FDA My Studies

Release 2019.05

(WCP Application, User Registration Server, iOS App, Android App, Resources and Response Server)

Setup Instructions

Version 1.0

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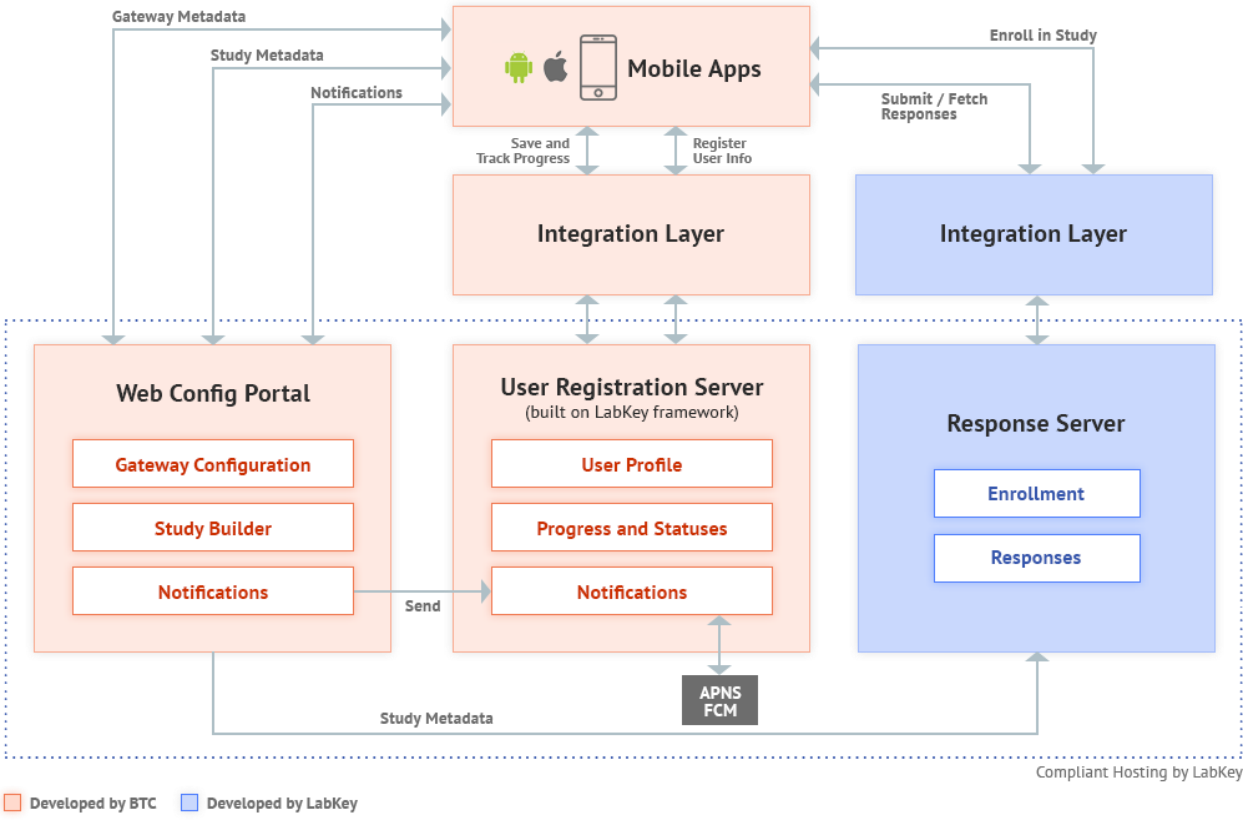
1 High-Level Technical Architecture



1.1 Components

Web Configuration Portal (WCP)

The Web Configuration Portal is a web-based application that provides mechanisms to create and manage content for studies that can be made available to patients/participants via the mobile apps. It also provides corresponding 'Metadata' webservices to the mobile apps, and to the Response server that holds the data or 'responses' provided by participants as a result of their participation in the mobile-app based study.

The WCP application is built on Java.

The WCP allows you to

- Manage Users of the WCP (also referred to as Admins, WCP 'Users' would typically be researchers carrying out the study)
- Manage App-level Notifications
- Create New Studies or View/Edit/Manage existing ones.

- For each study,
  - Set up Study Information and Settings
  - Set up Eligibility and Informed Consent Modules
  - Set up Study Activities (Surveys or Questionnaires, and Active Tasks)
    - This includes setting up activity content and schedule
  - Set up Study Resources
  - Send out Study-specific Push Notifications
  - Take actions with a Study such as Launch Study, Publish Updates, Deactivate etc.

Push Notifications:

Notification content that is created in the WCP is sent over to the User Registration Server, whose web services are utilized for the same. The User Registration server then actually sends out the notification to mobile app users that are the intended audience for the notification.

User Registration Server

('User' refers to the mobile app user or study participant)

The User Registration server is built on the LabKey framework. It leverages LabKey's User and Registration modules to provide registration services for mobile app users. It helps manage the mobile app user's app activity and maintains the user's app usage and study participation metadata. This server however, does not contain any actual Study 'Response' data (Response Data is saved in the Response server against an anonymized Participant ID).

The User Registration server is thus primarily used for the following

- User Registration (Handling App Sign Up and Sign In related flows)
- User Profile and App-level Preferences
- User's App Usage and Study-specific Participation Metadata (study participation status, activity completion status etc.)
- Firing Push Notifications to Mobile App Users

Mobile Applications

- FDA MyStudies comprises of iOS and Android mobile apps intended for study participants to use. These apps helps capture study data from participants via surveys and active tasks, after taking them through a process of ascertaining eligibility to participate in the study, and providing electronic informed consent.

- The iOS app leverages Apple's ResearchKit framework and the Android app leverages ResearchStack to present studies for users to enroll and take part in.

Response Server

Response server is built by LabKey. It is the data store for the responses captured from mobile app users. It also provides access to this data to authorized members of the research team, for analysis purposes.

The Response Server thus primarily facilitates the following:

- Participant Enrollment into a Study
- Response Data Storage
- Access to the Response Data for analysis

2 WCP and Webservices Setup Instructions

2.1 Installation Required

2.1.1 Java 8 or 9

The link below gives access to instructions for installing the JDK and JRE on Oracle Solaris, Windows, Linux, and OS X computers.

https://www.java.com/en/download/

2.1.2 Tomcat 8

The link below will assist you in downloading and installing Apache Tomcat, and using many of the Apache Tomcat features.

https://tomcat.apache.org/tomcat-8.0-doc/setup.html

2.1.3 MySQL 5.6

The link below describes how to obtain and install MySQL or to upgrade an existing version of MySQL to a newer version.

https://dev.mysql.com/doc/refman/5.7/en/installing.html

2.1.4 Maven

The link below will assist you in installing Maven

https://maven.apache.org/install.html

2.1.5 Git Repository

Source code for WCP application and Web Services is available at:

https://github.com/PopMedNet-Team/FDA-My-Studies-Mobile-Application-System

The following folders are to be used:

- **WCP** (Source code of the WCP)
- **WCP-WS** (Source code of WCP Web Services)
- **Resources** (This application is deployed in server for storing the resources required by the web apps)

2.2 Configuration

2.2.1 Initial Configuration

HPHC_My_Studies_DB_Create_Script.sql script file should be executed in MySQL and this file is found inside the sqlscript folder.

The file path is given below:

https://github.com/PopMedNet-Team/FDA-My-Studies-Mobile-Application-System/tree/2019.05/WCP/sqlscript

hphcAuditLogs folder should be created inside the server and the path should be configured inside *application.properties* for fda.logFilePath parameter.

Ex: fda.logFilePath=/usr/local/hphcAuditLogs/

2.2.2 Properties Files

application.properties file should be downloaded from the root folder of the GitHub MyStudies repository and stored in the system/server.

The file path is given below:
https://github.com/PopMedNet-Team/FDA-My-Studies-Mobile-Application-System/tree/2019.05/WCP

Given below are the configurations within the file that needs to be changed.

smtp.portvalue=25 #Should be changed to actual SMTP port

smtp.hostname=127.0.0.1 #Should be changed to actual SMTP IP

fda.imgUploadPath=<Tomcat installed path>/webapps/fdaResources/
#<Tomcat installed path> will be changed to actual path

acceptLinkMail =http://localhost:8080/fdahpStudyDesigner/createPassword.do?securityToken=
#localhost:8080 will be changed to domain name

login.url=http://localhost:8080/fdahpStudyDesigner/login.do
#localhost:8080 will be changed to domain name

signUp.url=http://localhost:8080/fdahpStudyDesigner/signUp.do?securityToken=
#localhost:8080 will be changed to domain name

db.url=localhost/fda_hphc
db.username=****
db.password=****
#“db.username” value will be changed to actual username of database.

#“db.password” value will be changed to actual password of database.

hibernate.connection.url=jdbc:mysql://localhost/fda_hphc
hibernate.connection.username=****
hibernate.connection.password=****
#“hibernate.connection.username” value will be changed to actual username of database.
#“hibernate.connection.password” value will be changed to actual password of database.

fda.smd.study.thumbnailPath = http://localhost:8080/fdaResources/studylogo/
fda.smd.study.pagePath = http://localhost:8080/fdaResources/studypages/
fda.smd.resource.pdfPath = http://localhost:8080/fdaResources/studyResources/
fda.smd.questionnaire.image=http://localhost/fdaResources/questionnaire/
fda.smd.gatewayResource.pdfPath=http://localhost:8080/fdaResources/gatewayResource/App_Glossary.pdf
fda.smd.pricaypolicy=https://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/fda.smd.terms=https://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/

#for all the properties “localhost” will be changed to domain name.

Folder for Audit log files:

fda.logFilePath="/usr/local/hphcAuditLogs/
#Create a folder "hphcAuditLogs" inside the server and update to the same

#User registration server root URL:
fda.registration.root.url = https://hphc-fdama.labkey.com
#https://hphc-fdama.labkey.com – Should be replaced with actual URL

Changes in Tomcat configuration File

Below are the changes required to the Tomcat context.xml file and it can be found at: <tomcat installed path>/tomcat/conf/
Add the below parameters in context.xml file inside <context> tag.
<Parameter name="property_file_location_prop" value="/usr/local/" override="1"/>
<Parameter name="property_file_name" value="application" override="1"/>
<Parameter name="property_file_location_config" value="/usr/local/application.properties" override="1"/>
<Parameter name="property_file_location_path" value=" /usr/local/application.properties" override="1"/>

messageResource.properties file for web application available at /src/main/resources folder inside project directory and below are the changes required:

https://github.com/PopMedNet-Team/FDA-My-Studies-Mobile-Application-System/tree/2019.05/WCP/fdahpStudyDesigner/src/main/resources

max.login.attempts=3 #Maximum continuous fail login attempts by a user.
password.resetLink.expiration.in.hour=48 #Reset password link will get expired after the specified hours.
password.expiration.in.day=90 #User generated password expiration in days.

lastlogin.expiration.in.day=90 #User will get locked if he has not logged in for specified days.
password.history.count=10 #User cannot reuse the last 10 generated passwords for change password.
user.lock.duration.in.minutes=30 #User lock duration in minutes after crossed Maximum continuous fail login attempts limit.

fda.smd.notification.title=HPHC My Studies #Local notification title.
fda.smd.email.title=The HPHC My Studies Platform Team #Email notification title

authorizationResource.properties file for web services application can be found at /studyMetaData/src/main/resources folder inside project directory. Given below are the changes required:

https://github.com/PopMedNet-Team/FDA-My-Studies-Mobile-Application-System/tree/2019.05/WCP-WS/src/main/resources

{UUID used to uniquely identify app}=android.apptoken #Android unique identifier.
{android package name}=android.bundleid #The unique identifier for all Android apps
{UUID used to uniquely identify app}=ios.apptoken #iOS unique identifier.
{iOS package name}=ios.bundleid #The unique identifier for all iOS apps

2.3 Build

To build the application(s), run the command given below from the project root folder(s).

mvn clean install

2.4 Deployment

Once the build is successful, the .war files will be generated inside the target folder. To deploy, copy these .war files and paste them inside the 'webapps' folder of the Tomcat installation path and restart the server.

2.5 Test the application(s)

After deploying the builds, hit the below URLs to verify the application's status

Web application:

http://localhost:8080/fdahpStudyDesigner

will redirect you to login page. Below is the default username and password

User name: superadmin@gmail.com

Password: Password@1234

Web services:

http://localhost:8080/StudyMetaData/ping

will display "It Works!"

3 User Registration Web Services

3.1 Getting started

The User Registration web services are built on the LabKey environment. To start this project, you need to set up the LabKey development machine; the link given below will guide you through this process:

https://www.labkey.org/Documentation/wiki-page.view?name=devMachine

Once the Labkey development environment is set, clone the GitHub repositories such as **UserReg-WS** into the /server/customModules folder.

Switch to the release 19.1 branch and then do a **git pull**

3.2 Build

3.2.1 User Registration Web Services

Once the setup is done, you should be able to build the distribution with the commands given below

- gradlew cleanBuild
- gradlew deployApp -PdeployMode=prod
- gradlew -PdeployMode=prod :server:customModules:fdahpUserRegWS:distributions:Registration:distribution

Once the build is complete, you will find the distribution file at below path:

{LABKEY_HOME}/server/dist/ Registration

LBAKEY_HOME is the root folder where you cloned the labkey code

3.3 Deployment

Move the above distribution file from {LABKEY_HOME}/server/dist/ Registration/ to your Tomcat 'webapps' folder, unzip the folder and restart the server.

3.4 Test the application

http://localhost:8080/labkey/fdahpUserRegWS/ping.api

will display "It Works!"

4 iOS Setup

4.1 Introduction

This section explains how to setup the FDA MyStudies iOS app and Install and run it on an iPhone.

4.2 Requirements

4.2.1 IDE

Xcode 9 and above can be used to run application. You can install Xcode from MAC App Store.

4.2.2 iOS

Application is supported on iOS 11 and above, and uses ResearchKit 2.0

4.3 How to open Project in Xcode

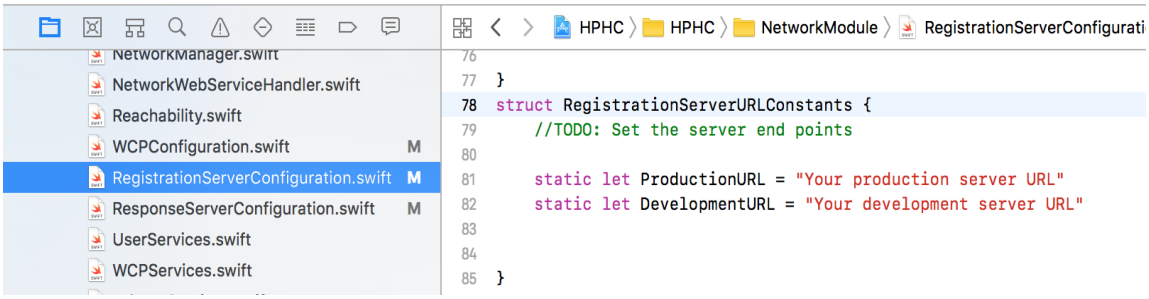
- Download the project from Github or clone.
- To open project in Xcode go to the project location on your Mac Machine and look for the file named "**HPHC.xcworkspace**" and double tap on it.

4.4 How to change Server URLs

4.4.1 Registration Server

Look for "**RegistrationServerConfiguration.swift**" file in Navigator Section and tap on it.

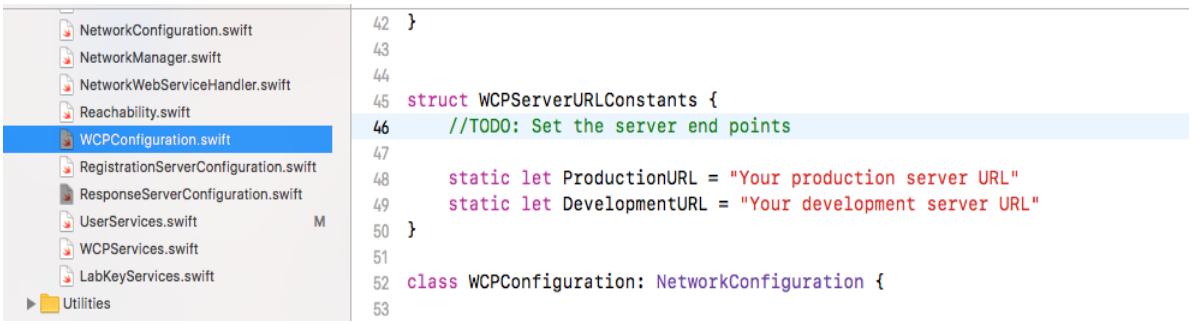
Add your Production and Development Server URLs.



4.4.2 WCP Server

Look for "**WCPConfiguration.swift**" file in Navigator Section and tap on it.

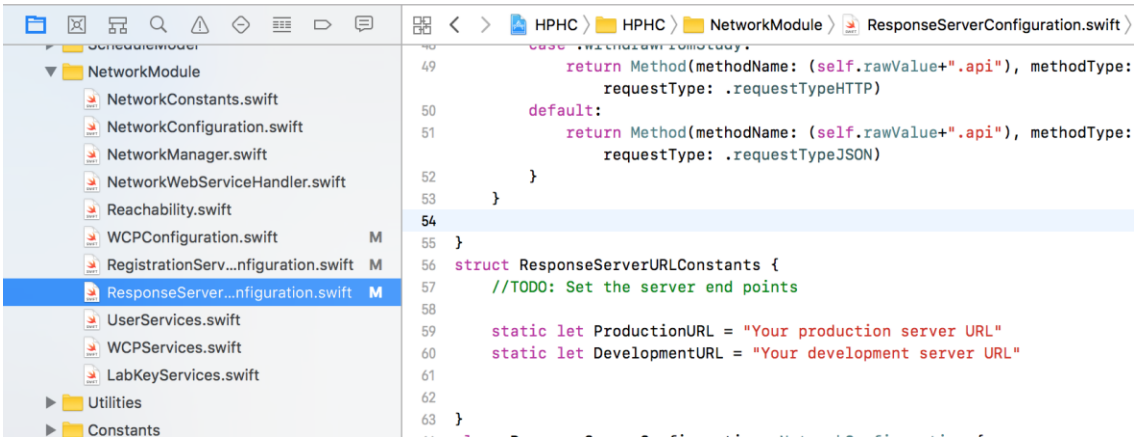
Add your Production and Development Server URLs.



4.4.3 Response Server

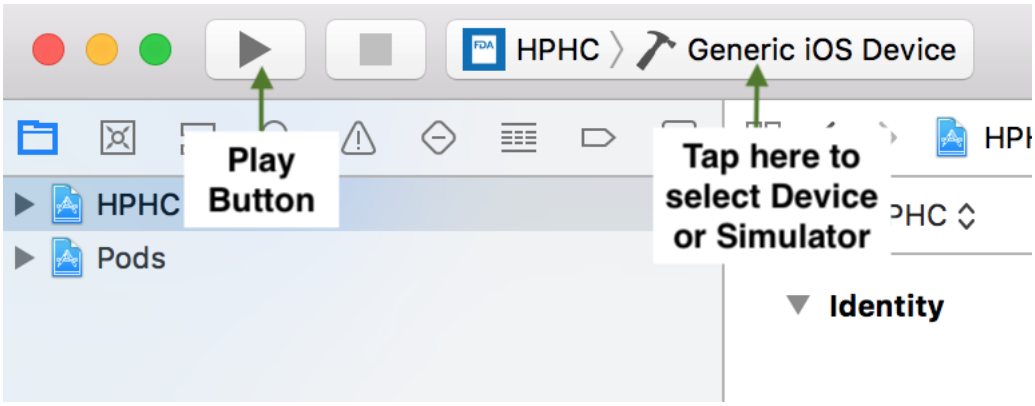
Look for "**ResponseServerConfiguration.swift**" file in Navigator Section and tap on it.

Add your Production and Development Server URLs.



4.5 How to Build and Run

Application can be run on iPhone Simulator OR iPhone Device.



4.5.1 Run on Simulator

To Run on Simulator, select a simulator from the simulator listing and click on the Play button.

4.5.2 Run on Device

To build and run application on your iPhone device, connect your phone with power cable to mac machine.

iPhone name will be listed under Device, select iPhone and click on Play button

5 Android Setup

5.1 Introduction

This section explains how to setup the FDA MyStudies Android app and Install and run it on an Android device.

5.2 Requirement

5.2.1 IDE Environment Setup

Download Android Studio from the following link and set up the environment.
https://developer.android.com/studio/index.html

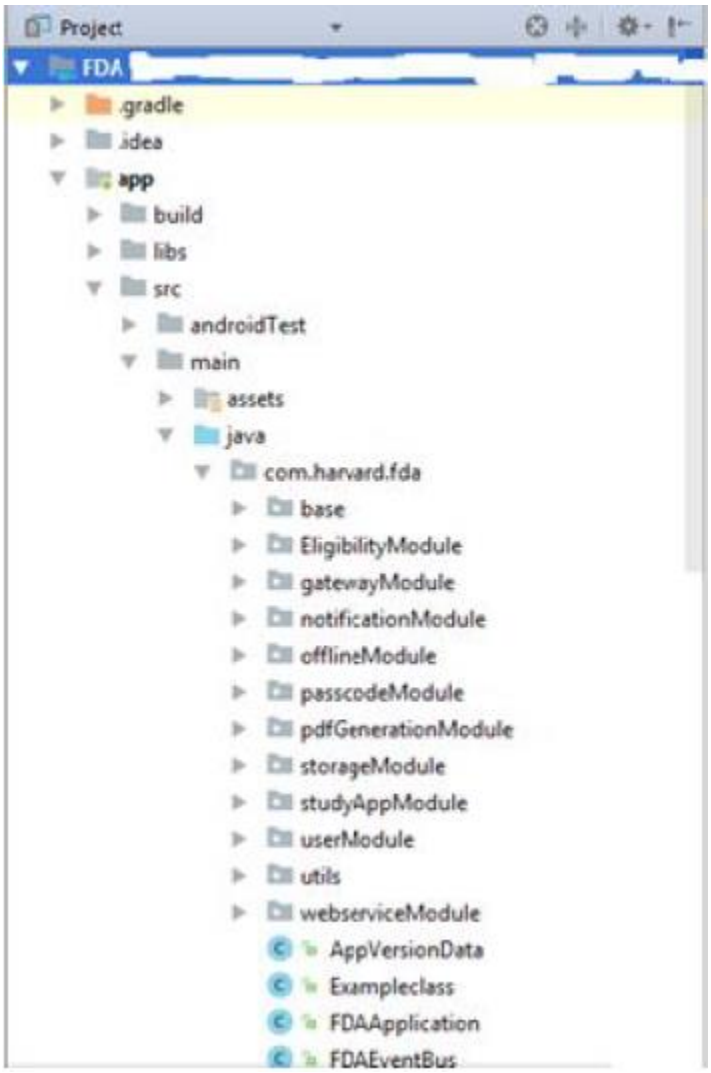
5.2.2 Android OS Support

The application can be run on Android OS starting from Kitkat and up to Pie.

5.3 Steps to pull code from Github

a. After setting up the IDE environment do integrate **GIT** version control system.
b. Copy the app's source code link from the GitHub repo.
c. Open Android Studio and go to : **File > New > Project from version control > Git**. This will open a window and then copy the link to **Git Repository URL** field.
d. Set the path to which Project has to clone in **Parent Directory** field.
e. Give Directory name in **Directory Name** field.
f. Click on **Clone** button which will download the source code and user can open the MyStudies source code in new window.

5.4 Steps to change API URL



Go to **utils** package from base package **com.harvard.fda** and open **Urls.java** file to put in your server URLs

Update the constant **BASE_URL_WCP_SERVER**, with the WCP server URL.
Update the constant **BASE_URL_REGISTRATION_SERVER**, with the User Registration server URL
Update the constant **BASE_URL_RESPONSE_SERVER**, with the Response Server URL.

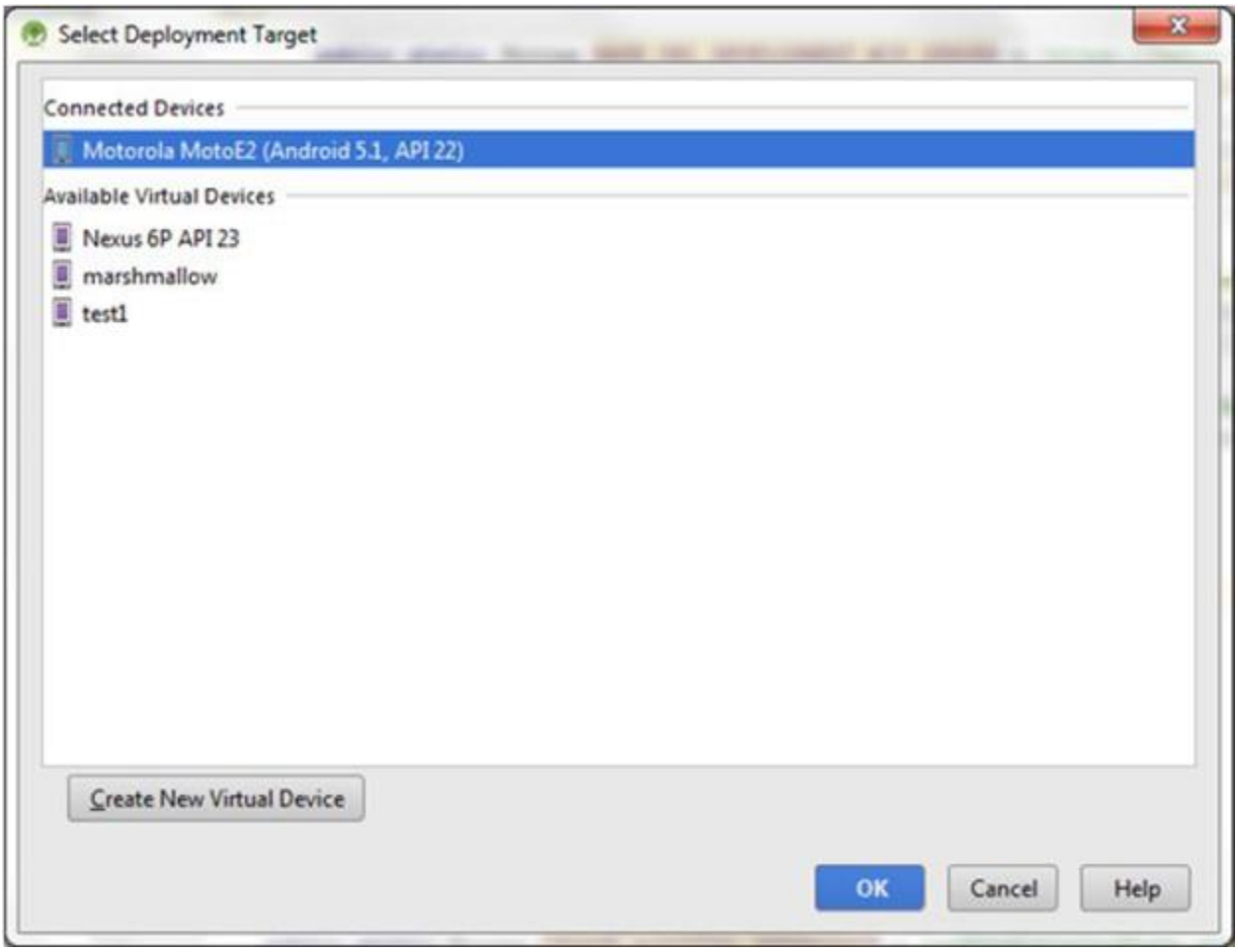
5.5 Steps to install Android app

App can be installed to device or emulator from Android Studio by clicking on the Run button in the Menu bar (image1), which will open a window to choose between emulator and device (image2).

image1 (icon in red circle is the Run button)

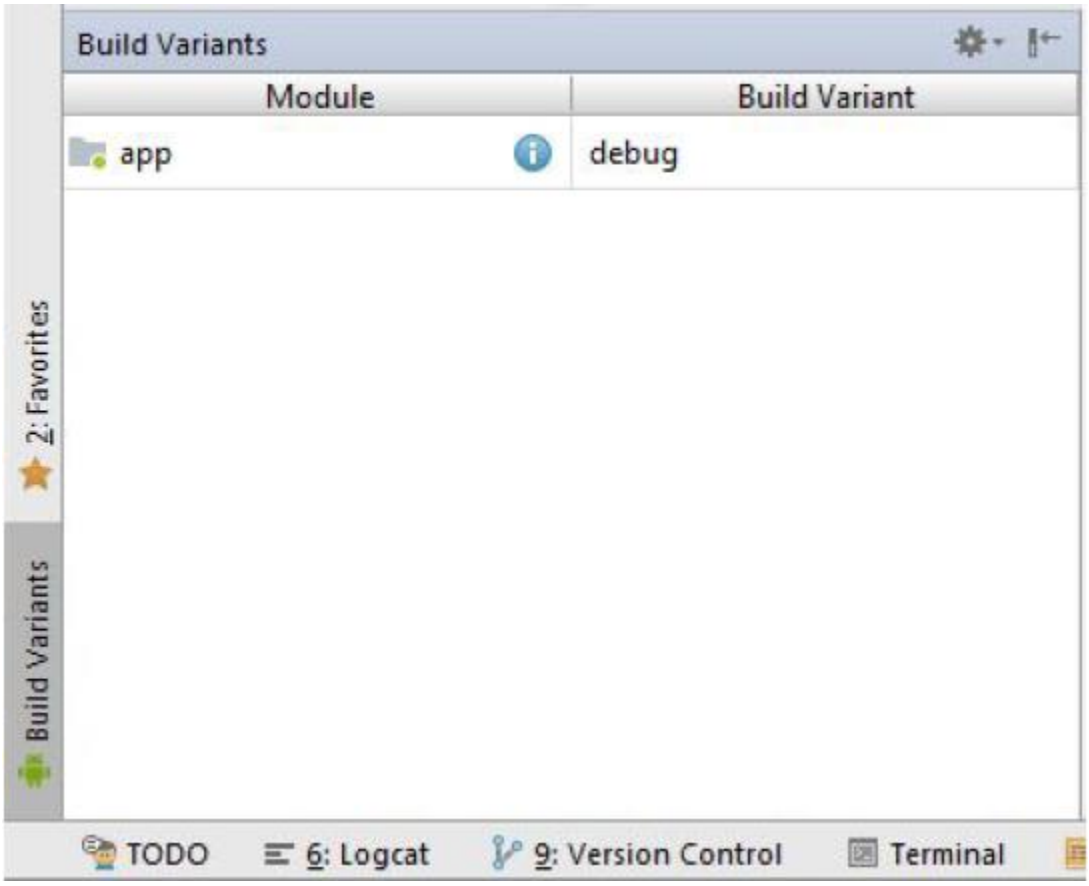
image2

(this image shows real connected devices and available virtual devices or emulators)

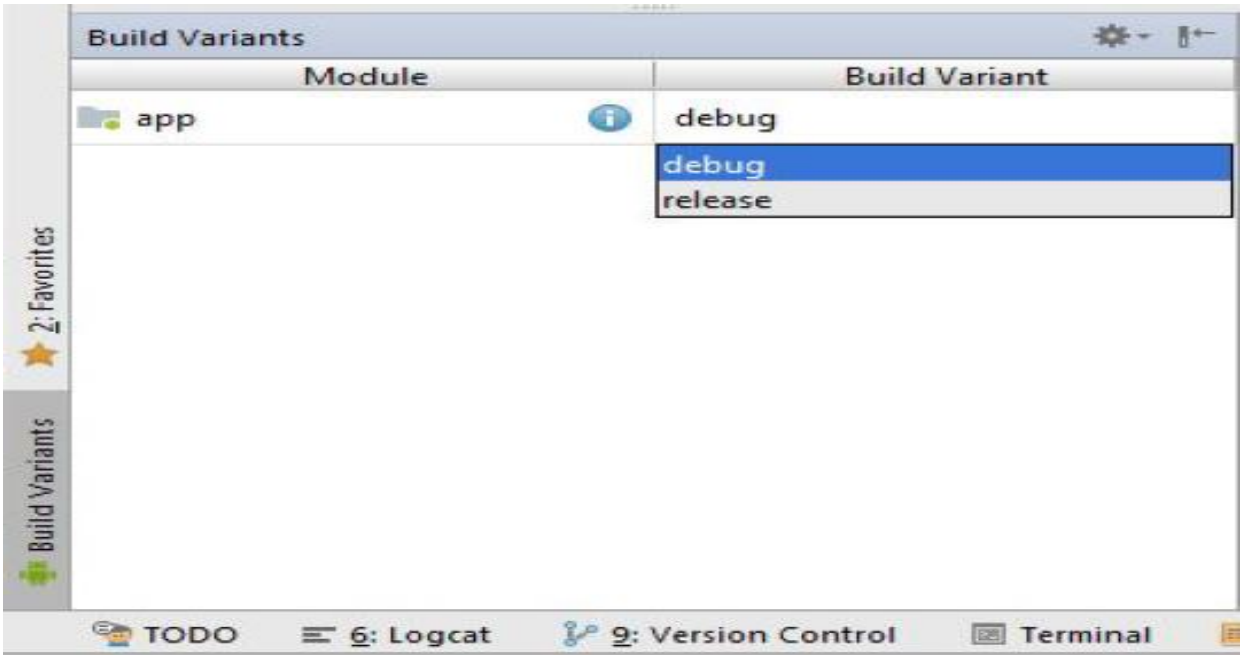


5.6 Creating the Android app build

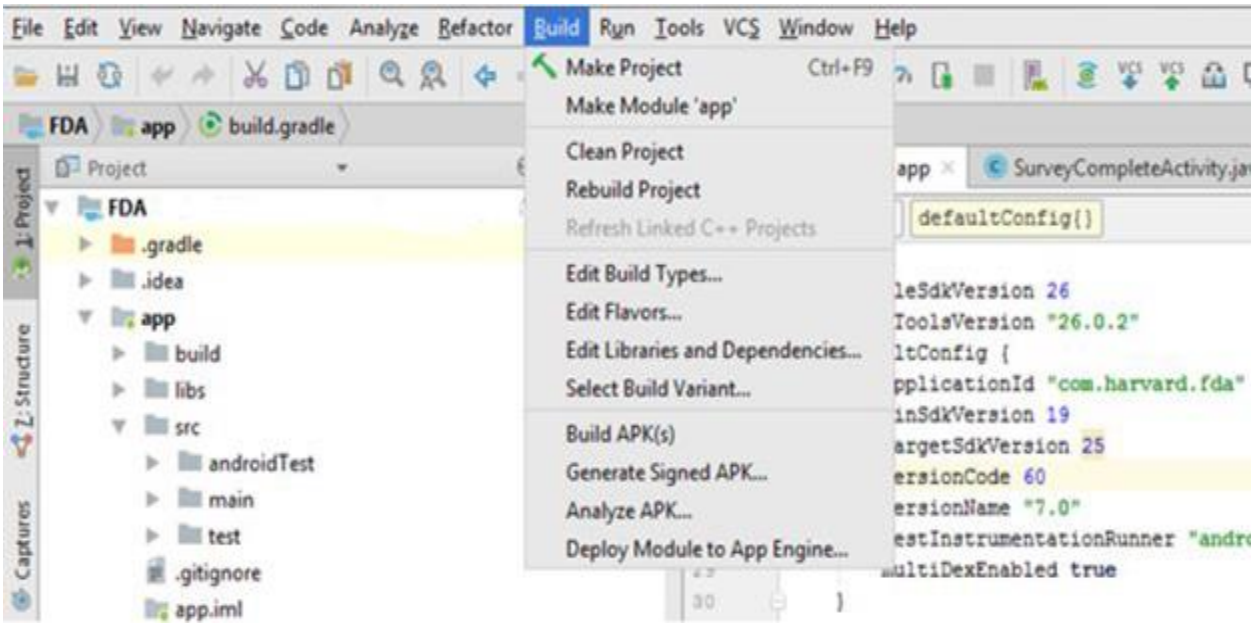
a. First increment the **versionName** and **versionCode** in **build.gradle** file in App Directory from Project Explorer.
b. Click on **Build Variants** and in Android Studio and click on the area where **debug** text is displayed.



c. Select **release** option from the list.

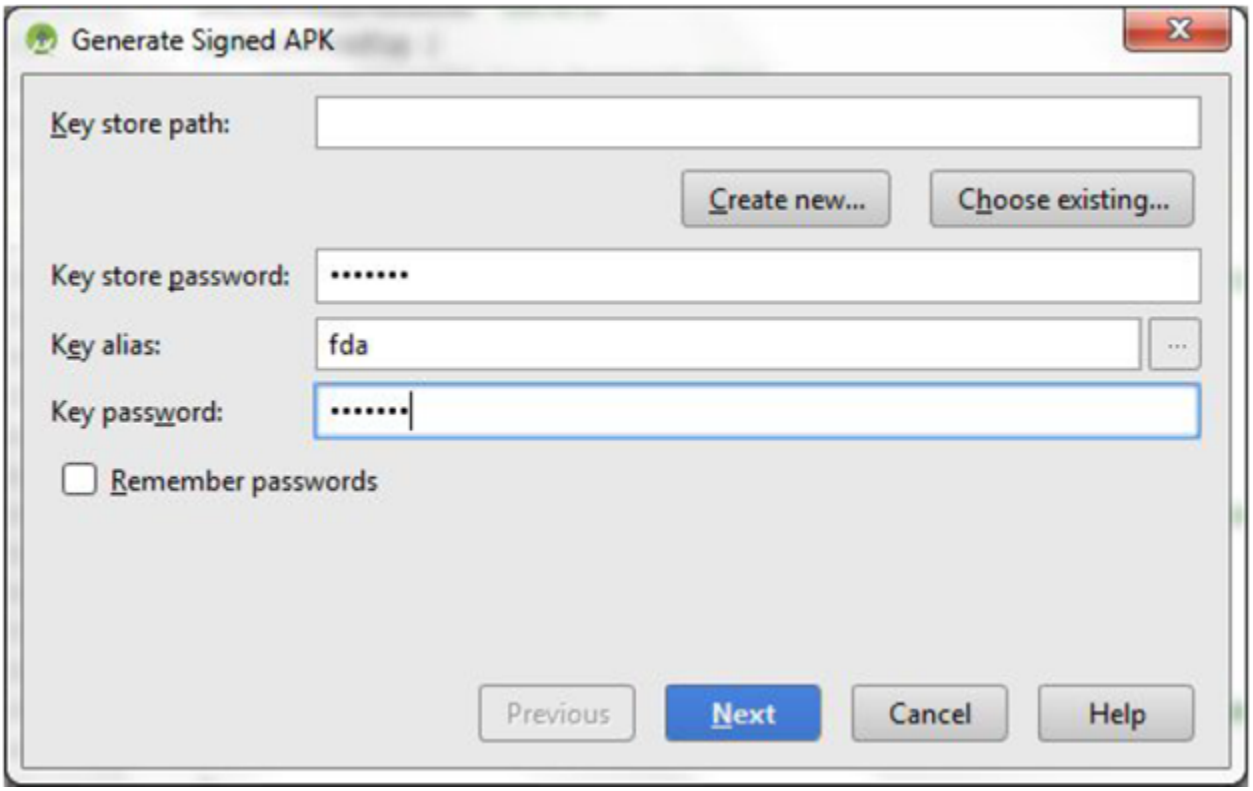


d. Click on **Build** from the menu bar and select **Generate Signed APK**.



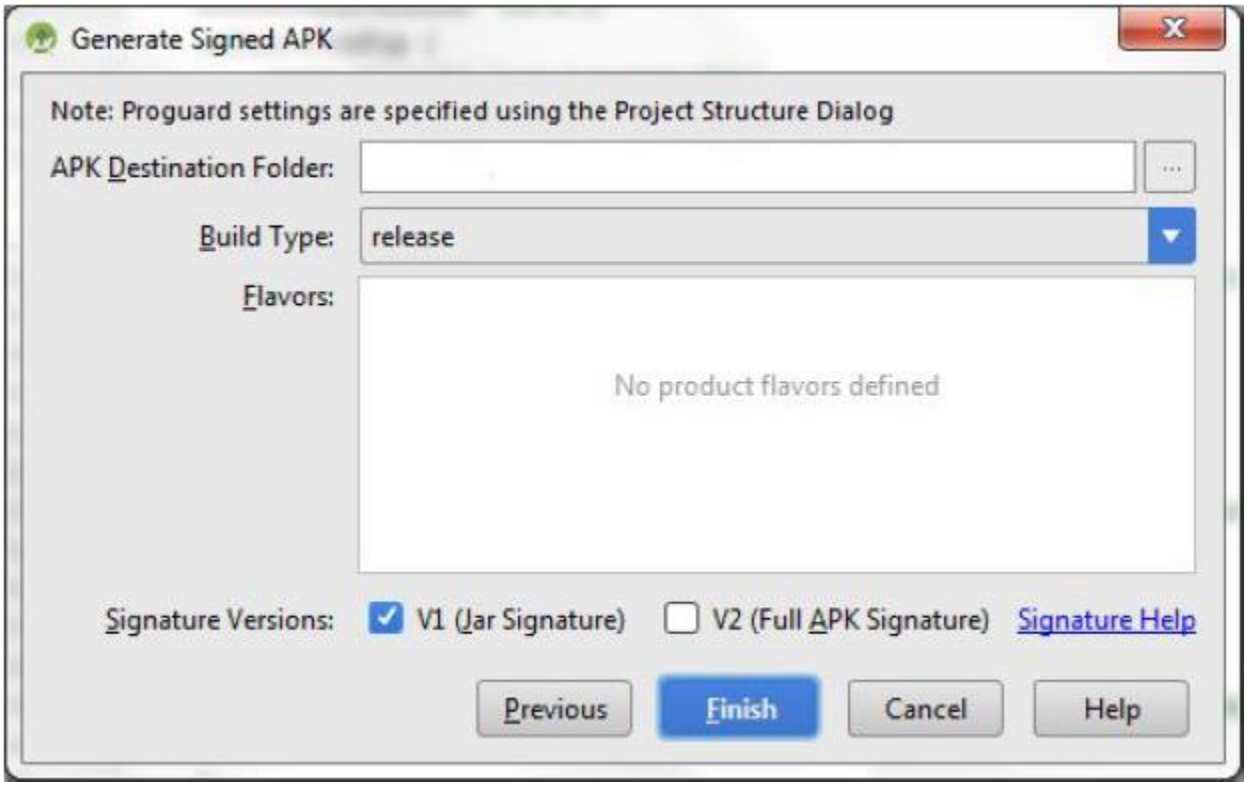
e. Download the **keystore.jks** from the following link <Keystore Location>

f. In the new window opened enter the details about keystore



- Key store path: Browse to the path of the downloaded keystore by clicking on **Choose existing button**.
- Enter Key store password as **"welcome"**.
- Key alias: fda
- Enter Key password as **"welcome"**
- Click **Next** button.

g. In the new window enter the details:



- Enter the **APK Destination Folder** to which the build will be generated.
- Select **release** as **Build Type**
- Select the check box **V1(Jar Signature)**
- Click on **Finish** button, which will generate the Android build.

6 Response Server Setup

Please refer to LabKey documentation on the Response Server setup at

https://github.com/PopMedNet-Team/FDA-My-Studies-Mobile-Application-System

7 Create Study and Run

Once you have set up all the different components and applications of the MyStudies solution, you are ready to create your study via the WCP, publish it to the mobile app and run through the user flow of a study participant who would use the mobile app to participate in the study. Given below is a high-level description of the process you would need to employ, for the same.

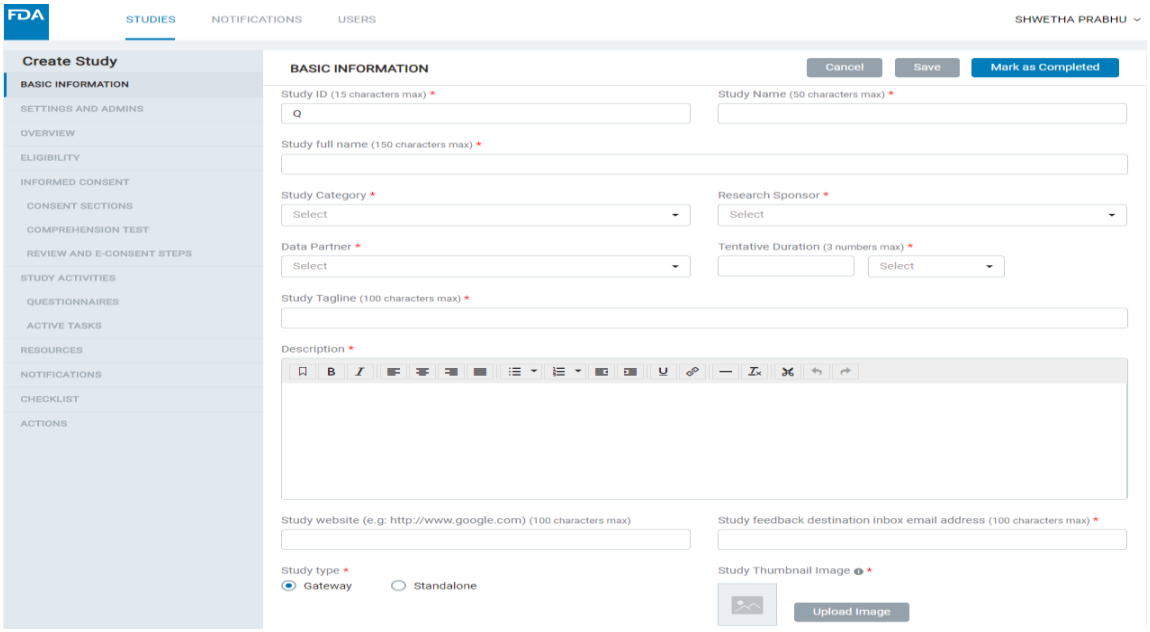
7.1 Create the study in WCP

Sign in to the WCP, and click on Studies > Create New Study. Follow the series of steps shown below to set up content for your study.

(The WCP user is referred to as 'Admin' in the sections below)

7.1.1 Basic information

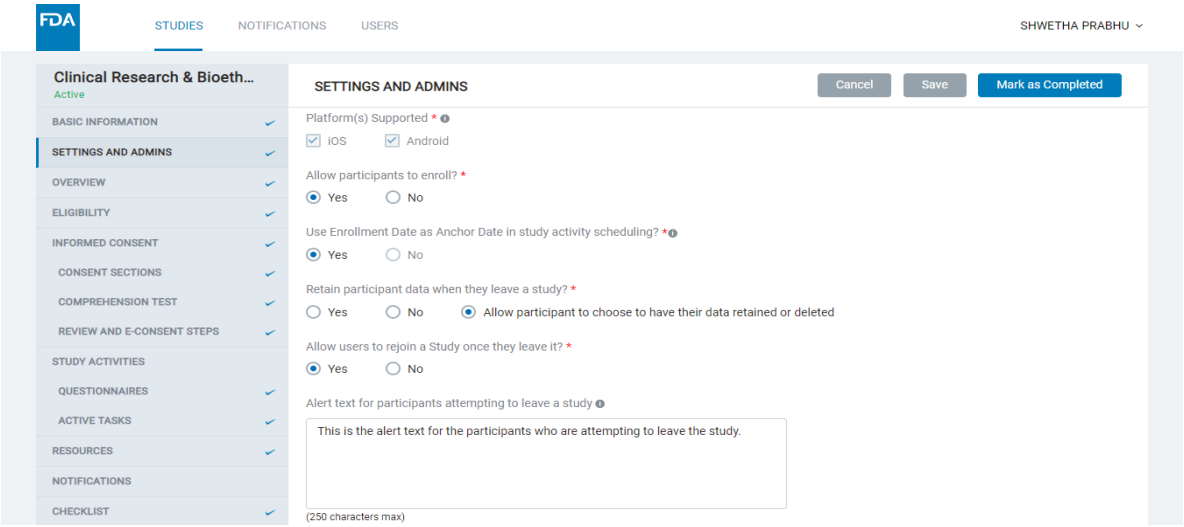
- Here, the Admin should enter a Study ID (which should be unique for each study), Study Name, Study Category, Research and Data partners, Study Description and select Standalone or Gateway as the Study Type. (All studies marked as Gateway would appear in a single 'gateway' model app. If a Study is marked as Standalone, it would not appear in the Gateway app and instead a single 'Standalone' mobile app can be created that will house just that one study.)
- If Admin chooses Study Type as Gateway, a Study Thumbnail Image should be uploaded as well.



7.1.2 Settings & Admins

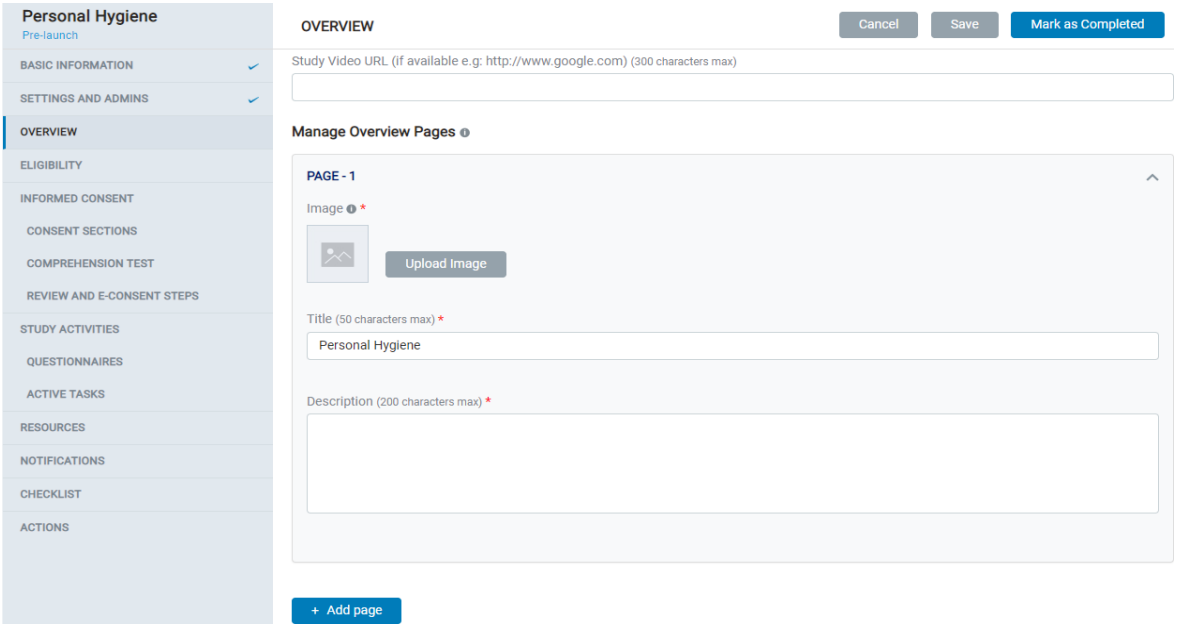
- Here, the Admin can choose the platform(s) supported, set Enrollment as being open or closed for the study, choose Yes or No to allow Enrollment Date to be used as an Anchor Date to scheduling study activities or resources, set options to retain data for a participant when they

leave a study, allow/deny participants to rejoin study once they leave it and define confirmation text for users when they attempt to leave the study.



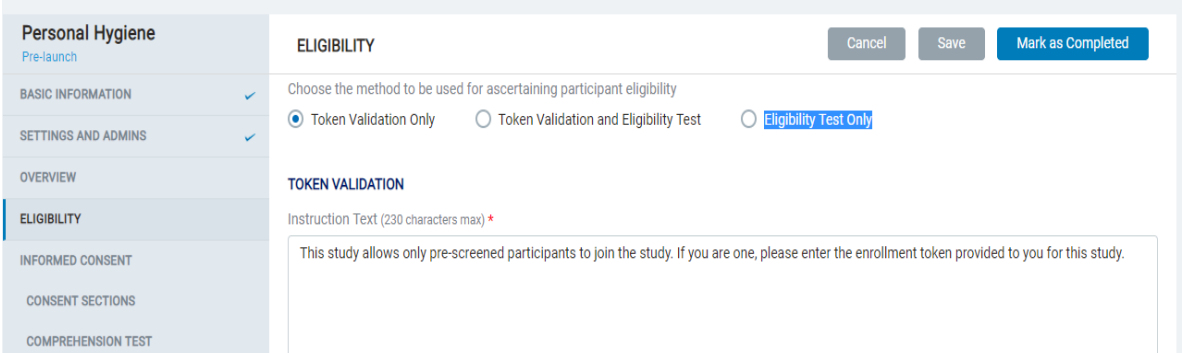
Overview

- In Overview, the Admin can add multiple pages for a study, which will be reflected in the Mobile app under Study Overview screens.
- Each Page contains Title, Description and an Image. Admin can also add a Study Video URL on the first page of the Study Overview.



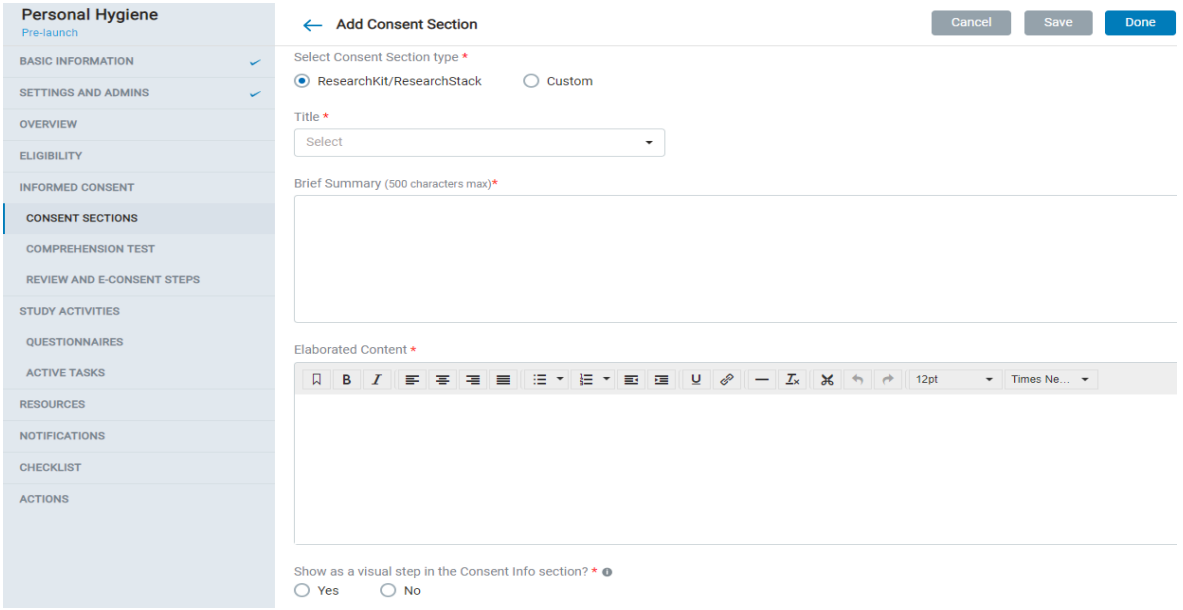
7.1.3 Eligibility

- In Eligibility section, Admin can choose and set up content for the desired method to be used for ascertaining participant eligibility - Token Validation Only, Eligibility Test Only or Token Validation & Eligibility Test.



7.1.4 Consent section

- In Consent Sections, the Admin can add ResearchKit/ResearchStack based (pre-formatted mobile UI) or Custom consent section types and fill in content accordingly.
- Each consent section contains Title, Display Title, Summary and Elaborated content.
- The admin can also choose to display the Consent Section as a Visual Step in the mobile app.

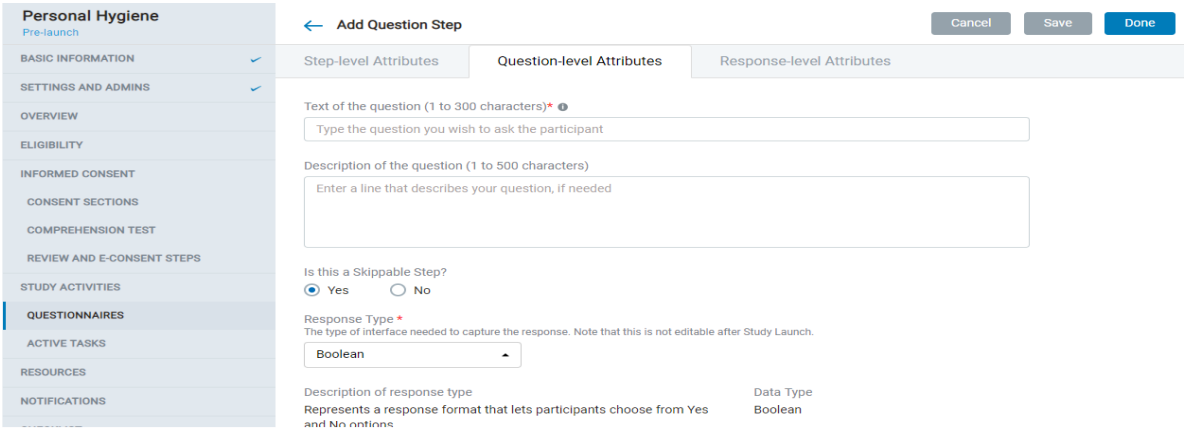


- The Admin can allow participants to take a Comprehension Test of the Consent material and set up comprehension test questions and a minimum score needed to pass the test.

- In the Review Consent screen, the Admin can choose from either the auto-generated consent document (Concatenated Consent Sections) or create a Custom consent document to be used in the app.

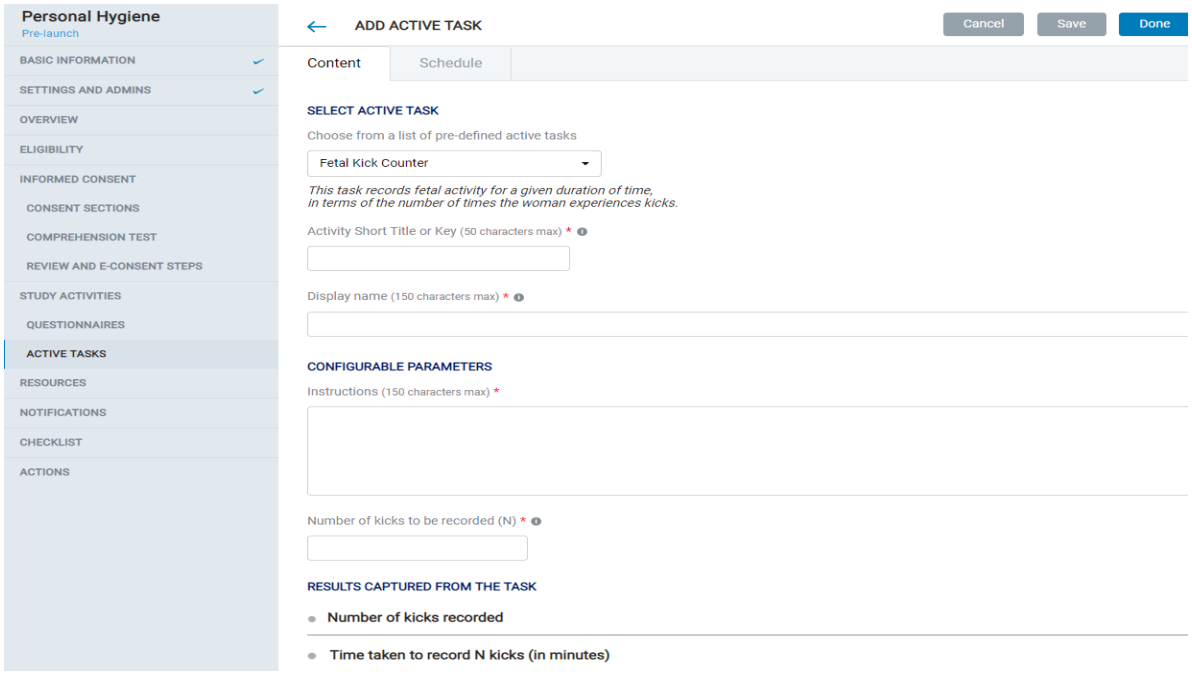
7.1.5 Study Activities – Questionnaires

- The admin can create questionnaires with a combination of Instruction Steps, Question Steps and Form Steps.
- Each Question Step comprises of Step-level Attributes, Question-level and Response-level Attributes that offer a number of provisions to design the kind of questionnaire and study experience you need.
- A Form Step is essentially a set of Question Steps, in the mobile app, all Questions that belong to a Form appear on a single screen.
- A number of scheduling options are provided that the admin can choose from to determine the schedule of the survey in the mobile app.



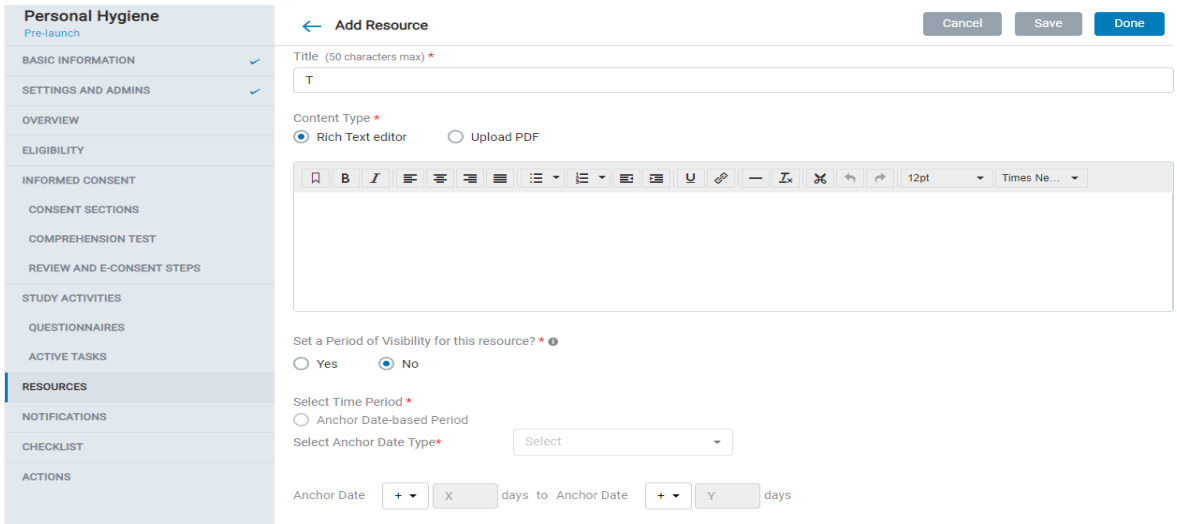
7.1.6 Study Activity – Active Tasks

- Admin can choose to add active tasks to the study from the options available in the WCP.
- Once an active task is selected, the admin needs to fill in values for its configurable attributes.
- A number of scheduling options are provided that the admin can choose from to determine the schedule of the active task in the mobile app.



7.1.7 Resources

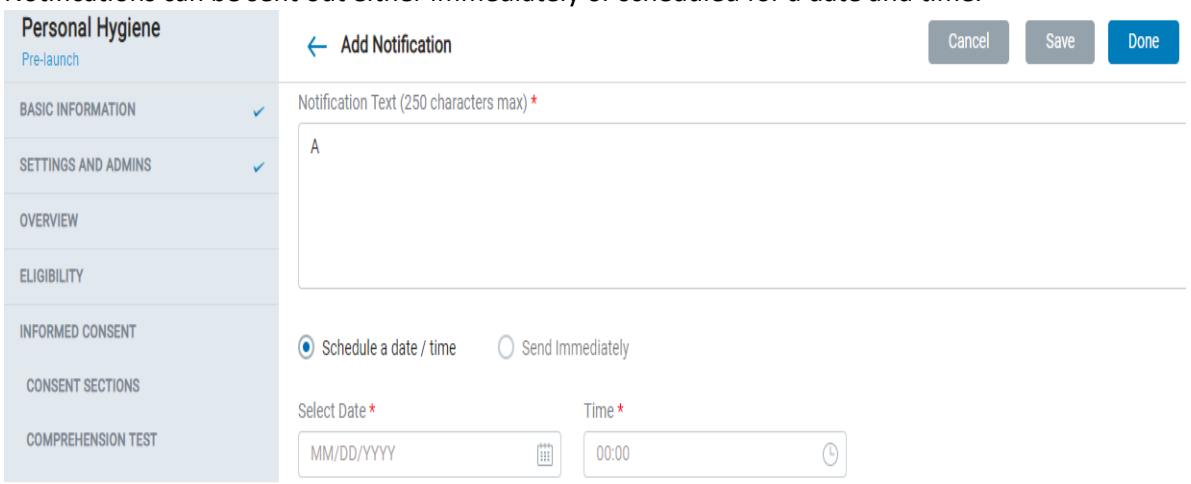
- Admin can add resources' content either using a text editor or by uploading a PDF. These resources will be reflected in Mobile app in the Resources section of the study.
- Resources can be made available in the app for specific time periods using the Period of Visibility settings. There is also a provision to notify mobile users when a new resource is available.



7.1.8 Notifications

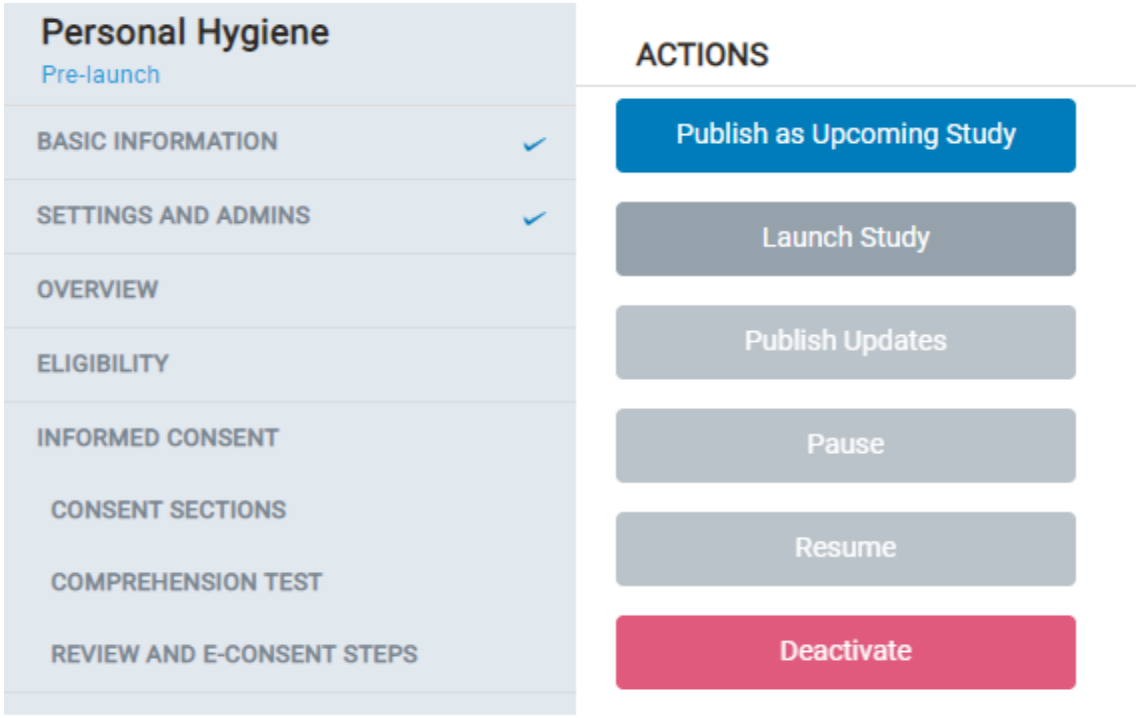
- Admins can create and send study-specific push notifications to participants

- Notifications can be sent out either immediately or scheduled for a date and time.



7.1.9 Actions

- In this section, the Admin sees various Actions that can be taken with a Study.
- Admins can choose to publish the study as an upcoming one, launch the study to start enrolling participants and collecting data, publish updates ongoing to existing studies or Pause/Resume or deactivate them.



7.2 Create Study on Response Server, and Generate Enrollment Tokens

- Once your study has been set up on the WCP, and the Response Server setup is ready too, login to the LabKey admin portal
- Create your Project
- Create your Study space/folder using the same Study ID you used to create the Study in the WCP.
- Once this is done, enrollment tokens can be created for the Study (if Token Validation method is being used for ascertaining eligibility), these are distributed to users of the mobile app to participate in the study.
  (Please refer to LabKey documentation for more details on steps to set up a study on the Response Server)

7.3 Study Participation using the mobile application

- Launch the mobile app installed on your phone
- Sign up with a valid email ID and password and follow the instructions to set up your user account
- After successful sign up, if using a gateway type of app, there would be list of studies to choose from (all published to the app using the WCP)
- Pick a study for which you have the enrollment token and proceed, OR, choose a study that does not require a token to be used but has an eligibility questionnaire/test instead.
- To join the selected study, complete the Enrollment Token Validation/ Eligibility steps and the Informed Consent process – this involves reviewing Consent Sections, taking a Comprehension Test (if available for the study) and then doing a final review of and agreeing to the full Consent Document. The process ends with an e-signature after which the app generates a signed Consent Document PDF.
- Once into the Study, you can participate in activities that are listed out as per the schedule in which they are to be taken.
- You can also view various statistics and trends on the Study Dashboard and access Study Resources.
- At the app level, there are also other miscellaneous features such as a Notifications section, Account/Preferences section and provisions for participants to provide feedback or contact a designated email inbox for enquiries.