Architecture
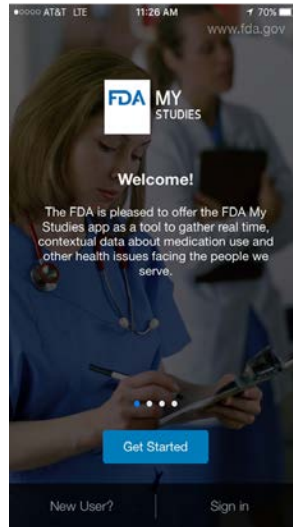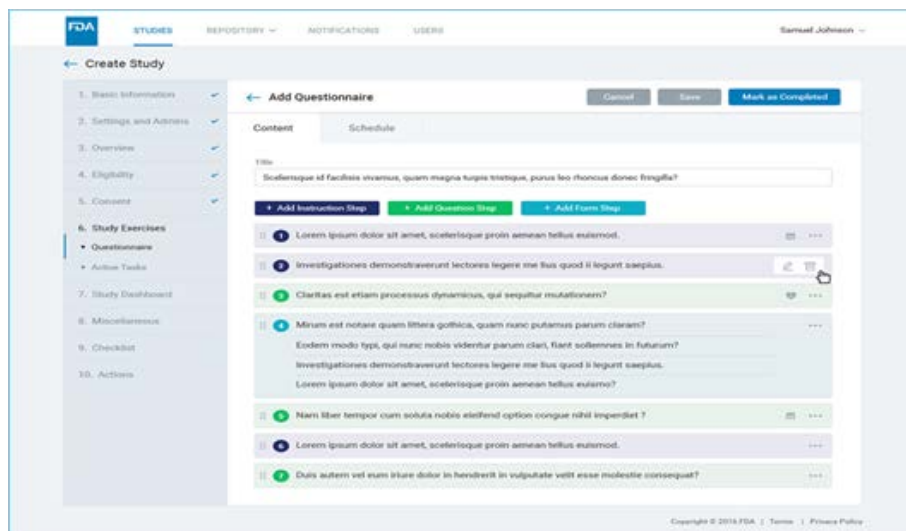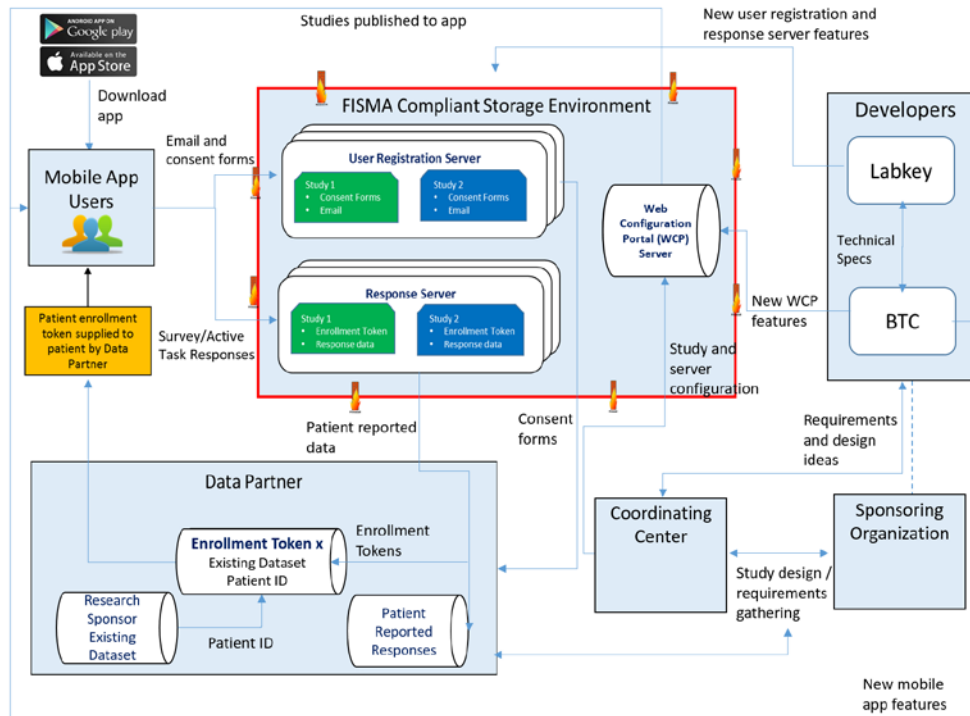
- Mobile App
  - Standard frameworks - ResearchKit (iOS), ResearchStack (Android)
  - Optional gateway capability

- Web-based configuration portal
  - Configure Study Elements (including questions and active tasks)
    - Custom recurrence and frequency
    - Logical branching
  - Create and Manage Resources and Notifications
    - Flexible notifications
    - Study Dashboards
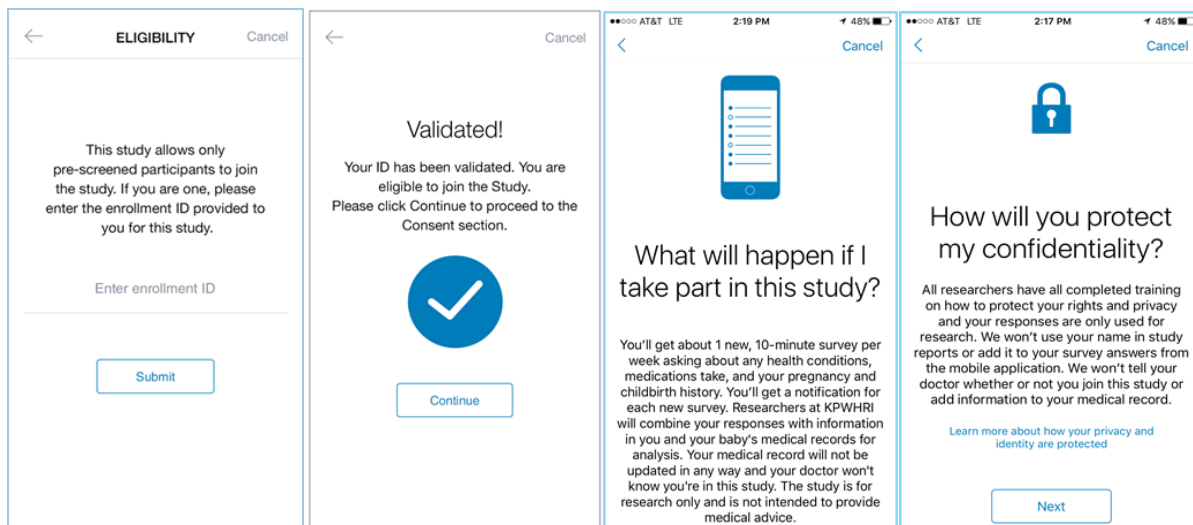 - Create patient enrollment tokens

- Secure Storage Environment
  - FISMA complaint
  - Partitioned for distributed research
  - Responses can be downloaded in broadly compatible formats (e.g., for use in R, SAS, Excel, etc.)

Enrollment and Consent

- Pre-select a cohort from electronic health data
- Recruit and distribute enrollment tokens for pre-selected cohorts
- Participants download the app in iOS or Android app stores
- Participants review eligibility information and provide informed consent through the app

Available Question Types

Boolean

Selection Survey

Do you consent to a background check?

Yes

No

Next

Skip   Cancel

Value Picker

Selection Survey

What is your blood type?

Select an answer

A+
A−

Next

Skip   Cancel

Image Selection (Any Images)

Image Choice

Pick a color

Tap to select

Next

Skip   Cancel

Single Select

Selection Survey

How many hours did you sleep last night?

Less than seven

Between seven and eight

More than eight

Next

Cancel

Multi Select

Selection Survey

Which symptoms do you have?

Cough

Fever

Headaches

None of the above

Next

Skip   Cancel

Numeric

Selection Survey

How old are you?

Tap to answer years

Next

Skip   Cancel

Time

Date Survey

What time do you get up?

10	50	
11	51	
12	52	AM
1	**53**	**PM**
2	54	
3	55	
4	56	

Next

Skip   Cancel

Date

Date Survey

When is your next meeting?

Fri Aug 17	10	52	
Sat Aug 18	11	53	
Sun Aug 19	12	54	AM
Today	**1**	**55**	**PM**
Tue Aug 21	2	56	
Wed Aug 22	3	57	
Thu Aug 23	4	58	

Next

Skip   Cancel

Open Text (Limited or Unlimited)

Selection Survey

How did you feel last night?

Tap to write

Next

Skip   Cancel

Validated Email

Selection Survey

What is your email?

apple.com

Invalid value

Invalid email address: apple.com

Cancel

Next

Skip   Cancel

Scale (Vertical or Horizontal)

Scale

On a scale of 1 to 10, what is your mood?
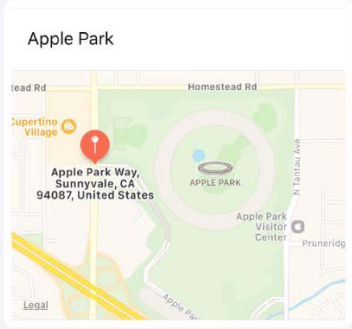
8.725

10

1

Next

Skip   Cancel

Location

Location Survey

Where are you right now?

Apple Park

Apple Park Way, Sunnyvale, CA 94087, United States

Next

Skip   Cancel

Form Step: Combine Question Types into a Single Form

More information on ResearchKit: http://researchkit.org/docs/docs/Survey/CreatingSurveys.html

Current Capabilities

Capability	Details
Digital informed consent w/e-signature	Informed consent can be divided across several screens for easier retention. Participants sign the final consent document after swiping through all screens. The storage environment stores participant consent forms as PDFs. Participants can access their consent form in the app and have the option to email it to themselves. Survey responses and consent forms are stored separately and accessed with different credentials.
Eligibility test	An optional, configurable survey style module used as a double check that participants meet eligibility criteria. It can be used in conjunction with an enrollment token.
Enrollment token	An optional 8-character alphabetic token created in the storage environment used to restrict survey access to a pre-determined cohort. It can be used in conjunction with the eligibility test.
Informed Consent Comprehension Test	An optional, configurable survey style module used as a double check that participants understood the Informed Consent form.

Capability	Details
Survey scheduling and recurrence by calendar time	Surveys within a study can be scheduled to be sent daily, weekly, monthly or on a custom schedule. The ability to send surveys based on participant enrollment date is planned.
Branching logic	Survey questions can branch to future questions in the same survey based on participants' responses. A question cannot branch to a previous question.
Data validations	- Restrict open text responses to specific numbers, letters, special characters, or a combination of the three. - Enforce an answer length and/or restrict an answer to a single line. - Enforce dates in the past or future. - Configure an error message when a user enters a string that is now allowed.
Ability to provide feedback to participants on a dashboard	<u>Default</u> (Always appears on dashboard): Study completion % and % of activities completed on time (before expiration). <u>Configurable</u> (Only appears on dashboard if created in Web Configuration Portal (WCP)): Minimum, median, or maximum numerical responses, trend line graphs.
Ability to embed a video	A video can be placed on the home screen for a study to provide additional information about the study. It can be viewed before participants chose to consent.
Ability to push resources to participants	PDFs, links to external websites, or short blocks of text can be made available to study participants. Resources can be made available on a pre-determined schedule or based on an anchor date chosen by researchers. The anchor date must be the answer to a question in any survey.
Ability to send participants smartphone notifications about the study (i.e. not text messages)	Notifications can be sent via the WCP to all app users or all participants in a study. They can be scheduled based on calendar time. Notifications cannot be sent to individual users.
Ability to use existing Apple Health data as a response to questions	iOS only More info: https://www.apple.com/ios/health/
Ability for participants to modify completed responses	Surveys are saved locally to participants' phones, so responses can be modified until the participant submits a survey, or until the survey is no longer available in the app.
Ability to complete surveys without internet access	Once surveys are available on the mobile app, answers can be entered and stored locally on the phone until internet access is available again.
Consistent look and feel across devices on which surveys are accessed	The apps have the same functionality on iOS and Android phones, but behave slightly differently on each and match the look and feel of the respective frameworks to ensure familiarity to the user.
Ability to publish a standalone app that contains a single study	The system is designed to publish several studies to a single app that acts as a gateway to those studies. However, the system allows for creation of a standalone application that exists outside of the gateway application. The standalone app would need to be approved by each app store independently of the gateway application.

Capability	Details
Ability to mark individual data elements as PHI	The storage environment allows study administrators with appropriate permissions to mark individual columns in result tables as PHI to restrict their visibility to specific users. Study participants never have access to the storage environment.
Ability to partition access to response data by site	The storage environment utilizes a folder structure and allows permissions to be configured at each folder level. A study is the top-level folder and can have many sub folders for each participating organization.
Ability to Export response data in many common formats (Excel, SAS)	Data can be exported in SAS, Excel, R and other scripting languages. Automatic/recurring data extraction is also possible with some development effort.
HIPAA- and FISMA-compliant data storage	FISMA guidelines regarding auditing, monitoring and event logging are in place on the storage environment. Data are encrypted in storage.

Branding

Utilizing the MyStudies platform requires branding so it is easily recognizable by participants. Branding involves the color scheme, app icon, home screen image, and study thumbnail(s) used in the app. It does not include formatting of questions and responses as their look and feel is determined by the ResearchKit and ResearchStack frameworks to ensure consistency across apps that utilize those frameworks.

Upcoming Capabilities

Public release of these enhancements is planned over the next several months.

Capability	Details	Estimated Release
Ability to base survey schedule on enrollment date	Surveys can be distributed based on a set schedule linked to enrollment date rather than calendar time.	3-4 months
Text suggestions for open text responses based on a provided list of values	Participants will be presented with text suggestions when answering open text questions. Suggestions will be based on a list of values provided by the study team.	3-4 months
Advanced branching logic and the ability to use previous responses to dictate subsequent questions and surveys	Responses can be configured to dictate the following: - Text snippets in a subsequent question - Questions or groups of questions that appear later in a survey - Response options that appear in a question later in a survey	8-9 months