## 

**FDA My Studies System**

**Business Requirements and Functional Specifications Document**

**Submitted By:**

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# **Objectives**

* Build native iPhone and Android mobile apps that will house FDA studies. People who download the app from the app stores can enroll and participate in the studies if they satisfy the eligibility criteria for the same.
* Build a web app, hereby referred to as the ‘Web Configuration Portal’ which is an administration console for the mobile app. Authorized admin users can login and manage studies, a content repository, and notifications and also manage users for the Web Configuration Portal, based on permissions assigned.
* Design both the mobile app and the Web Configuration Portal in a generalizable way that will allow the features to be used across studies for study content generation and study administration.

# **Project Summary and Background**

The Department of Population Medicine (DPM) has been contracted by the U.S. Food and Drug Administration (FDA) to lead this project. The project seeks to design and develop mobile applications to conduct health research studies primarily for the collection of patient‐provided information for use in Comparative Effectiveness and Drug Safety Research. There will also be a web configuration porta (web app) that will be used for study content management and study administration. Response data from study participants will be stored on a separate secure environment dedicated for the purpose of data analysis and research.

The pilot study will be for a cohort of pregnant women who will be pre-identified for the study and that will be linked with their data collected by a participating clinical partner (also referred to in this document as “Data Partners”). The mobile applications must be compatible with iOS or Android devices and built using open-source frameworks for creating research applications (i.e., Apple ResearchKit and Android ResearchStack).

DPM resides within the Harvard Pilgrim Health Care Institute, and is an appointing department of Harvard Medical School. DPM’s core mission to improve health care delivery and population health through innovative research and teaching. It informs policy makers who make decisions about insurance coverage, and individual clinicians and patients who need reliable evidence about what treatments and medications work best for specific conditions. DPM studies issues such as medication safety and effectiveness, obesity prevention, nutrition, maternal and child health, vaccination policy, health care disparities, uses of electronic medical record technology, and cancer screening and prevention.

# **Name of the app**

* Mobile app – FDA Health Studies Gateway, FDA Listens!, FDA Interactive (tentative)
* Web Configuration Portal – FDA Health Study Management Portal (tentative)

# **Glossary**

* FDA – Refers to the US Government Food and Drug Administration and specifically the group from the FDA that is involved in this project.
* HPHCI – Refers to Harvard Pilgrim Health Care Institute and specifically the group from the FDA that is involved in this project.
* Client – As used in this document, refers to the party responsible for providing sign-offs or approvals for BTC deliverables.
* Mobile app – the iPhone and Android app being built, to house FDA health studies, that users can download and use to take part in the studies
* Web Configuration Portal – the web application being built to act as an administration console for moderating study and other content on the mobile app.
* User – refers to a person using the mobile app
* Participant – refers to a user who joins a study and actively participates in it
* Admin – refers to a person who is an authorized user of the Web Configuration Portal
* Study – refers to a research study being conducted using the mobile app
* Questionnaire – refers to the surveys (or sets of questions) presented to a participant in a study
* Active Task – refers to a simple exercise or activity that study participants are asked to perform with specific instructions provided for the same. The mobile app collects data from the device as the participant carries out the task. Once the task is complete, the collected data is submitted for the study analysis.
* Study Activities – Questionnaires and Active Tasks of a study are collectively referred to as Study Activities
* QA – refers to a question that is part of a questionnaire in a study. It includes the question text, and answer options (if available, to the participant)
* Step - A screen in the mobile app encountered during a study activity. Each screen is called a step. A Step could be an instruction, a single question screen or a form (multiple questions on a screen).
* Instruction Step – A screen that displays a message or an instruction in the context of a study activity
* Question Step – A screen that displays a QA
* Form Step - A Form Step represents a set of QA all rendered on the same screen (vertically scrollable) on the mobile app, responses for which are submitted together, when the screen or form is submitted.
* Response – Answer provided by a participant for a QA
* Response Data – The response data per participant per study refers to the collective set of QA responses as well as data collected by the mobile app when the participant carries out an active task, in the course of study participation. Response data gets submitted by the mobile app to the secure backend response data store from where it Is used for downstream research and analysis for the study.
* Data Partner – an organization conducting the study in association with the FDA and facilitating the recruitment process of study participants as well as the downstream analysis of response data.
* Resources - Reading material provided to users in the form of rich text or PDFs aimed at making their usage of the mobile app more engaging and informative.
* Anchor Date - A 'date of significance' used as a reference to calculate time elapsed in order to render relevant resource content within the mobile app.
* RTE – Rich Text Editor

# **Types of Mobile Apps and Studies**

* The mobile app will be designed to be a ‘Gateway App” that houses several studies
  + This means that the app will make available to users, a list of studies that are created using the Web Configuration Portal, that people can read about and choose to join.
  + This app is the primary one being developed for this project, and is referred to as the FDA Health Studies Gateway mobile app.
* There will also be the provision to spin up, on a need-basis, a standalone mobile app for just ONE study. Such an app is referred to as a ‘Standalone Study App’
  + All functionality in a standalone app will pertain to one study only.
* Each time a study is created on the Web Configuration Portal, the admin can choose to mark it as
  + Gateway Study
  + Standalone Study
* Studies of the type Gateway, will be a part of the Gateway mobile app.
* For each study of the Standalone type, a new app will need to be generated and deployed to the App Store.
* All Studies whether Gateway or Standalone, will by default follow the same content and layout structure.
  + Standalone apps can have UI/feature customization applied, if needed, but within the limits of the overall supporting framework designed for this project.
  + Cost for such customization will be mutually agreed upon on a case-by-case basis before implementation.

# **Functional Specifications for the mobile app**

## Sections of the mobile app

* The Gateway app will comprise of the following main sections
  + Gateway Welcome
  + Gateway List of Studies
  + User Sign Up / Sign In
  + User Profile and Preferences
  + Resources
  + Notifications
  + A ‘Reach Out’ Section
  + The Study Zone, which has the following sections
    - Overview
    - Eligibility
    - Consent
    - Study Activities
      * Questionnaires
      * Active Tasks
    - Study Dashboard
    - Resources
* The Standalone app will comprise of
  + User Sign Up / Sign In
  + User Profile and Preferences
  + Notifications
  + The Study Zone
* Notes
  + In the following sections and field level descriptions in this document, the \* mark against a user-input field indicates that it is a mandatory field for the user of the application, to fill in.
  + Character limits and other rules for fields would be applied during development depending on space availability on the screens, and flow-implementation necessities.
    - If this is in conflict with any business requirement (for example, needing a particular number of characters), it would be mutually discussed and agreed upon with the client

## Gateway Welcome

* This section is meant to be the landing area of the app that is seen each time at app launch prior to user sign-in
* It comprises of the following
  + A set of swipe able screens with information about the gateway app
  + The first screen will have
    - The app name and the FDA logo
    - A brief write-up of 3-4 lines
    - Background image
    - A link to the FDA website
    - A link to a video about the app
      * The link must open to a video player that plays the video within the app
    - A ‘Get Started’ button that navigates to the Gateway List of Studies
    - Shortcuts to Sign Up or Sign In to the app
  + Each subsequent swipe-able screen will have
    - A title
    - A brief write-up of 3-4 lines
    - Image
    - A link to the FDA website
    - A ‘Get Started’ button that navigates to the Gateway List of Studies
    - Shortcuts to Sign Up or Sign In to the app
* Content for all these screens is hardcoded into the app

## Gateway List of Studies

* This is a section that lists out all studies that are available for app users to explore
* Each Study will be listed with
  + Study Name (a short version)
  + Study Category
  + Research Sponsor Name
  + 1-line description or tagline
  + Study Status
    - * Active
      * Paused
      * Upcoming
      * Closed
* Once the user has signed in to the app, the list of Studies in this Dashboard screen gets personalized in the following manner:
  + Each study listing will additionally have the user’s Participation Status
    - In Progress
    - Yet to Join
    - Completed
    - Withdrawn
    - Not Eligible
    - Bookmarked

(Participation Status definitions are as given below

* + - In Progress - Studies the user is actively participating in
    - Yet to Join – Studies that the user is yet to join
    - Not Eligible - Studies for which user has tried eligibility test but failed
    - Completed - Studies the user was a part of in the past and has completed
    - Withdrawn - Studies the user has left and is no longer part of
    - Bookmarked - Studies bookmarked by the user)
  + The personalized dashboard will also have the following information for studies that the user is a part of
    - Study Completion Percentage
      * Calculated as (completed + missed activities) / total activities, where a missed activity is defined as one which was not attempted or which was partially completed before the lifetime of the activity expired
    - Overall Study Adherence Percentage
      * This is computed as Overall Adherence Percentage = Activities Completed/ (Activities Completed + Activities Missed) where a missed activity is defined as one which was not attempted or which was not fully completed before the lifetime of the activity expired
    - In both of these calculations, every run of the activity is to be considered while arriving at activity totals.
* The following filters would be available to apply on the Study List
  + Study Categories
    - All available study categories
  + Study Statuses
  + Participation Statuses (only if the user is signed in)
* The following filters would be applied by default
  + Study Categories – All
  + Study Status – Active and Upcoming
  + Participation Status (In Progress, Yet to Join, Bookmarked)
* Filters last applied by the user must be retained for the session of app usage
* There would also be a keyword search available that would index
  + Study Name
  + Study Tagline
  + Study Category
  + Study Research Sponsor
* Studies in the list would always follow the below ordering
  + If the user is signed in, Active and In Progress studies would be at the top
* Tapping on a Study will direct the user to the Study Zone of that Study (see corresponding section for details about the Study Zone)
* The following actions are allowed in the Dashboard, with each study, with Sign Up/In being a pre-requisite
  + Join the Study (NA for Upcoming or Closed Studies)
  + Resume (if the user has already joined the study in the past)
  + Bookmark the Study (NA for Closed Studies)

## User Sign Up and Sign In

* The is an app level Sign Up and not a registration for any Study in particular
* Sign Up needs the user to provide the following information
  + Email\*
  + Password\*
  + Agree to Terms and Privacy Policy\*
* Upon submitting the Sign-Up form, the user is sent an email with a link to click on to verify themselves
  + Clicking on the link redirects to a browser/app page stating successful verification
  + The link is valid to be used only once and has a pre-determined lifetime after which it expires.
* Verification step in the mobile app
  + Upon revisiting the app, the app will have a Verification step to perform a server-side validation on whether email has been verified.
    - This step of verification completes the Sign-Up process
    - User is allowed to proceed upon successful validation
  + User can also request for the verification email to be re-sent in case they are unable to complete verification with the earlier one.
* Post verification, user is asked to set up a passcode\* to access the app
  + Users are required to set up a 4-digit passcode that can be used to dismiss the app-level lock screen on the phone to access the app.
  + The passcode cannot be used as an alternative to signing in to the app.
  + It is mandatory to set up passcode for the app
* For subsequent Sign-ins,
  + The user needs to provide registered email\* and password\* to sign in.
* There will be a provision to request help with password in case the user needs it
  + Upon submitting the registered email address\*, an email is sent out with a temporary password
  + The user can sign in using the temporary password\* and will be required to set up new password before proceeding to use the app
    - Setting up a new password will have fields for New Password\* and Confirm Password\*
  + The temporary password is valid to be used only once and has a pre-determined lifetime after which it expires.
* The Sign Up and Sign in process described applies to Standalone Study apps as well.
  + Standalone apps would have their own Sign Up process
  + A user registered on the Gateway App cannot use the same user account on a Standalone app and vice-versa.
  + However, this does not restrict the user from using the same credentials (same email and/or password) for their accounts in various apps that may comprise the suite of Gateway and Standalone apps.
* Once the user is signed in, they need not Sign In each time they visit the app unless they are signed out.
  + Apart from an explicit sign out, auto-sign-out can happen in special cases as a security measure.
  + The possible cases in which auto-sign out can happen are listed below:
    - Multiple sign-ins across devices is not allowed, so a user will get signed out from the app on one device if they sign in to the app on another.
    - If the user resets password via the ‘Forgot Password’ flow on another device and signs in to the app using the newly set password
    - If the app is deleted and reinstalled, a fresh sign-in to the app will be required.

## User Profile

* This section allows the user to maintain profile information and app preferences
* The following fields will be available
  + Email (display only)
  + Change Password (by providing the current password\*, a new one\* and then confirming the new one\*)
  + Change Passcode (by providing the current passcode\*, a new one\* and then confirming the new one\*)
  + Turn Notifications ON/OFF
  + Receive study activity reminders: Yes/No
    - If the user chooses Yes, users will get reminders when a new study activity is available and when an activity is due for completion
    - There will be a pre-determined lead time for reminding users when activities are about to expire.
      * The lead time for each activity will vary depending on the scheduling of the activity. For e.g. 1 hour prior for a daily activity and 1 day prior for a weekly activity.
      * See the Notifications and Reminders section for more details
  + Sign Out
    - User gets signed out from the app on their device
    - Subsequent visits to the app would need the user to sign in again to view personalized information or to participate in studies.
    - Users will not receive push notifications if they are signed out of the app
      * However, the Notifications screen in the app will still be able to refresh itself and display an updated list of notifications when the user visits the app.
    - Sign Out clears all user context from the app and deletes all the corresponding in-app stored information from the device.
  + Delete Account
    - This is an action to delete the user’s FDA app account.
    - If the user deletes their account, all associated information (study and user preferences) must be deleted as well.
    - Account deletion will automatically result in a withdrawal of the user from all studies that they are a part of
    - Deletion is preceded by a confirmation screen letting the user know the consequences of deleting their account. The behavior is described below:
      * The user sees a screen that seeks confirmation on account deletion. The message would read “You have chosen to delete you FDA app account. This will result in automatic withdrawal from all Studies. Below is a list of studies that you are a part of and information on how your response data will be handled with each after you withdraw. Please review and confirm.’
      * There would be a list of Studies and against each a text indicator of whether data will be retained or deleted and if it is a user choice, there would be a toggle switch button next to the study that lets them choose.
      * The bottom of the screen would have two options
        + ‘I agree, proceed to deleting my account’
        + ‘I do not wish to delete my account’
      * These buttons are similar to OK and Cancel where Cancel assumes that the user does not want to delete their account at that point in time.
    - Leave Study
      * This action will be available in the Profile section for a Standalone app only.

(For studies that belong to the Gateway app, the Leave Study action would be provided in the Resources/Actions section of the Study Zone of that study. Please see the Study Resources/Actions section for more details on the outcomes of the Leave Study action.)

* + - * Also, this action will be available only if users have an option to ‘Rejoin’ the study after they leave it. This is a setting made by the admin in the WCP
      * If the Rejoin option is not available, users would just have a Delete Account action that results in both - user leaving the study as well as the user’s account getting deleted.
      * Handling of participant response data (retention, deletion or participant choice) on leaving the study is again dependent on the admin setting in the WCP.
    - On choosing to Leave Study or Delete Account, the user would see an alert that informs them about the availability of the Rejoin provision for the study, and about the participant data handling once they leave the study.
    - The final action of Leave Study or Delete Account would be subject to user providing confirmation after seeing these alert messages.

## Resources

* This section provides reading materials for users of the app in terms of resources as well as app legal terms and privacy policy
  + All content is hardcoded into the app.
* The Resources section would have the following
  + List of App-level Resources (reading material)
    - These are resources that are not specific to any Study but about the app in general
      * Examples: About the FDA, A Gateway project initiative etc.
    - Each resource will be presented with
      * Title
      * Content, in one of the following formats
        + Rich Text
        + PDF
  + Legal Text
    - App Terms
    - Privacy Policy

## Reach Out

* This section has outlets for users to reach out to the FDA
* The following options are made available to users
  + A Feedback form
    - The form allows users to reach out with feedback on the app
    - This will always be anonymous feedback
    - The form will have the following elements
      * Subject line field\*
      * Text area to for the user to write content\*
      * A Submit button
    - Upon successful submission of the form, the content reaches the designated email inbox address (for the gateway app) as configured in the Web Configuration Portal by the admin
      * Anonymous feedback must reach the inbox in an identity-less manner from a generic application-based email address
  + A Contact Us form
    - The form allows users to reach out for any help or queries they may have on the app
    - This is not an anonymous means of reaching out to the FDA or HPHCI
    - The form will have the following elements
      * First Name\*
      * Email (pre-populated with registered email if the user is signed in) \*
      * Subject Line\*
      * Message\*
        + A text area field for the user to write the body of the message
      * A Submit button
    - Upon successful submission of the form, the content reaches the designated email inbox address (for the gateway app) as configured in the Web Configuration Portal by the admin
      * Admins can reach out to the user over the user-specified email address in response to their queries

## The Study Zone (mobile app)

* The Study Zone has the following sections
  + Overview
  + Eligibility
  + Consent
  + Study Activities
    - Questionnaires (or Surveys)
    - Active Tasks
  + Study Dashboard
  + Resources/Actions
* Users mandatorily need to go through the Overview, Eligibility and Consent sections before being allowed to participate in a Study
  + Participants would also be required to go through Consent each time the admin publishes an update to the Consent content via the WCP
* Once the user has completed the Consent, they would subsequently always directly land on the Study Dashboard each time they visit the study. This screen also allows them to access
  + Study Activities (and resume activities from where they left off)
  + Study Resources/Actions

## Overview

* This is a quick snapshot of what the Study is about intended to help the user quickly gauge if the Study is relevant for them
* It comprises of
  + A set of swipe-able screens that carry information about the study, with each screen having
    - A title
    - Description
    - Image
    - Link to Video (on first screen only)
    - Link to Study Website
    - Link to View/Email Consent PDF
  + Buttons to
    - Join the Study
    - Bookmark the Study

## Eligibility

* Users will have to go through the eligibility test section for the first time before joining the study
* Depending on how the Study is configured on the Web Configuration Portal, there could be 3 ways of determining eligibility
  + ID validation only
  + ID Validation AND Eligibility Test
  + Eligibility Test only
* ID validation only
  + This mechanism is to be used for studies wherein prospect participants are pre-screened via an offline process and identified as being eligible for the study.
  + Each such participant is given a unique enrollment token for the study, by the participant-recruiting organization
  + On the mobile app, the user sees instructions to enter a valid enrollment token for the app to verify their eligibility for the study
  + The participant needs to enter the enrollment token\* provided to them.
  + Once submitted, the app communicates with the back-end to determine if enrollment ID entered is valid
    - If found eligible, the user is allowed to proceed
  + Enrollment tokens must be unique for a participant in a study and can be used only once and only for the study it was created for.
* Eligibility Test
  + The eligibility section consists of a simple set of questions and answering all of them correctly is mandatory to proceed
  + Each question would have Yes or No as answer options and the user needs to select any one to provide a response to the question
  + Answering every question is mandatory\*.
  + Each answer option (Yes and No) will have a Pass/ Fail attribute that contributes to eligibility
  + Based on the user’s responses, the app will determine whether the user is eligible to take up the study
    - The user must score a pass for every question in order to be considered eligible
    - If the user gets a ‘fail’ for a question, the test ends at that point and the user is informed that they are not eligible for the study.
* If eligible, users can move forward by joining the study, else they are redirected back to Gateway List of Studies with an appropriate message

## Study Consent

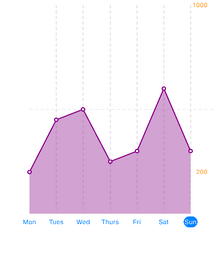
* Consent Information
  + The study consent section will consist of content related to the study being conducted and all the associated terms and conditions.
  + The users can swipe through to navigate between various screens to see various ‘Consent Items’ such as for example, Time Commitment, Privacy, Data Gathering etc.
  + Each of these will have
    - An image
    - Title
    - Brief description
    - Elaborated description
* Comprehension Test
  + Admins creating the study on the Web Configuration Portal can choose to have participants take a comprehension test to gauge their understanding of the Consent sections.
  + This section is not mandatory for every study to have but for those that have it the following points are applicable:
  + Users will have to undertake a test that ascertains their understanding of the Study terms
  + Users are presented with a set of questions all of which are mandatory to answer
  + Each question will have a set of answer options
    - The user can select one or more of the answer options as part of their response
    - Each answer option will have a Correct/Incorrect attribute that specifies whether it contributes to the correct answer
    - The correct response to the question would be the user selecting ANY or ALL of the answer options marked with a Correct attribute, as configured by the admin.
    - Only the specified combinations of answer options can be the ‘correct response’ to the question. Any other combination selected by the user will amount to them giving the ‘wrong response’ for the question.
  + Every ‘correct response’ makes the user attain a point that adds up to the final score at the end of the test
  + Attaining a minimum score is necessary to clear the test
  + If the user clears the test, they can proceed to the next step of providing consent
  + If the user fails the test, they are redirected to the Consent Info section with a message asking them to retry the test.
* Permission for data to be shared
  + Based on whether the Web Configuration Portal admin configures this as a required step, the user will be asked to provide permission for their response data to be shared with 3rd parties.
  + Depending on the user’s response, the user is allowed to proceed depending on the Web Configuration Portal setting of whether permission is mandatory to proceed.
  + Note that the WCP or mobile app has no role in the response data actually getting shared or not shared with 3rd parties.
    - The WCP and mobile apps will only capture the user’s decision to allow or not allow the sharing of their response data with 3rd parties.
* Review and Agreement to Terms & Conditions (Consent Document)
  + Users will view the detailed Terms & Conditions (also called as the Consent Document) about the study and will have to agree or disagree to this
  + If the user disagrees, there is no further action by the user and the app will get redirected to the welcome screen
  + If the user agrees, there is confirmation popup that is seen asking them to explicitly mark that they agree with the Consent Document content for taking part in the study
  + For more information on how the Consent Document gets created, please refer to the Web Configuration Portal section in this document.
* Electronic consent

If the user agrees to the consent in the previous step,

* + The app will present an e-consent form to the user that could have one or more of the following
    - First Name\*
    - Last Name\*
    - E-signature\*
      * Users will have to draw their signature on this screen and it will be captured as an image
  + Upon submitting the e-consent form, the app will display an acknowledgement to indicate the end of the consent process and the participant will be redirected to the Study Dashboard
  + There would be an option for the participant to view and email the signed version of the consent document in PDF format.
    - This will have the participant’s first name, last name, signature and date-time of consent captured on it.
  + Participants would also be required to go through Consent again each time the admin publishes an update to the Consent content via the WCP (see WCP section for more details)
    - If they are actively midway with an activity, they would be allowed to complete it before being asked to go through the Consent module
    - In all other scenarios, including questionnaires paused for resumption at a later point, the participant is required to first go through the revised Consent and then proceed to continue study participation.
  + A record of every Consent document (with version information) as agreed to by the participant, along with the date and time of providing such consent, needs to be saved as part of the participant’s study records on the database.
  + If the consent document is created by rich text keyed in by the admin into the WCP, it will not be possible to capture the participant’s first name, last name, signature and date-time of consent, onto the Consent Document.
    - The participant would still need to go through the steps of agreeing, providing first name, last name and signature to successfully complete the Consent process, on the mobile app.

## Study Dashboard

* This screen is a dashboard specific to each Study
* Once the user has completed the consent step in a Study, they will always land on this screen when they access a Study
* The Dashboard will have 3 primary sections
  + Overall Study Participation Report
    - Content Summary: This section summarizes where the user is with respect to participation in the Study (more details below). It includes the indicators of stud
    - This section will appear in the dashboard for every study
  + Charts
    - Content Summary: This section will have various visualizations of the user’s response data
    - Appears in the study dashboard subject to configurations made by the admin in the Web Configuration Portal
  + Statistics
    - Content Summary: This section will have statistics of significance, generated based on the user’s response data, such as for example, the average hours of activity per day.
    - Appears in the study dashboard subject to configurations made by the admin in the Web Configuration Portal
* Overall Study Participation Report: This section will contain the following information
  + Status of the Study (refer to the Web Configuration Portal section for how an admin can launch, pause, deactivate a study)
    - Active
    - Paused
    - Closed
  + Overall Participation Status of the participant in the study
    - In Progress
    - Completed
    - Withdrawn
  + Study Completion Percentage
    - Calculated as (completed + missed activities) / total activities, where a missed activity is defined as one which was not attempted or which was partially completed before the lifetime of the activity expired
  + Overall Study Adherence Percentage
    - This is computed as Overall Adherence Percentage = Activities Completed/ (Activities Completed + Activities Missed) where a missed activity is defined as one which was not attempted or which was not fully completed before the lifetime of the activity expired
  + Ratio of completed activities versus total activities
    - A breakup is provided within the completed and total sets of activities to indicate the proportion of Questionnaires versus Active Tasks in these sets.
  + Current Day Report
    - Completed versus pending activities due for the current day
  + Upcoming Activities
    - Next upcoming task or questionnaire that is due for completion
* Charts
  + This section will support line charts for visualization of response data.



* + - Each chart would correspond to a time range set by the admin
      * Depending on how the admin configures the chart on the web app, the user would be allowed to roll the chart into previous/next time windows corresponding to the same time range.
    - See the Web Configuration Portal section for more details on how charts can be configured for the app.
  + Statistics
    - This section would have simple statistics presented to the user based on their response data
    - Numbers such as averages, total or summations and numbers based on simple queries of response datasets would be supported.
    - The user can choose one of the below time ranges and view refreshed statistics for the same

Current Day

Current Week

Current Month

(Rollback option provided for the above three options. This allows the user to move the selected time window to the previous or next one)

Custom Start and End Date

* + - See Web Configuration Portal for more details on admin functionality for generation of stats for the mobile app.
* Study Dashboard information should be available to users even when offline.
* The Study Dashboard would also provide users with an option to ‘share’ screenshots of their dashboard information via email, with other people.

## Study Activities

* A Study can have two types of activities
  + Questionnaires
  + Active Tasks
* It is mandatory for a Study to have at least 1 activity
* Each activity will have a frequency and lifetime of validity, configurable on the Web Configuration Portal
* The admin can configure on the Web Configuration Portal, the order in which these activities need to be taken by the user

## Questionnaires

* A Study can have 0 or more questionnaires
* Each such questionnaire is a combination of one or more of the following
  + Instruction Step
  + Question Step
  + Form Step
* The steps appear in the order configured by the admin.
* Each questionnaire is available to the user in the app based on its schedule, as set by the admin on the WCP
  + The frequency for questionnaires could be one of the following
    - One-time
    - Daily
    - Weekly
    - Monthly
    - Manually scheduled periods of time
* A question step carries one question (QA) on the screen whereas a form step can have multiple questions (QA) on the screen
* Each QA in the questionnaire would consist of
  + Question text
  + The response or answer interface that could be 1 of
    - Scale (horizontal or vertical)
    - Continuous Scale (horizontal or vertical)
    - Text Scale
    - Value Picker
    - Image Choice
    - Text Choice (single select or multiple select)
    - Boolean
    - Numeric
    - Time of the day
    - Date
    - Text
    - Email
    - Time Interval
    - Height
    - Location (map location selector)
* Depending on how the questionnaire is configured on the Web Configuration Portal,
  + A form or question step may or may not be skippable
  + A step that is not skippable needs the user to mandatorily answer it before proceeding to the next step
* All validations at step level must happen before the participant moves to the next step in questionnaire
* The Questionnaire State information needs to be known to the app for handling the user experience of continued participation in a study.
* The Questionnaire state comprises of
  + Last completed action information (last screen or question the user was on)
  + Status of the Questionnaire
    - Yet to Start
    - In Progress
    - Completed (once the user submits the questionnaire from the last screen of the questionnaire)
    - Abandoned (if not completed before the questionnaire expires)
* As long as the Questionnaire is In Progress, the user should be allowed to resume the questionnaire
  + The participant can resume an ‘In Progress’ questionnaire by selecting it from the study activity list.
  + On selection, the questionnaire is created with unanswered questions only.
  + The participant will not be allowed to visit the previously answered questions.
  + Once the remaining questionnaire is complete, all responses gets submitted to

The response data storage environment.

* User’s responses for all steps in the questionnaire are only submitted to the storage environment only when the user completes and submits the entire questionnaire.
* If a questionnaire expires before completion, all responses captured until then in partial completion of the survey, are lost and no partial survey submission is made to the response data storage environment.
* Users will be able to go back and forth in a questionnaire to change responses to QA until all the responses get submitted together at the end of the questionnaire. However, the following exceptions hold good:
  + If the user happens to terminate the app (from the phone’s app switcher for example) before submitting a survey and then launches the app again, s/he would reach the study dashboard, select the same survey again and would be able to resume the questionnaire for the unanswered questions only.
  + If the user deletes the app and reinstalls it, before submitting a survey or before completing a survey, the responses collected on-device until then will be lost and she needs to start the questionnaire again.
  + Auto sign out: If the user encounters an auto-sign out (after signing in on another device for example), response data that was saved on-device until then will be lost. The user would need to take the survey from start on the new device.
  + Sign Out: If the user does an explicit sign out from the app before completing and submitting a survey, the app will attempt to submit the responses collected thus far and update the survey state on the server, before completing the sign out operation. This will allow users to resume the survey on next sign in, for the unanswered questions.
* Questionnaires can be set up in various ways to have features such as different types of branching, reading data from HealthKit etc. and with attributes that help capture anchor date, dashboard data etc. Please refer to the WCP section for more details on these aspects.

## Active Tasks

* An active task is an activity the user needs to physically or mentally perform while interacting with the app according to explicit instructions provided for the same.
* Each Study can have 0 or more active tasks
* Each active task is available to the user in the app based on its schedule, as set by the admin on the WCP
  + The frequency for questionnaires could be one of the following
    - One-time
    - Daily
    - Weekly
    - Monthly
    - Manually scheduled periods of time
* An active task can consist of 1 or more steps depending on the task that is selected for the study on the Web Configuration Portal. The steps would typically be
  + Introduction
  + Instructions
  + Active task step (where the user performs the activity)
  + Task Complete Information
* The Task State information needs to be known to the app for handling the user experience of continued participation in a study.
* The Task State comprises of
  + Last completed action information (last screen or step the user was on)
  + Status of the Task
    - Yet to Start
    - In Progress (if the user is on any of the Steps)
    - Completed (once the user completes the Task and has reached the last step)
    - Abandoned (If the user has started but not completed the Task before its lifetime expires)
* For tasks that are not Completed or Abandoned, participants would need to take the task from start each time they access the task from the activity list.
* The data captured during the Active Task is submitted to the response data storage environment at the end of the Task.
* The kind of data captured for each task will vary for each Active Task
* The following active tasks are in scope
  + Fetal Kick Counter (iOS and Android)
  + Tower of Hanoi
  + Spatial Span Memory
* The Fetal Kick Counter task
  + This is a task to allow the user to time how long it takes to feel N fetal movements (kicks) were N is a number that can be configured by an admin.
  + The active task will include a timer screen that asks the user to tap the phone whenever they feel a kick. Once N kicks are reached, the timer will stop.
  + The task will ask users to confirm final N and time before submitting. Users can edit the final count of kicks and final time if desired.
  + The task will remain active in the background if the user quits the app from the task screen.
  + Results captured for the task
    - Time taken for N kicks (this will also be a dashboard element that can be plotted in charts and stats)
    - Duration over which kick count is recorded (start timestamp, end timestamp)
    - Number of kicks recorded
* Tower of Hanoi
  + The user is asked to solve the classic Tower of Hanoi puzzle in a minimum number of moves.
  + To solve the puzzle, the user must move the entire stack to the highlighted platform in as few moves as possible.
  + This task measures the user’s problem solving skills.
  + A Tower of Hanoi task finishes when the user completes the puzzle correctly or concedes that they cannot solve the puzzle.
  + Results captured for the task
    - Puzzle solved or unsolved
    - Number of moves
* Spatial Memory Task
  + In this task, the user is asked to observe and then recall pattern sequences of increasing length in a game-like environment.
  + The task collects data that can be used to assess visuospatial memory and executive function.
  + Results captured for the task
    - Score
    - Number of games (played)
    - Number of failures

## Study Resources / Actions

* This section will have a list of helpful reading materials (resources) for the user
  + Study Overview (redirects to Overview screen)
  + Consent Document PDF
    - This will be the participant’s signed version of the Consent document
  + Protocol PDF (if available)
  + Additional Study Resources
    - These are additional resources set up by the admin via the WCP
    - Each resource is presented with
      * Title
      * Content: This could be in one of the following formats
        + Rich text
        + PDF document
  + All resources that are available in PDF form would allow the user to
    - View the PDF in a document viewer within the app
    - Email the PDF to an address of their choice using the phone’s mail client application
  + Resource content delivered to the mobile app can be tailored to each user based on their responses to study questionnaires or based on time elapsed from an ‘anchor date’. Please see the Web Configuration Portal section for more details.
* This section will also have a ‘Leave Study’ option
  + App asks for a confirmation if the user wishes to leave the study
    - As part of this, the user is shown a message about whether they can rejoin the study if they leave it AND also conveying what happens to their response data once they leave the study.
    - Depending on how the admin has set up the study, the user could be asked to choose to have their response data deleted or retained.
    - Once the user has read and agreed to the above message (and if given a choice, chosen for or against retention of response data), the app executes the Leave Study action.
  + Date of leaving the study is recorded by the app and saved on the server
  + User is delinked from the Study as an active participant.
    - User’s data related to the study, that is on-device must be deleted.
    - User’s response data on the backend must be deleted or preserved depending on how the study has been set up by the admin.
  + If the study allows participants to re-join a study, they need to undergo the eligibility, consent processes again and will be considered a new participant for the study, when they join the study again, whose response data is recorded against a new participant record for that study.

## Notifications and Reminders

* The app will receive push notifications sent from the server.
* The user can choose to allow or disallow these push notifications
* Audience for the notifications
  + All app users must receive push notifications that are ‘app-wide’ notifications
  + Only study participants with ‘Participation Status = In Progress’ must get study-related notifications
* All notifications that a user is entitled to receive must also be available in a Notifications screen in the mobile app
  + This list must be available to users even if they have disallowed push notifications.
  + This list is populated into the screen using a web service call
  + The notifications will be visibly differentiated as ‘read’ versus ‘unread’
* On tapping the notification in the push notification view or in the mobile app Notifications screen, the user must get redirect to the corresponding screen of the mobile app
* List of notification scenarios is as given below. Note that some of these can be implemented as local notifications based on the info available on device
* App wide notifications: Users must be notified when
  + A new study is available (just launched by admin)
    - Redirects to Gateway List of Studies screen
  + Admin creates an app-wide notification (based on the notification schedule set up by the admin in the WCP)
    - Redirects to Gateway List of Studies screen
* Study-related notifications: Participants enrolled in a study must be notified when
  + The study is paused or deactivated
    - Redirects to Gateway List of Studies screen
  + There is a new study activity available (applies to new runs of an existing activity as well as completely new activities)
    - Redirects to Study Activity List
  + When the run of an activity is due for completion (please see the WCP section for more details on frequencies and lifetimes of study activities).
    - Participants must be alerted that an activity is about to expire
    - These must redirect to the first step screen of the activity.
    - Such alerts are sent out in advance of the expiry by a certain lead time
    - The lead time would be configured as follows
      * One time activity
        + 24 hours before expiry
      * Daily (once a day) activity
        + Reminder will be clubbed with the daily ‘activity available’ reminder stating that the period of expiry is 24 hours.
      * Daily (multiple times a day) activity
        + Reminder will be clubbed with the ‘activity available’ reminder stating that the period of expiry is for x hours where x is based on activity schedule settings in the WCP.
      * Weekly activity
        + 24 hours before expiry
      * Monthly activity
        + 72 hours before expiry
      * Manually scheduled activity
        + Reminder will be clubbed with the ‘activity available’ reminder stating that the period of expiry is for x hours/days where x is based on activity schedule settings in the WCP.
  + Congratulatory messages indicating 50pc or 100pc completion of a Study
    - Redirects to Study Dashboard
  + Motivational messages when a user misses a study activity urging them to not miss out on the next and giving them an indicator of their overall study adherence.
    - Redirects to Study Dashboard
  + A new resource being available in the app based on the period of visibility functionality (see Web Configuration Portal section for more details on how anchor/other date can be used to show up resources in the mobile app in a time-contextual manner)
  + Additional push notifications can be managed using the Web Configuration Portal
* Users who turn off notifications for the app will be given periodic reminders once a week to turn on notifications to get latest updates.

## User Participation Statuses for a Study

* As a recap, the Study Zone has the following sections
  + Overview
  + Eligibility
  + Consent
  + Study Activities
    - Questionnaires (Question-and-answer questionnaires)
    - Active Tasks
  + Study Dashboard
  + Resources/Actions
* A user’s status with respect to a Study is defined as follows:
  + Yet to Join (includes the scenario where they have entered the Study Zone after tapping on the Join Study button from the Overview screen but haven’t yet completed the Consent process)
    - If a user revisits a Study while in this status, they must restart from the Overview step.
  + Not Eligible (if they have gone through the eligibility module for the Study and found themselves to be ineligible for it)
    - If a user revisits a Study while in this status, they must restart from the Overview step.
  + In Progress (if they have completed Consent but not yet Completed the Study)
    - If a user revisits a Study while in this status, they must directly be navigated to the Study Dashboard screen to resume participation in the Study Activities from where they last left off.
  + Completed (if they have participated in all the Study Activities AND the Study has been declared Closed by the admin)
    - If a user revisits a Study while in this status, they are directed to the Study Dashboard that will show the status as ‘Completed’
      * All dynamic elements on the Dashboard such as Current/Upcoming activities will be shown as NA.
      * Charts and stats will be displayed for the last time period prior to study completion, as per the time range configured by the admin. E.g. if the configured time range was ‘current week’, the chart will show data for the last week before study completion.
    - They will have continued access to the Study Resources section
    - The Study Activities section will be disabled
  + Withdrawn (if they have completed Consent but choose to ‘Leave Study’ before completing the Study)
    - If a user revisits a Study while in this status, they must restart from the Overview step.
    - Depending on how such Studies are configured, the user may or may not be allowed to join the Study again.

## Offline Capabilities

* The app will save the following information locally on the device for offline availability
  + Gateway Welcome screens information (hardcoded into app for current phase)
  + Gateway List of Studies
  + Study Overview Information
  + Study Dashboard Information
  + Study Activities
  + Study Resources
* Edits made to the above sections (where applicable) or response data captured as part of activities, will be stored locally on device and updated to the server upon network availability.
* Users are notified when their responses don’t get submitted due to network issues and are notified that the responses will be automatically submitted once the app has network available again.
  + If a user attempts to sign out when pushing of responses to the server is pending or in-progress, they are warned that their data will be lost upon sign out. In such cases, they can choose to sign out later.

# **Functional Specifications for the Web Configuration Portal**

## Sections of the Web Configuration Portal

* The Web Configuration Portal would have the following functional sections
  + Sign In
  + Manage Users
  + My Account
  + Manage Studies
  + Manage Repo (deferred for a future phase, currently out of scope)
  + Manage (App-wide) Notifications
* Notes
  + In the following sections and field level descriptions in this document, the \* mark against a user-input field indicates that it is a mandatory field for the user of the application, to fill in.
  + Character limits and other rules for fields would be applied during development depending on space availability on the screens, and flow-implementation necessities.
    - If this is in conflict with any business requirement (for example, needing a particular number of characters), it would be mutually discussed and agreed upon with the client
  + In cases of image upload, the field must be accompanied by an information button, that on click, provides guidelines on the image size, format etc. that can be uploaded.

## Admin Sign In

* Admins can sign in by providing
  + Registered Email\*
  + Password\*
* Help with password:
  + A Forgot Password link is provided
  + Upon submitting their registered email\*, user gets an email with a link to reset password
  + Upon successfully resetting password (with New Password and Confirm Password\* fields), user is redirected to the Sign In screen
  + The email link is valid to be used only once
* One set of admin credentials comes pre-packaged with the application

## Manage Users

* Admins can create users or manage existing user records
* Creating a user involves specifying the following
  + First Name\*
  + Last Name\*
  + Email\*
  + Phone Number
  + Pick one of a list of roles seen in a dropdown\*
    - The list of roles will be fetched from the database
  + Assign permissions (one or more of the following) \*
    - Manage Users
      * View
      * View and Edit
    - Manage Studies
      * Create a Study
      * Study-wide permissions
        + A list of Studies is shown
        + Users can be assigned one or more Studies from this list

Ability to select/de-select all studies would also be provided as part of the selection interface.

* + - * + For each study, the following permissions are available

View

View and Edit

* + - Manage App-Wide Notifications
      * View
      * View and Edit
  + Once a user is added, she gets an email with a link to Sign Up
    - The Sign Up form will pre-populate the following fields that the user can edit
      * First Name\*
      * Last Name\*
      * Email (will be non-editable)
      * Phone\*
    - The form will also allow user to set up password\* and confirm the same\*
    - The form will need the user to Agree to Terms and Privacy Policy\* before successful submission
    - The email link is valid to be used only once
    - Registered emails must be unique across the application
* Managing existing user records will have the following provisions
  + A list of WCP admin users is displayed with the following columns
    - First and last name
    - Email
    - Role
    - Actions
      * View
      * Edit
      * Deactivate
  + Ability to sort the list by column
  + Ability to filter the list by
    - Role
    - Keyword search indexing first name, last name and email
  + Ability to edit a user record
    - The following fields can be edited
      * First Name\*
      * Last Name\*
      * Email\*
      * Phone\*
      * Role\*
      * Permissions\*
    - When a user record is thus updated
      * Email uniqueness is validated
      * Upon successful update, the user is notified via email that their user record was updated by the admin
      * The user is signed out of current sessions upon next user action, and asked to sign-in again
      * If the role is updated, the new role must reflect wherever displayed across the application
  + Deactivating a user record
    - The admin can choose to deactivate an admin user
    - The deactivated user no longer has access to the application
      * Current sessions will get auto-signed out on next user action
      * Fresh sign-in attempts will throw up a message indicating that user does not have access to the app
    - The mention of such users in any other part of the application will be removed
    - Deactivated users can be reactivated at a later point
  + Users who have been invited to join the application but who haven’t set up their accounts as yet, will be displayed in the list of users but will have the Activate/Deactivate button disabled.
    - New users cannot be added with emails already utilized for such users.

## My Account

* This section is for the currently signed in user to manage their own account information
* The following fields will be allowed for edit
  + First Name\*
  + Last Name\*
  + Phone\*
  + Password\*

## Manage App-wide Notifications

* This section is for the admins to manage notifications meant for anyone who is using the Gateway app and has signed up on the same
* These notifications are not specific to any Study
* To add a notification, the admin can
  + Enter notification text\*
  + Schedule a date/time of the notification OR send it out immediately\*
* To schedule a notification, the admin can select a date and time in EST or PST time zones.
  + The notification will reach all app users as per the selected date and time
* Admins can also view a list of existing notifications and edit its text or scheduling info, if it hasn’t been sent out yet
* There will also be provisions to
  + Re-send an existing notification (immediate or scheduled) even if it has already been fired previously in the past
    - The notification details screen will maintain a log of the multiple times the notification has been sent out to users.
  + Copy an existing notification into a new one

## Manage Studies

* This section is for the admins to manage existing studies and to create new ones
* The user is presented with a list of studies that has the following columns
  + Study ID
  + Study name (shorter version)
  + Study Category
  + Project lead
  + Research Sponsor
  + Status
    - Pre-launch
      * Applicable for studies that are yet to be launched for the first time including studies that have been published as Upcoming Studies
    - Active
    - Paused
    - Deactivated
* The following actions can be taken with each study
  + View
  + Edit
  + Copy into New
    - This will go to the Create a Study flow with all fields and sections pre-populated except Study ID.
    - This is exactly similar to creating a new study except that the content is pre-filled
    - The admin would still need to take explicit actions in the ‘Actions’ screen to effect changes to study status i.e. actions such as Launch or Publish Updates.

## The Study Zone/ Creating or Editing a Study

* This comprises the following sections
  + Basic Information
  + Settings and Admins
  + Overview
  + Eligibility
  + Consent
    - Consent sections
    - Comprehension test
    - Review and e consent steps
  + Study Activities
    - Questionnaires
    - Active Tasks
  + Resources
  + Notifications
  + Checklist
  + Actions
* The following would need to be taken care of for each study
  + View and Edit permissions based on the permissions assigned to each user
  + In each screen/section, there would be action buttons called Cancel, Save, Done or Mark as Completed
    - Cancel – will redirect the user to the parent screen discarding any changes that have been done to the content on the screen.
    - Save – will save all the latest content on the screen, into the database, in draft mode
    - Done – will run any validations applicable for the screen and upon successful submission, will save latest content on the screen, into the database
    - Mark as Completed - will run any validations applicable for the section and upon successful submission, will save latest content of the section, into the database. Will also mark the section as Completed.
* The admin would first need to ‘Mark as Complete’ the Basic Information and Settings and Admins sections and can then proceed to filling up the rest of the sections in any order. The Actions section is to be typically used once all the other sections have been filled out.
* At any point, a study can have two working versions (also read the Actions section of the WCP for a better understanding of what actions are available to the admin)
  + Draft version: This will be available if
    - If the study has not been launched as yet i.e. Admin is yet to take the ‘Launch’ action with the study.
    - If the study has been launched but there are updates being made that are yet to be published i.e. there are updates available but the admin is yet to take the ‘Publish Updates’ action for these updates
  + Live Version
    - The version of the study that is currently live
    - Whenever the admin does a Launch or Publish Updates action, the draft version becomes the new live version.
* Depending on whether the study has been marked for IOS, Android or both, the WCP fields of study creation must show the admin only the values that are applicable to the selected platform(s). For example, to add an active task for a study running on both platforms, the only available active task should be the Fetal Kick Counter
* Study metadata being stored in the WCP server database would need to store versions and corresponding version content of all items of the Study that pertain to Consent and Study Activities.
  + Version numbers of these items will be 1.0 at the time of study launch and must be incremented when the admin does a successful ‘Publish Updates’ action.

## Basic Information

* The section captures basic information about the study
* The admin needs to fill in the following
  + Study ID\* – validated for uniqueness
  + Study name\*(shorter version)
  + Study full name\*
  + Study Category\*
    - Pick one from dropdown
    - Dropdown values populated from pre-defined table on the application server database
  + Research Sponsor\*
    - Pick one from dropdown
    - Dropdown values populated from pre-defined table on the application server database
  + Data Partner\*
    - Pick one or more from dropdown
    - Dropdown values populated from pre-defined table on the application server database
  + Estimated Duration in weeks/months/years\*
    - This is only for administrative information purposes
    - There is no business logic in the app that is tied to this field.
    - Input range: 1-999
  + Study Tagline\*
    - 1-line description of the study
    - Used for display in the mobile app
  + Study Description\*
    - Rich text editor
  + Study website
    - To be checked for valid website address format
  + Study Type\*
    - Gateway
      * If Gateway, a thumbnail image needs to be uploaded for display in the list view in mobile app
    - Standalone
      * Standalone studies should not appear in the Gateway app
      * Likewise, a Standalone app would cease to function (once the admin takes the Publish Updates action for the study) if its type has been changed from Standalone to Gateway

## Settings and Admins

* The section is for configuring study settings and managing admins for the study
* The following settings are available:
  + Platforms supported\* (mandatory field)
    - iOS
    - Android

(depending on this, the study will be available on one or both platforms, field-level options available to the admin for study creation in the WCP, must be restricted based on this selection accordingly)

* + Is the Study currently enrolling participants?
    - Yes
    - No (default)

(depending on this, the study in the mobile app must allow or disallow users from joining the study)

* + Allow user to rejoin s the Study once they leave it?
    - Yes (default)
    - No

(depending on this, users must be allowed to rejoin a study after they withdraw from it and if study enrollment is open for the study)

* + Retain participant data when they leave a study?
    - Yes (default)
    - No
    - Allow participant to choose to have their data retained or deleted

(based on this, participant response data must be retained or deleted in the response server database. The mobile app must also handle the Leave Study flow accordingly.)

* The admin working on this section can also manage list of admins assigned to the Study if they have the Mange User permission. Such admins will have the
  + Ability to add/delete admins from the Study and give them permissions with the study
  + Ability to mark one of the study admins as the Project Lead
    - Note that there is no business logic attached to designating one of the admins as the Project Lead except for displaying the admin’s name on labels that need to display the Project Lead for a study.
* Upon marking this section as Completed, the admin sees a warning message as follows: ‘You have chosen “ “ for the retention of participant response data when they leave a study. Your Consent Document must be worded to convey the same. Click OK to proceed with completing this section or Cancel if you wish to make changes.’ Where “ “ needs to be filled with one of Yes, No or Participant Choice depending on the admin’s selection on the screen.

## Overview

* This allows the admin to manage content for the Overview section of the Study
* The following fields are available
  + Study Video URL
  + Page 1\*
    - Image\*
    - Study Title (pre-populated) \*
    - Description (3-4 lines) \*
  + Page 2
    - Image\*
    - Title \*
    - Description (3-4 lines \*
  + Page 3
    - Image\*
    - Title\*
    - Description (3-4 lines) \*
  + Page 4
    - Image\*
    - Title\*
    - Description (3-4 lines) \*
  + Page 5
    - Image\*
    - Title \*
    - Description (3-4 lines) \*
  + The page will also show suggested topics for the above, these are just guidelines for the admin to understand what kind of content would be useful to add in the above-mentioned sections. The following are examples of suggested topics:
  + Purpose of the Study
  + Who’s conducting the Study?
  + Basic Eligibility (in bulleted point form)
  + How your data will be used?
  + What’s in it for you? Why you should be a part of the Study.

## Eligibility

* This allows the admin to manage content for the Eligibility section of the Study
* The admin has to first select the eligibility mechanism that is applicable
  + ID validation only
  + ID validation + Eligibility Test
  + Eligibility Test only
* Based on this, fields show up on-screen for the admin to fill up the corresponding sections
* ID validation
  + Admin has to
    - Enter Instructional Text
      * On-screen text: *Text that the mobile app user will see when requested for the enrollment ID to get themselves verified as eligible participants for the study*
* Eligibility Test
  + Admin can add QA content here or edit existing QA
  + Adding a QA
    - The admin would need to
      * Enter question text\*
      * Response Options are by default Yes and No
      * For each Response Option
        + Choose the Pass/Fail attribute\*
    - Additional rules
      * Both answer options cannot have Fail attribute
      * The admin is allowed to set the order of the QA
      * To be eligible for the study, the user must have scored a pass for every question answered
  + Managing the existing set of QA
    - The admin can take the following actions
      * View
      * Edit
      * Delete
      * Position as per desired order
      * Add new Question

## Consent

* This allows the admin to manage content for the Consent section of the Study
* Note that having a Consent section within a study on the mobile app is mandatory and the admin cannot choose to handle consent offline without this section being present on the mobile app
* The following subsections are available
  + Consent / educational Information
  + Comprehension Test
  + Review and E-consent
* Consent / Educational Info
  + The admin can add/manage a list of Consent Items (content pieces) under this
  + Each content item can be one of the two types
    - ResearchKit provided Consent item
      * ResearchKit already provides a few Consent Items screens by default.
      * The UI for such screens is already built out by the framework with the relevant onscreen GIF image and its animation.
      * These Consent Items allow the title and text to be modified as needed
    - Custom-defined Consent item
      * These are to be used in cases where the available ResearchKit list of Consent Items do not suffice
      * Admins would be able to define the title and content text for each item but the UI for all such Consent Items will follow a standard default UI that the mobile app spins up. The UI cannot be tailored for each custom Consent Item.
  + To add a Consent item, the admin needs to specify the following
    - Consent Item Type\*
      * ReseachKit
      * Custom
    - Title\*
      * Picked from a dropdown if type ResearchKit
        + Once the admin selects this, they will be presented with another field calling ‘Display Title’ to modify the default title as suited to their study.
      * Entered manually if Custom
    - Content needs to be added in text form\*
      * A brief summary\* (3-4 lines)
      * An elaborated version of content on the Consent Item\*
    - Choose display level\*
      * Show as a visual step in the Consent Info section? Yes / No
        + If the admin selects No here, the item is made a part of the Consent Document but is not shown as a visual step/screen in the Consent Info section on the mobile app
  + The admin can decide the order in which the content items are seen in the mobile app
* Comprehension Test
  + The admin can mark whether or not this is required for the Study\*
  + If required, the admin will need to
    - Add QA content
      * Add Question text\*
      * Answer Options \*
      * Mark each answer option as Correct/Incorrect\*
      * Mark correct response to the question as being ANY or ALL of the ‘correct’ answer options
    - Specify order of the questions
    - Specify the minimum score needed to pass the test
* Review and E-Consent
  + This consists of the following sub-sections
    - Share Data Permission
      * This is a section that allows admins to specify if as part of the Consent process, participants need to be asked to provide permission for their response data to be shared with 3rd parties.
      * The admin can
        + Choose if this is needed in the app\*
        + If needed, specify the following

On-screen text:

Title\*

1 line description or tagline\*

Short Description for RO\* (Research Organization or Data Partner)

Long Description for RO\* (Research Organization or Data Partner)

Learn More text\*(elaborated Content that explains how data will be shared)

* + - * + See a preview that showcases how the fields entered above would translate to the screen on the mobile app
        + Choose app behavior based on permission

Allow user to proceed if permission not provided? Yes/ No

* + - Consent Document for Review
      * This section is meant for the admin to confirm the content seen by users in the Review Terms (Consent Document) screen on the mobile app
      * Each time a change is made to the Consent Items or the Share Data permissions, the admin must be automatically redirected to the Consent Document Review step and must mandatorily review and confirm the Consent Document in order for the changes to be saved as a new version of Consent Document.
      * The content for this section can be generated in the following ways:
        + The elaborated versions of each consent item in the Consent information section are concatenated together to form the Consent document

These portions cannot be edited by the admin. If they need to be edited, the admin would need to do it in the Consent Info section

* + - * + Alternatively, the admin can choose to have an entirely new text content provided in RTE for the Consent Document content in a formatted manner.

Content would need to be keyed into a RTE

If this option is selected, the Consent Items are not used to create the Consent Document.

They will still appear as Visual Steps in the Consent Info section if the admin has chosen to allow this in the ‘Choose Display Level’ field.

Also, the admin is warned that if this option is chosen for the Consent Document, the PDF generated on the mobile device for the Consent Document cannot capture the user’s first name, last name, signature or date/time of providing consent as part of the Consent Document.

This provision only works for the Consent Document created using concatenated Consent Items.

At the end of the Consent section, as the last step for the admin to freeze the Consent Document, the admin is shown a warning message when the changes are saved. “You have a setting that allows study data to be retained /deleted or left to participant choice even if the participant withdraws from the Study. Please ensure you have worded Consent Terms in accordance with this. “. The message will have OK and Cancel options

Additionally, if the admin has opted to have the Share Data permissions for the Study, they see the following warning

‘You have chosen to ask users to provide permission for sharing their data with 3rd parties. Please ensure you Consent Document is worded accordingly.’ The message will have OK and Cancel buttons.

* + - E-consent form
      * The admin sees the elements of the e-consent form as provided to the user in the mobile app
      * Elements on the e-consent form
        + Agree/Disagree to Study Consent terms

Admin can define a message (in a text area) to be shown to users to confirm they have read and agree to the Consent Document content.

Note to admin: Text message on app to confirm review and agreement of the Consent Document

* + - * + First name
        + Last name
        + E-signature
* The Consent Document gets updated each time there is an update to the Consent Items resulting in an update to the Consent Document, or an update made directly to the Consent Document in the Consent Document review sections
  + Upon successful publishing of these updates by the admin, the Consent Document should be recorded against a new version in the WCP database.
* Study participants must be made to go through the Consent process again on the mobile app each time there is a new Consent Document version available.
  + If they are actively midway with an activity, they would be allowed to complete it before going through the new Consent

## Study Activities

* This is where the admin can manage a list of questionnaires and tasks for the study
* It is mandatory for the app to have at least one activity prior to launch and each time updates are published.
* The admin can take the following actions
  + Create a new questionnaire or task
  + View/edit an existing questionnaire or task
    - The WCP database maintains version information in such cases.
    - Each time the admin does a ‘Publish Updates’ action for these updates, the activity must get saved against a new version.
    - Content and date/time of creation of each version also needs to be maintained for referencing purposes
    - Note: When responses are submitted from the mobile app, they must carry the activity ID and version number.
  + De-activate an activity
    - This will no longer allow the activity to be edited
    - This will no longer allow the activity to present itself in the mobile app

## Questionnaires

* A Study can have 0 or more Questionnaires
* Admins can manage a list of questionnaires for the study
  + View
  + Edit
  + Delete

## Questionnaire Concepts

* A questionnaire is a set of one or more ordered set of steps (screens on the mobile app)
* Each step corresponds to one screen on the mobile app
* Each step can be one of the following types
  + Instruction Step
    - Lays down instructions for the user
  + Question Step
    - Carries one QA per screen
  + Form Step
    - Carries multiple QA per screen
* Repeating a set of QA in a questionnaire
  + There might be cases when it is necessary to repeat a set of QA for the participant to respond to
  + This can be handled using a Form Step by creating the repeatable set of QA within a form and applying a repeatable property to it.
  + This is done as follows:
    - While creating a Form Step, the admin can check a box that says ‘Allow form repetition’
    - Once this box is checked, the admin needs to specify the text for a button that will make the form grow (with a vertical or horizontal scroll on the mobile app) at runtime in the app. For example, the button text could be ‘I have more medications to add’ or simply ‘Add More’
    - When the mobile app user clicks this button on the form in the app, the set of QA present in the form will get repeated for them to fill in responses.
    - The button will persist on the Form Step for the user to use for as many as repeatable sets as is required.
* Branching Logic and Conditional Navigation
  + This is the ability to decide on a particular ‘path’ or ‘route’ of steps the participant must take within the questionnaire based on the responses they provide to QA.
  + Route definition is achieved with the help of the following
    - Master order of the steps as set up by the admin – this is the default route
    - Destination step attribute provided at the answer option level for each QA that will help determine if the participant needs to follow a new branched out route
  + In creating the steps, assigning destinations to QA answer options and thereby creating routes for a participant in a questionnaire, no two steps must ever appear more than once in the same route
    - This means that the participant must encounter each step in their ‘route’ of steps within a questionnaire, only once.
  + Every questionnaire by default ends with an in-built step called the Completion Step which denotes the end of the questionnaire activity in the mobile app. If no destination is provided for a particular step and if there is no next step available in the default route of steps, the application considers the next step in the route to be the Completion Step that will end the survey or questionnaire.
  + Note that while specifying destination steps, the admin can choose not only from existing steps but also opt to choose the Completion Step as the destination.
  + Branching within a form would not be allowed
    - This means that destination steps for QA within a form would not be available for the admin to configure.
* Populating a follow-up QA with content based on the response given by the participant to a prior QA
  + This can be achieved by using branching logic
  + The admin would need to create a new QA for each possible variant of the response that might be chosen by the participant in the original question
  + Once these QA have been created, the admin needs to define them as destination steps for each applicable response that is possible to have for the prior question.
    - It is not mandatory to have a destination for response option or value in the prior question.

**Adding/editing a questionnaire**

* To add/edit a Questionnaire, Questionnaire Content and Scheduling must be managed

## Questionnaire Content

* + The admin must first specify
    - Activity Short Title or Key\*
      * A human readable step identifier and must be unique across all activates of the study
    - Activity title (used for display in the mobile app)
  + The admin can create the questionnaire content by adding one of these two types of content/screens
    - Instruction Step
    - Question Step
    - Form Step
  + Once steps are created and added to the questionnaire, a list of steps is available for viewing.
  + The list has the following information
    - Type (color coded)
    - Position or order
    - A teaser view of the instruction/question/form title
    - Indicators to mark whether the QA uses
      * HealthKit
      * Is of type Date format
        + Colored if used as anchor date
      * Has numeric/double data types as response captured
        + Colored if used for dashboard
  + The following actions can be taken with the existing list of Steps
    - * View
      * Edit
      * Delete
      * Reorder
  + Branching: There would be an option to “Apply Branching’ to the questionnaire
    - If this option is exercised, each step in the list of steps would get a default ‘destination step’
    - This is the step the user must land on after completing the current step if there is no other condition applied at step level that will necessitate going to another step
    - By default, the destination step will be the next step in the master order of steps created by the admin
      * This can be over-ridden at step level
    - When branching is applied, each step in the list of steps must show an indicator of the destination step it has.
      * Destination step information is shown with Step Position and Short Title or Key

## Adding an Instruction Step

* + To add/edit an Instruction Step, the admin would need to fill in the following fields
    - Step title or Key\* (1 to 15 characters)
      * *A human readable step identifier and must be unique across all steps of the survey*
    - Step Type (non-editable)
      * Instruction Step
    - Instruction Title\*
    - Instruction Text\*

## Adding a Question Step

* + To add/edit a Question Step, the admin has to fill up 3 subsections
    - Step-level attributes
    - Question-level attributes
    - Response-level attributes

Note: Question-level attributes and Response-level attributes together define a QA in a survey. The attributes may slightly vary depending on whether the QA is used in a form step or question step.

* + **Step-level attributes**
    - Step title or Key\* (1 to 15 characters)
      * Note to admin: A human readable step identifier and must be unique across all steps of the survey
    - Step Type
      * Question Step
    - Default Destination Step\*
      * Note to admin: The step that the user must be directed to from this step
      * Dropdown selection (eg value = **Step 4**: DosageQuestion)
  + **Question-level Attributes**
    - Text of the question\*
      * Note to admin: The question you wish to ask the participant
    - Description of the question
      * Note to admin: Enter a line that describes your question, if needed
    - Is this a skippable question? Yes/No
    - Response Type\*
      * Note to admin: The type of interface needed to capture the response
      * Selected from dropdown e.g. numeric open response
    - Description of response type (non-editable field)
      * Note to admin: A numeric answer format to provide response using a numeric keyboard.
    - Data Type (non-editable field)
      * Double
    - Add response data to line chart on app dashboard?
      * Yes/No (show expanded fields if it is Yes)
    - Use response data for statistic on dashboard?
      * Yes/No (show expanded fields if it is Yes)
  + **Response-level attributes (this set of attributes will vary based on the response type, as captured in the Appendix section)**
    - Response Type\* (non-editable field here)
      * Note to admin: The type of interface needed to capture the response
      * Numeric open response
    - Description of response type (non-editable field)
      * Note to admin: A numeric answer format to provide response using a numeric keyboard.
    - Data Type (non-editable field)
      * Double
    - Style
      * Integer
      * Decimal
    - Units (1 to 10 characters)
      * Note to admin: Units to be displayed for the field
      * (Text box to enter text)
    - Placeholder Text (1 to 15 characters)
      * Note to admin: Text that must be seen inside the field as a hint to the participant
      * (text box to enter text)
  + Notes on special cases of response types and additional response-level attributes:
    - If a QA has a text choices type of response with single-select mechanism
      * Allow the admin to specify a destination step for each answer option
      * If no destination is provided, the next step in the default order becomes the destination
      * Note: If there is branching logic applied in a questionnaire, every step must mandatorily have a destination step defined for each path/route chosen including the default one.
    - If a QA that has a date response type will have the following additional attribute to allow definition of an anchor date for the study
      * A checkbox called ‘Use for Anchor Date’
      * Selecting this would mean that the mobile app uses response data from this question, will become the Anchor Date for that user for the study
      * If this attribute is selected and if the parent questionnaire has a recurring frequency, the admin is informed that they first need to change the frequency to make it a one-time questionnaire in order to use this attribute.
    - If the response type is of data type such as numeric or double, the admin can

To define a condition and define a destination step to be applicable if TRUE and an alternative destination step if FALSE

To define the condition, the admin would be able to use simple operators to define mathematical or logical conditions with the variable that is the participant response. For example, the condition could be x > 5, where x is the person’s number of years spent experiencing a condition. So if this is TRUE based on participant response value given for x, the next step to show up would be a particular destination step as defined by the admin.

The condition will be defined by a series of steps that helps create a formula

This involves selecting from function types that allow for basic mathematical and logical operators such as +, -, /, \*, > , <, AND, OR

For each function type, the admin must select the inputs to the function

The inputs could be

Response element (variable)

Another function

Constant value

For each function that gets inserted to the formula, the admin needs to again define the inputs to that function

This continues in a nested manner until the formula is created completely with every function being defined with its inputs.

Note for functions such as sum or product, the user can choose to add more than two inputs to the function using a + button

The condition/formula defined by the admin may result in a TRUE or FALSE output, upon running it with response data replacing the variable. A destination is provided for each case. In both cases of TRUE and FALSE, if no destination is provided, the next step in the default order becomes the destination

To help the admin follow the right syntax in defining the condition, on-screen help tips would be available.

Also, a Formula Preview Calculator would be provided for admins to

View the created formula

Provide an input for the variable

View the output and confirm if the formula is working as expected

Output would be the actual result of the calculation as well as the TRUE/FALSE output

* + - If the response type is of data type such as numeric or double, the admin can also choose to

Allow the user to provide the response by having the app read a value from HealthKit (applicable for iOS only)

If this option is selected, admins would need to select ONE of a pre-defined list of HealthKit quantity data types as the source of the data

A note is provided to admins as follows:

Please note that only the most recent value available in HealthKit would be read by the app

Access to HealthKit data is subject to the user providing permissions for the app to read the data

* + - * At the time of running the questionnaire in the mobile app, the participant would be asked if they will allow the app to read data from HealthKit on their device
        + If the permission is provided, the answer(s) on the step screen is pre-populated with response data from HealthKit and the user can edit it if needed, before submitting the responses.

## Adding a Form Step

* + To add a Form Step, the admin would need to fill in
    - Two sets of attributes namely,
      * Step Level Attributes
      * Form level attributes
  + **Step-level attributes**
    - Step title or Key\* (1 to 15 characters)
      * Note to admin: A human readable step identifier and must be unique across all steps of the survey
    - Step Type
      * Form Step
    - Is this a skippable Step? (Yes/No)
    - Default Destination Step\*
      * Note to admin: The step that the user must be directed to from this step
      * Dropdown selection (e.g. value = **Step 4**: DosageQuestion)
  + **Form-level Attributes**
    - Make form repeatable? (Yes/No)
      * If Yes,
        + Repeatable Form Button text
        + Note to admin: Enter text the user should see and tap on, to repeat the form. Eg. I have more medications to add
    - A list of QA that make up the Form with the following actions for each
      * View
      * Edit
      * Reorder
      * Delete
    - A button to ‘Add New Question”
    - On click of Add/Edit Question within the Form-level attributes
      * The admin is navigated to a new screen that has the following
        + Question-level attributes (same as that for Question Step with the exception of the Skippable property)
        + Response-level attributes (same as that for Question Step)

## Questionnaire Scheduling

* + - The frequency of a questionnaire decides its schedule i.e. how often the user needs to take it
    - Each time a questionnaire appears in the app by virtue of the frequency assigned to it by the admin, it is said to be a unique ‘run’ of the questionnaire
    - The lifetime of each run of the questionnaire is the time span for which it is considered valid for the user to participate in.
    - The lifetime of the questionnaire as a whole is the time period for which it is available in the app (in the form of multiple runs where applicable).
    - The admin can choose one of the following frequencies for the questionnaire and set the associated fields accordingly.
      * One time
        + Date/Time of launch\* (pick one)

Launch with study

Choose start date/time

* + - * + Lifetime of the questionnaire\* (pick one)

Study Lifetime

Choose end date/time

* + - * Daily
        + Time(s) of the day for daily occurrence\*

Allow user to select one or more times

* + - * + Start date (pick a date) \*
        + Number of times to repeat the questionnaire\*

(text box for entering a number)

* + - * + End date

(display only)

* + - * + Lifetime of each run of the questionnaire = Until the next run comes up
        + Lifetime of the questionnaire

Display - Start Date – End Date

* + - * Weekly
        + Day/Time (of the week)\*
        + Start Date\*
        + Number of times to repeat the questionnaire\*

(text box for entering a number)

* + - * + End Date

(Display only)

* + - * + Lifetime of each run of the questionnaire = Until the next run comes up
        + Lifetime of the questionnaire

Display - Start Date – End Date

* + - * Monthly
        + Select Date/Time (of the month)\*

Show a note “If the selected date is not available in a month, the last day of the month will be used instead.”

* + - * + Start Date\*
        + Number of times to repeat the questionnaire\*

(text box for entering a number)

* + - * + End Date

(Display only)

* + - * + Lifetime of each run of the questionnaire = Until the next run comes up
        + Lifetime of the questionnaire

Display - Start Date – End Date

* + - * Manually Schedule
        + Select time periods

Choose start and end date with time stamp of each\*

Add multiple start/end times as needed.

* + - * + Lifetime of each run = As defined by the start and end times selected above
      * Notes
        + If a questionnaire run is missed by the user, it doesn’t queue up in the app. It gets replaced by the next one as per scheduled frequency
        + All questionnaires show up on the app based on the schedule set by the admin but with the mobile device time zone as the reference.
        + Once a study is launched, the questionnaire schedule cannot be edited on the WCP. This functionality will be enabled only in the last sprint of the current phase of the project.

## Active Tasks

* Each Study can have 0 or more active tasks
* Admins can manage a list of tasks for the study with the following actions
  + View
  + Edit
  + Delete
* To add/edit a task, the admin needs to
  + Select task type
  + Set configurable parameters
  + View result types and select ones to add to dashboard charts/stats.
* The list of fields per task is as given below
* Fetal Kick Counter
  + This task records fetal activity for a given duration of time, in terms of the number of times the woman experiences kicks.
  + Activity Short Title or Key\*
    - A human readable step identifier and must be unique across all activates of the study
  + Display name\*
    - A name that gets displayed for the task in the app
  + Configurable parameters
    - Instructions\*
      * Text Area
    - Duration over which to record the kick count\*
      * (>0, < 24 value in hours, decimals allowed)
  + Results captured from the task (display only)
    - Duration over which kick count is recorded
    - Number of kicks recorded
      * Add response data to line chart on app dashboard?
        + Yes/No (shows expanded fields if it is Yes)
      * Use response data for statistic on dashboard?
        + Yes/No (shows expanded fields if it is Yes)
* Tower of Hanoi
  + This task measures a person’s problem-solving skills
  + Activity Short Title or Key\*
    - A human readable step identifier and must be unique across all activates of the study
  + Display name\*
    - A name that gets displayed for the task in the app
  + Configurable parameters
    - Instructions \*
      * Text Area
    - Number of Disks\*
      * Pick number from dropdown (1 to 10)
  + Results captured from the task (display only)
    - Puzzle Solved / Unsolved
    - Number of Moves
      * Add response data to line chart on app dashboard?
        + Yes/No (shows expanded fields if it is Yes)
      * Use response data for statistic on dashboard?
        + Yes/No (shows expanded fields if it is Yes)
* Spatial Span Memory
  + The task collects data that can be used to assess visuospatial memory and executive function.
  + Activity Short Title or Key\*
    - A human readable step identifier and must be unique across all activates of the study
  + Display name\*
    - A name that gets displayed for the task in the app
  + Configurable parameters
    - Instructions\*
      * Text Area
    - Initial Span\* *(The sequence length of the initial memory pattern)*
      * Numeric text box
    - Minimum Span\* *(The minimum pattern sequence length)* 
      * Numeric text box
    - Maximum Span\* *(The maximum pattern sequence length)* 
      * Numeric text box
    - Play Speed\* *(The time per sequence item; a smaller value means faster sequence play.)* 
      * Select time interval in seconds
    - Maximum Tests\* *(The maximum number of rounds to conduct)* 
      * Numeric text box
    - Maximum Consecutive Failures\* *(The maximum number of consecutive failures the user can make before the task is terminated.)* 
      * Numeric text box
    - Require Reversal? \* (Boolean value that indicates whether to require the user to tap the sequence in reverse order.)
      * Yes/No
  + Results captured from the task (display only)
    - Score
      * Add response data to line chart on app dashboard?
        + Yes/No (shows expanded fields if it is Yes)
      * Use response data for statistic on dashboard?
        + Yes/No (shows expanded fields if it is Yes)
    - Number of Games
      * Add response data to line chart on app dashboard?
        + Yes/No (shows expanded fields if it is Yes)
      * Use response data for statistic on dashboard?
        + Yes/No (shows expanded fields if it is Yes)
    - Number of Failures
      * Add response data to line chart on app dashboard?
        + Yes/No (shows expanded fields if it is Yes)
      * Use response data for statistic on dashboard?
        + Yes/No (shows expanded fields if it is Yes)
  + Active Task Scheduling
    - The frequency of a task decides its schedule i.e. how often the user needs to take it
    - Each time a task appears in the app by virtue of the frequency assigned to it by the admin, it is said to be a unique ‘run’ of the task
    - The lifetime of each run of the task is the time span for which it is considered valid for the user to participate in.
    - The lifetime of the task as a whole is the time period for which it is available in the app (in the form of multiple runs where applicable).
    - The admin can choose one of the following frequencies for the task and set the associated fields accordingly.
      * One time
        + Date/Time of launch\* (pick one)

Launch with study

Choose start date/time

* + - * + Lifetime of the task \* (pick one)

Study Lifetime

Choose end date/time

* + - * Daily
        + Time(s) of the day for daily occurrence\*

Allow user to select one or more times

* + - * + Start date (pick a date) \*
        + Number of times to repeat the task \*

(text box for entering a number)

* + - * + End date

(display only)

* + - * + Lifetime of each run of the task = Until the next run comes up
        + Lifetime of the task

Display - Start Date – End Date

* + - * Weekly
        + Day/Time (of the week) \*
        + Start Date\*
        + Number of times to repeat the task \*

(text box for entering a number)

* + - * + End Date

(Display only)

* + - * + Lifetime of each run of the task = Until the next run comes up
        + Lifetime of the task

Display - Start Date – End Date

* + - * Monthly
        + Select Date/Time (of the month) \*

Show a note “If the selected date is not available in a month, the last day of the month will be used instead.”

* + - * + Start Date\*
        + Number of times to repeat the task \*

(text box for entering a number)

* + - * + End Date

(Display only)

* + - * + Lifetime of each run of the task = Until the next run comes up
        + Lifetime of the task

Display - Start Date – End Date

* + - * Manually Schedule
        + Select time periods

Choose start and end date with time stamp of each\*

Add multiple start/end times as needed.

* + - * + Lifetime of each run = As defined by the start and end times selected above
      * Notes
        + If a task run is missed by the user, it doesn’t queue up in the app. It gets replaced by the next one as per scheduled frequency
        + All active tasks will show up on the app based on the schedule set by the admin but with the mobile device time zone as the reference.
        + Once a study is launched, the task schedule cannot be edited on the WCP. This functionality will be enabled only in the last sprint of the current phase of the project.

## Study Activities: Adding elements to the Study Dashboard

* The admin can choose to add a response data element to the study dashboard in the form of line charts or statistics
* This can be done by opting at a QA level or active task level, to add a certain response data element or result type (in case of active task) to the dashboard as a line chart of statistic.
  + This must be followed by setting up up the configurable attributes of the chart or statistic.
* Only response data elements that are numeric (double data type) in nature can be added to the dashboard and so, the chart/stat options are only provided for
  + QA having response types
    - Scale
    - Continuous Scale
    - Numeric
    - Time Interval
    - Height
  + Active Tasks results of data type numeric or double
    - Please see Active Task section for the list of results that have this option
* The provision to ‘add line chart’ is also not available if the frequency of the activity is set to ‘one-time’
* Adding a line chart to the dashboard needs the admin to specify the following
  + Time range for the chart\*

The options available here depend on the scheduling frequency set for the activity

* + - If Frequency = daily (once)
      * Days of the current week
      * Days of the current month
    - If Frequency = daily (multiple times a day)
      * 24 hours of current day
        + Note to admin: The number of X axis divisions = number of runs defined within a day
    - If Frequency = weekly
      * Weeks of the current month
    - If Frequency = Monthly
      * Months of the current year
    - If Manual schedule, then
      * Run-based
        + Note to admin: A max of x runs will be displayed in each view of the chart.
  + Allow rollback of chart?
    - Yes/ No
    - Note to admin in an I (information) icon: The chart will be allowed to rollback until the date of enrollment into the study.
  + Title for the chart\* (30 characters max)
    - Text box
* Adding a statistic to the dashboard needs the admin to specify the following
  + - * + Short name\* (20 char max) - should be unique across all Stats in the Study

Text box

* + - * + Display name for the Stat\* (e.g. Total Hours of Activity Over 6 Months) (50 char max)

Text box

* + - * + Display Units\* (e.g. hours) (15 char max)

Text box

* + - * + Stat Type for image display\*

Choose from dropdown (pre-defined types – TBD by client)

Activity

Sleep

Weight

Nutrition

Heart Rate

Blood Glucose

Active Task

Baby Kicks

Other

* + - * + Formula for to be applied\*

Summation of responses gathered over specified time range

Average of responses gathered over specified time range

Maximum of a set of responses gathered over specified time range

Minimum of a set of responses gathered over specified time range

* + - * + Time ranges options available to the mobile app user (applicable for all Statistics, in common) – display only

Current Day

Current Week

Current Month

*Note to the admin: A Rollback option will be provided for the above three options*

Custom Start and End Date

## Study Resources, Branding and Notifications

* Resources
  + This section allows the admin to manage Resources content for the Study
  + The admin can view, edit or delete existing resources
  + The admin can also add a new resource by
    - Adding a title\*
    - Adding content\*
      * Rich text editor OR
      * Upload a PDF
  + There will be a pre-defined Resource field for uploading the Protocol PDF of the study. However, this is not a mandatory resource.
  + The admin can choose to time the delivery of resource content to users of the mobile app by defining a Period of Visibility for it in the following way
    - Define an anchor date (can be done while creating a questionnaire)
    - Once the anchor date has been defined, the next step is to set up the resources to appear in the mobile app at the right time.
      * Towards this end, the admin would mark for each resource created for the study, a 'period of visibility in the app'
      * This is marked by defining a start date and end date\*.
      * The start and end dates would be in the form of time elapsed from the anchor date. For example, the admin for a pregnancy study could choose to show the 2nd trimester related PDF from 'anchor date+ 90 days' to 'anchor date + 180 days' where anchor date = the date the woman conceived.
    - The admin can also choose to set a custom start and end date for defining the period of visibility for the resource.
    - The end date for a POV must always be greater than the start date and the start date must fall on a date greater than or equal to Study Launch Date.
      * This is validated at Study Launch
  + The admin must also define a text for the notification\* that must go out to the user each time a new resource is added (if there is no period of visibility defined) OR each time a resource becomes available to the user based on the period of visibility that has been defined.
    - This notification must reach users for all instances of new resource availability except those that coincide with study launch.
* Branding
  + THIS SECTION HAS BEEN DEFERRED FROM CURRENT PHASE TO A FUTURE PHASE
  + The mobile app should still be created so as to allow for selected colors to be applied for background and tint when a new executable file is created for a Standalone app.
  + Deferred scope:
    - The admin can specify the following for branding purposes in the mobile app
      * Choose a color for
        + Background
        + Tint (primary color)
      * User is allowed to see a preview of one screen of the mobile app, with the colors selected
      * Upload logo image
* Notifications
  + This section is for the admins to manage notifications specific to a Study
  + Such notifications only reach mobile app users who have joined the Study
  + To add a notification, the admin can
    - Enter notification text
    - Schedule a date/time of the notification OR send it out immediately
  + Admins can also view a list of existing notifications and edit its text or scheduling info, if it hasn’t been sent out as yet
  + There will also be provisions to
    - Re-send an existing notification (immediate or scheduled) even if it has already been fired in the past
      * The notification details screen will maintain a log of the multiple times the notification has been sent out to users.
    - Copy an existing notification into a new one

## Checklist

* The section has a set of checklist items that the admin can mark as completed as and when they are done
* There is no business logic tied to admin actions here except for the following
  + If any of the items are left unchecked, the admin sees a warning if they attempt to publish as upcoming, launch or publish updates for a study.
* List of items in the checklist is configured via a pre-defined table in the application server database

## Actions with a Study

* The admin can take the following actions for a Study
  + Publish (as Upcoming Study)
    - Allowed if Study hasn’t been launched as yet
    - Not allowed, if the dates for study activities or resource availability are already crossed – in such cases the user needs to modify the dates and try again
    - Not allowed if the Participant Enrollment status information is set to Yes in the Basic Information section
    - A warning is shown if the checklist items are not all marked as complete OR if individual sections of study creation are not all marked as completed.
    - Outcomes
      * The Study starts appearing in the Gateway app under the Upcoming Studies list
      * Mobile app users can only explore such studies but won’t be able to join them as yet
      * The actions screen must refresh to show the status as ‘Published as Upcoming’ and allow for an ‘Unpublish’ action.
  + Start / Launch
    - Allowed if Study hasn’t been launched as yet
    - Not allowed if individual sections of study creation are not all marked as completed.
    - Not allowed, if end dates for study activities or resource availability are already crossed – in such cases the user needs to modify the dates and try again
    - Following warnings are shown prior to confirming the launch
      * Participant Enrollment Status information
      * A warning is shown if the checklist items are not all marked as complete
    - Outcomes
      * The Study starts appearing in the Gateway app
      * Participants can enroll for the Study if enrolling status is set to Yes on the Web Configuration Portal
      * Once this action is taken, the admin will not be allowed to change the Study Settings (data retention policy) going forward. This is because some users would have already consented to and joined the Study and the app cannot apply one property to old users and another to new users.
      * The Launch Study action can be taken only once in the lifetime of a study.
  + Publish Updates
    - This is for the admin to publish updates made to the Study while in Draft mode
    - This action is applicable for studies that have already been launched and which are in active state.
    - Not allowed if individual sections of study creation are not all marked as completed.
    - Not allowed, if end dates for study activities or resource availability are already crossed – in such cases the user needs to modify the dates and try again
    - Following warnings are shown prior to confirming the launch
      * Participant Enrollment Status information
      * A warning is shown if the checklist items are not all marked as complete
  + Pause or Resume
    - Pause is allowed if the Study has already been launched at a point in the past
      * Outcomes
        + Participant gets a notification
        + The Study is seen in the mobile app in Paused state
        + Participant is denied access to the Study in the app except Resources and Dashboard section
    - Resume if the Study is in the Paused state
      * Outcomes
        + Participant gets a notification
        + The Study is seen in the mobile app in active state
        + Participant is given access to the Study in the app
  + Deactivate
    - This is to be used if the Study has to be closed.
    - Notes
      * The Study must have been Launched already to be in deactivated state
      * Outcomes
        + Participant gets a notification and an email
        + The Study moves to the List of Closed Studies for users who were part of it and is taken off the app for other users
        + Data of the Study as saved on the WCP will be retained
        + Data of the Study on the mobile app is deleted
        + A deactivated Study cannot be reactivated.

# **Security and FISMA compliance**

* A set of controls would be implemented as functional and non-functional aspects of the WCP and mobile applications, to achieve the required level of security and FISMA compliance for this project.
* The list of security measures and controls that will be implemented, will be documented and shared with HPHCI for approval.

# **Non-Functional Requirements**

* The system must be able to cater to a growing participant base
* The WCP will be designed to be responsive
* The following devices will be supported
  + iOS device support: iPhone 6 and 7 series, running iOS version 9 series or 10 series
  + Android device support: Device resolutions of xhdpi, xxhdpi, xxxhdpi with Android version support of 4.4 and above. Two devices will be covered in testing.
* The mobile apps and the Web Configuration Portal will be designed to support additional languages in the future.
  + All app specific content (labels, buttons etc.) will be configured for English but can support additional languages by adding language bundles for each additional language
  + N**ote:** Since the study content is retrieved from the backend, there would need to be changes to the backend infrastructure components to support additional languages
* The apps will be available on the app stores and the client will need to have an Apple Developer Account and Google Play Store Account, to deploy the apps on the respective stores

# **Out of Scope**

* Providing option to choose language in the app (the app will be designed to be flexible to add multiple-language support in the future)
* Integrating with any other APIs or 3rd party systems other than the mobile infrastructure web services API
* Analyzing the data collected and stored via the mobile app as a part of the study
* Support for active tasks other than those specified in this document
* Anything that is not called out as a requirement in this document