Automation Features](#)).

Figure 4. Survey Home

The screenshot displays the 'Survey Home' page in the SHAPE system. At the top left is the SHAPE logo, and at the top right is a 'Logout' button. Below the header is a navigation bar with a back arrow and a menu containing 'OPEN', 'CLOSE', 'EDIT', 'ARCHIVE', and 'SCHEDULE'. The main content area shows the following details for the 'Diabetes Patient Experience Cohort Survey':

- Survey Name:** Diabetes Patient Experience Cohort Survey
- Status:** Open
- Subtitle:** Cohort study survey for diabetes patients
- Description:** This survey contains targeted questions for diabetes patients who are participating in the FDA cohort study. The goal is to have the patients provide patient experience data over a set period of time.
- Informed Consent:** 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...
- Privacy:** Private

Once a survey is created, the administrator can then update the survey, create questionnaires within the survey, add respondents, and track respondent progress once a survey is open and collecting data.

Respondent Enrollment

The administrators can add respondents to the survey by either uploading a CSV file of multiple respondents or manually inputting the respondent's information. The CSV file contains respondent IDs, as well as three security questions and the respondent's responses to those security questions. The following structured CSV file must be completed and imported into the SHAPE Admin App.

Figure 5. CSV Multiple Participant Upload Example File

	A	B	C	D	E	F	G
1	registration_code	security_question_1	sq_1_answer	security_question_2	sq_2_answer	security_question_3	sq_3_answer
2	88888888	What is the name of your favorite childhood friend?	some answer	In what town or city did you meet your spouse/partner?	some answer	What was your dream job as a child?	some answer
3	77777777	What is your favorite color?	some answer	What was your high school mascot?	some answer	What is your favorite travel destination?	some answer

Once respondents are uploaded to the SHAPE App, they are included in the list of respondents that can be added to questionnaires.

Figure 6. Survey Respondents

QUESTIONNAIRES HEALTH EVENTS RESPONDENTS PARTICIPANTS PROGRESS

Import Respondents: Browse... No file selected. SUBMIT

Respondent	First Name	Last Name	Email	Phone Nu...	Account C...	Date Regi...	Enabled	
123456	Sofia				Yes	03-30-2021	☒	DISABLE REMOVE
ibm-002	Holey				Yes	03-30-2021	☒	DISABLE REMOVE
ibm-003	William		PHI Removed		Yes	04-01-2021	☒	DISABLE REMOVE
11223344	Sarah				Yes	03-30-2021	☒	DISABLE REMOVE

Click Here → +

Alternatively, the administrator can manually add respondents by completing a form that collects the following information. If a respondent has already been uploaded to another survey within the organization, the administrators can use the search functionality to look them up by their unique ID and automatically import their information into the survey.

Figure 7. Search and Add Respondent

← Add Respondent	
Actions	Create New Respondent
Create New Respondent	Respondent Unique ID*
Search and Add Respondent	Security Question 1*
	Security Question 1's Answer*
	Security Question 2*
	Security Question 2's Answer*
	Security Question 3*
	Security Question 3's Answer*
	SUBMIT

Questionnaire Creation

Each survey is comprised of questionnaires. Each questionnaire contains a set of questions. The following information is needed to successfully create a new questionnaire:

- Title of Questionnaire
- Subtitle
- Description

Once the questionnaire is created, it will be shown on the landing page of the Survey it is associated with. The administrator can assign any of the following statuses to Questionnaires at any given time throughout the lifecycle of the study:

- *Open*. Change the questionnaire status to 'open' and make it visible to respondents. They will then be able to view and respond to questions. When the administrator opens the questionnaire, the 'Status' field will change to "Open".
- *Close*. Change the questionnaire status to 'Close' and no longer allow the questionnaire to be visible to the respondents. The collected data can now be downloaded.
- *Preview*. View the survey in an emulator that showcases the survey as if the administrator was viewing it on a device, similar to how the participant will view the survey when launched.
- *Edit*. Enables the 'Questionnaire Name', 'Subtitle', and 'Description' fields to be editable. When done editing, select the 'SAVE' button in the button menu on the top right section of the interface.

- *Archive*. Removes the questionnaire from the administrator's view. The data is only accessible directly from the database (i.e., a database administrator would need to retrieve anything related to this questionnaire once it is archived).

Question Types

The administrator creates the questions under the Questions tab (see Figure 8). The administrator can search for questions that already exist in the question pool or create a new question. The administrator can create different question types:

- Single Line Text
- Radio Button
- Date Time
- Checkbox
- Dropdown
- Slider
- Text Area
- Range – limits the min and max of the integer the respondent can enter
- Information (Info) Only – there is no response field for the respondents – images, tables, and text can be displayed for information sharing purposes

Figure 8. Question Creation

Add Question	
Actions	Create New
Create New	Single Line Text Radio Group Date Time Checkbox Select Slider Text Area Range Info Variable* Variable Name Question* Title Instruction* Full text Placeholder Placeholder text Required ☐ Instructions for Required Field A value is required for this question
Search and Add Questions	CREATE CREATE AND ADD TO THIS QUESTIONNAIRE

Once a new question is created, the administrator has the option to add the new question to the SHAPE Admin's question pool for easy inclusion in future questionnaires.

Skip Logic

SHAPE Admin was developed to support the development and inclusion of skip logic rules. The administrator can develop rules based on AND/OR logic. Within the AND/OR logic, the administrator must select the question to skip to and what parameters would trigger the skip. These skip parameters can be based off the participant's gender, age, or the responses provided to the current question.

Figure 9. Skip Logic Creation – Skip to Question Use Case

The screenshot shows the 'Rule Editor' interface. At the top, it says 'Rule Editor'. Below that, there is a line: 'If any conditions below are met, skip to question '. Below this line is a box containing 'condition 1: answer ' with a trash icon to the right. Below the box is a button with a plus sign and the text 'Add Condition'. At the bottom right, there are two buttons: 'SAVE CHANGES' and 'CANCEL'.

Through the Skip Logic functionality, study administrators can also add users to a specific follow-up questionnaire based on their response to a question in their current questionnaire. The following is an example of a situation where an administrator could add a user to another questionnaire based on if they responded “Female” to a question on their gender.

Figure 10. Skip Logic Creation – Add to Questionnaire Use Case

The screenshot shows the 'Rule Editor' interface. At the top, it says 'Rule Editor'. Below that, there is a line: 'If any conditions below are met, add to questionnaire Health Equity - Basics Follow Up'. Below this line is a box containing 'condition 1: answer is equal to Female' with a trash icon to the right. Below the box is a button with a plus sign and the text 'Add Condition'. At the bottom right, there are two buttons: 'SAVE CHANGES' and 'CANCEL'.

Electronic Health Records Pull

The SHAPE App worked with 1upHealth to integrate their API and functionality of allowing patients to access and authorize a one-time pull of their electronic health care data into the SHAPE environment. The respondents can perform a one-time data pull of their electronic health records (EHR) through the SHAPE App they access on their mobile device. This effort requires the respondents to know and log into their account with their EHR provider and consent to accessing and performing a one-time data pull into SHAPE through 1upHealth.

After respondents have completed the one-time data pull, administrators can access and download the EHR data through the SHAPE Admin App. A receipt log is accessible by a button on the SHAPE Admin App homepage. The receipt log shows the timestamp, respondent ID, participant name, EHR name, and path to the pulled data for the administrators.

Figure 11. EHR Receipts List

← EHR Receipts				
Timestamp	Respondent ID	Participant Name	EHR Name	Path
07/21/2021 11:31:58	ibm-004	Henry	Cerner Health Systems (demo)	
07/20/2021 12:36:36	123456	Peter	Cerner Health Systems (demo)	Paths hidden
07/20/2021 12:31:37	ibm-002	Haley	Cerner Health Systems (demo)	.

Communications

The SHAPE App was built to allow administrators to interact with participants of their surveys using multiple channels. An administrator can create a message and send that message to the group of participants in whole, but also to subsets of participants based on age and gender filters. During the participant's registration process, respondents are asked to select which channels they can be contacted through, such as email, SMS message or through the Shape App. Administrators can only select the channels that the participants have selected during their registration process.

The administrator will then be directed to a message creation template and will then be asked to enter the following information:

- Private or Public Survey
- Subject line
- Message
- Select the appropriate survey
- Select the appropriate questionnaire

- Optional: Enter age or gender filters
- Select the participants to receive the message and the communication channels to send the message

Figure 12. Message Creation

Email	SMS	In-App	Respondent ID	First Name	Last Name	Email	Phone Number	Enabled
☐	☐	☐	res0987	Bill	Clinton	shape.ibm.test+billclinton@gmail.com	345-678-9003	Yes
☐	☐	☐	res471	Michael	Jordan	shape.ibm.test+MichaelJordan@gmail.com	123-456-7890	Yes

The following message channels are available in the SHAPE App for the administrator to utilize:

- ***In-Application (In-App) Messages*** – these messages will be shown to all participants in the message center of the participant application side of SHAPE. This channel does not require the participant's authorization as it is within the application.
- ***Email Messages*** – these messages will be sent as an ordinary email from the SHAPE App to the participant's provided email address, given they have opted in to receive email message communications.
- ***SMS Messages*** – these messages will be sent to the participants in the form of a text message to the participant's provided telephone number, given they have opted to receive SMS message communications.

A list of delivered communications is also available to the administrator.

Figure 13. Sent Notifications Log

← Sent Notifications					
Timestamp	Subject	Message	Email	SMS	In-App
07/23/2020 11:46:42	testing	verifying messaging is working	N	Y	Y
07/22/2020 02:14:37	new notification	this is test on jul 22	Y	N	Y
07/09/2020 12:58:52	Test	Test	Y	N	N
07/08/2020 12:53:00	Jul 8 test message	This is test message for new code	Y	Y	Y
06/25/2020 02:58:08	testing	testing	N	N	Y
06/25/2020 02:58:04	Testing by Sanjay	time 12:57pm	N	N	Y
06/25/2020 10:43:35	test	test	Y	Y	Y

Push Notifications

The SHAPE app has been developed to interact with the native notification center of the respondent's mobile device. If the participant has chosen to enable push notifications the SHAPE app will push updates that will show on the respondent's home screen and application badges, as relevant. This will allow the app to inform respondents of survey or questionnaire launches, messages, and other notifications within their native device notification features.

Automatic Scheduled Jobs Features

SHAPE Admin App targets further reducing the burden on study administrators by providing them with the ability to schedule and predefine administrative tasks that are required when running a study.

The current use cases supported in SHAPE are:

- Add to follow-up questionnaire once previous questionnaire is answered
- Add to a questionnaire upon joining the survey
- Send reminder if they have not submitted a Self-Report
- Send a reminder if they have not completed a questionnaire

Study administrators can develop these jobs by selecting the "Schedule" button on the study home page (Refer to Figure 4). A pop up will appear that will guide the user through the form to create their target job. Administrators can toggle these jobs on and off, as well as edit and delete when they are no longer required. The jobs are run daily at 3pm EST and any actions that are applicable will be performed at that time.

Figure 14. Scheduled Jobs Home

Scheduled Jobs: Diabetes Patient Experience Cohort Survey

CLOSE

No jobs yet, click the button to add one

+ NEW JOB

The following fields are required to create a scheduled job for the “Send a reminder if they have not completed a questionnaire” use case:

- Job name
- Questionnaire that was not completed
- How long to wait before initial reminder to complete questionnaire is sent
- How frequently to continue reminding the participant if no action has been taken

Figure 15. Scheduled Jobs: Questionnaire Reminder

The screenshot displays a web interface for configuring a scheduled job. At the top, the title is "Scheduled Jobs: Public Survey 01" with links for "+ NEW JOB" and "CLOSE". Below the title bar, the job details are shown: "name: reminder notification", "type: Questionnaire Not Completed", and "status: new". A section labeled "Job Name" contains the text "reminder notification". The main configuration area is titled "After" and shows a dropdown menu set to "not completing questionnaire", followed by "Questionnaire 01 [open]", "for 7 days", and "send a reminder notification every 7 days". Below this, a "Notification Message" field contains the text: "Reminder! Please complete questionnaires for survey Public Survey 01 at your earliest convenience. Thank you!". At the bottom right of the form, there are "SAVE" and "DELETE" buttons.

For public surveys, it is required that a study coordinator/administrator sets up a scheduled job of type “Add to questionnaire upon joining the survey” to ensure that the users are presented with the open survey upon registering.

The following fields are required to create a scheduled job for the “Add to questionnaire upon joining the survey” use case:

- Job name
- Questionnaire to add participant to
- How long to wait before adding them to the follow-up questionnaire
- How long to make the questionnaire available for

Figure 16. Scheduled Jobs Creation: Joining Survey

The screenshot shows a web form titled "Scheduled Jobs: Public Survey 01" with a "+ NEW JOB" and "CLOSE" link in the top right. The form has a header section with "name: Add to questionnaire", "type: Survey Joined", and "status: new". Below this is a "Job Name" field with the value "Add to questionnaire". The main configuration section starts with "After" followed by a dropdown menu set to "joining this survey". This is followed by "add respondent to questionnaire", a dropdown menu set to "Questionnaire 01 [open]", and "after" followed by a dropdown menu set to "5" and "days, and remain available for" followed by a dropdown menu set to "7" and "days". At the bottom right of the form are "SAVE" and "DELETE" buttons.

The following fields are required to create a scheduled job for the “Add to follow-up questionnaire once previous questionnaire is answered” use case:

- Job name
- Questionnaire that was completed
- Follow-up questionnaire to add participant to
- How long to wait before adding them to the questionnaire
- How long to make the questionnaire available for

Figure 17. Scheduled Jobs Creation: Completing Questionnaire

The screenshot shows a web form titled "Scheduled Jobs: Public Survey 01" with a "+ NEW JOB" and "CLOSE" link in the top right. The form has a header section with "name: add to followu questionnaire", "type: Questionnaire Completed", and "status: new". Below this is a "Job Name" field with the value "add to followu questionnaire". The main configuration section starts with "After" followed by a dropdown menu set to "completing questionnaire". This is followed by a dropdown menu set to "Questionnaire 01 [open]". Below this is "add respondent to questionnaire", a dropdown menu set to "Questionnaire 02 [draft]", and "immediately" followed by a dropdown menu set to "3" and "days, and remain available for" followed by a dropdown menu set to "3" and "days". At the bottom right of the form are "SAVE" and "DELETE" buttons.

The following fields are required to create a scheduled job for the “Send reminder if they have not submitted a Self-Report” use case:

- Job name
- Amount of time to wait before notifying
- Frequency of which to re-notify if action has not been taken

- Notification message to include

Figure 18. Scheduled Jobs Creation: Not Creating Self Report

Scheduled Jobs: Public Survey 01 + NEW JOB CLOSE

name: reminder notification **type:** Self-Report Not Written **status:** new ^

Job Name
reminder notification

After not creating a self-report for 7 days, send respondent a reminder notification every 7 days.

Notification Message
A self-report has not been created recently for survey Public Survey 01. Consistently submitting self-reports helps improve the accuracy of the study. Please consider creating one at your earliest convenience.

SAVE DELETE

Data Export

Administrators can download the respondent provided data in both FHIR-formatted JSON and traditional JSON files. There are three data export file types within the SHAPE Admin:

- Questionnaire Data
- Self-Report Data
- EHR Data

Questionnaire Data

The administrator can download survey data on a questionnaire-by-questionnaire basis. The data consists of the participant's profile information, as well as their questionnaire responses. The administrator can initialize the download of their chosen data format type – JSON & FHIR-formatted JSON – by navigating to the survey of interest's home page. Once on the survey page, the administrator can download all the questionnaire data by selecting one of the two data export buttons on the questionnaire card.

Figure 19. Questionnaire Data Export



Diabetes Questionnaire -
6 Month

6 Month Diabetes Patient
Experience Questionnaire

Status: Draft
Date Created:08/25/2021 08:30:40

DOWNLOAD RESPONSES (JSON)

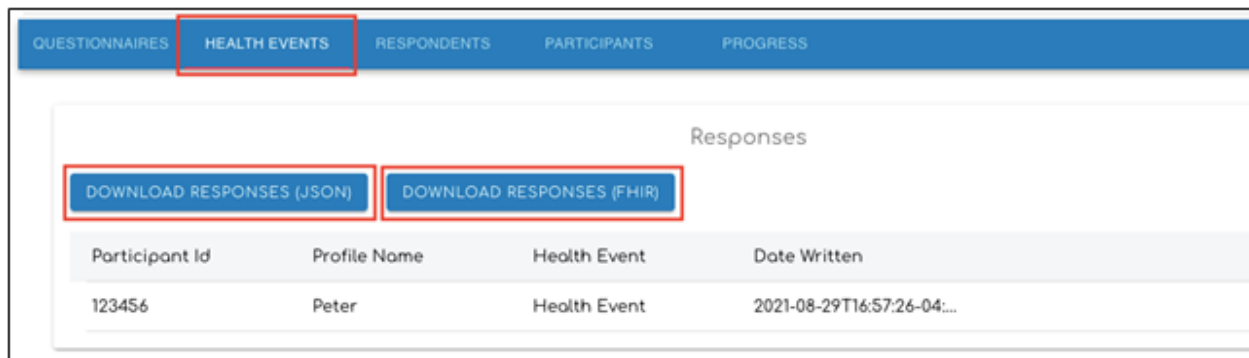
DOWNLOAD RESPONSES (FHIR)

DUPLICATE

Health Event Data

To download all the relevant Health Event entries for a specific survey, the administrator will need to navigate to the survey of interest and then select the Health Event tab on the menu ribbon. Within the Health Event tab, the administrators can download the data in JSON or FHIR-formatted JSON files.

Figure 20. Health Events Data Export



QUESTIONNAIRES HEALTH EVENTS RESPONDENTS PARTICIPANTS PROGRESS

Responses

DOWNLOAD RESPONSES (JSON) DOWNLOAD RESPONSES (FHIR)

Participant Id	Profile Name	Health Event	Date Written
123456	Peter	Health Event	2021-08-29T16:57:26-04:00...

EHR Data

To download all the relevant EHR data pulls by the participants in the survey, the administrator can navigate to the EHR Receipts log and pull the participant records of interest by double clicking the EHR receipt of interest. The administrator will then be displayed the download options to complete the process.

Current Capabilities

Capability	Details
Participant Enrollment	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.