FDA My Studies

Release 2019.10

Technical Setup Document

for

WCP Application, User Registration Server, iOS App, Android App and Web Resources

Version 1.0

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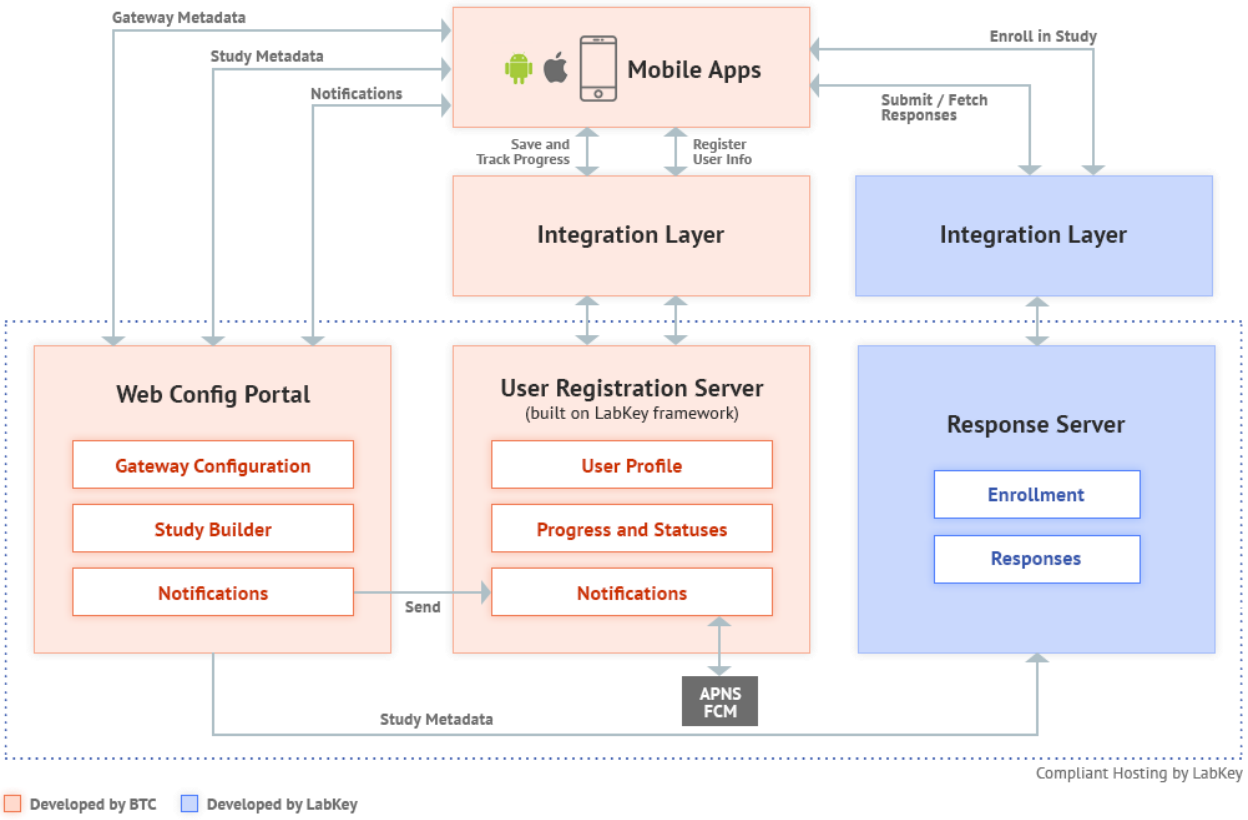
1 High-level Technical Architecture



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

- 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.

- Manage Users of the WCP as a Superadmin User or User who has the required permissions (also referred to as Admins, WCP 'Users' would typically belong to the research team carrying out the study and setting up content for it)
- Manage App-level Notifications

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/2019.10/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/2019.10/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 host/domain name

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

signUp.url=http://localhost:8080/fdahpStudyDesigner/signUp.do?securityToken=
#localhost:8080 will be changed to host/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 host/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/2019.10/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 expire after the specified hours.
password.expiration.in.day=90 #User password expiration in days.

lastlogin.expiration.in.day=90 #User will get locked if he/she has not logged in for specified number of 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

2.2.3 Settings for Bundle Id and App Token

authorizationResource.properties file for web services application can be found at /studyMetaData/src/main/resources folder inside project directory. Given below are the changes that would need to be made in this file:

https://github.com/PopMedNet-Team/FDA-My-Studies-Mobile-Application-System/tree/2019.10/WCP-WS/src/main/resources

{Unique Identifier}=android.apptoken #Android unique identifier.

{android bundleid}=android.bundleid

{Unique Identifier}=ios.apptoken #iOS unique identifier.

{iOS bundleid}=ios.bundleid

{Unique Identifier}=labkey.apptoken #LabKey response server unique identifier.

{LabKey Unique String}=labkey.bundleid

bundleID and AppToken are security parameters, used to carry out communicate between the WCP and other client applications, via the WCP webservices.

There will be 3 unique bundleID values and 3 unique AppToken values required to be created. Each of these bundleiD-AppToken sets will need to be used with the 3 types of client applications that will communicate with the WCP respecitvely i.e. MyStudies iOS apps, MyStudies Android apps, and the MyStudies Response Server.

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 in 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.

If your StudyMetaData project was created with StudyMetaData-0.0.1-SNAPSHOT.war name, change the file name from StudyMetaData-0.0.1-SNAPSHOT.war to StudyMetaData.war before deploying to tomcat wabapps.

2.5 Test the application(s)

After deploying the builds, hit the following URLs to verify the application status

Web application:

http://localhost:8080/fdahpStudyDesigner

Will redirect you to login page. The default username and password is:

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/modules folder. (If checked out into different folder/name please update path in settings.gradle, build.gradle of distributions folder and commands accordingly)

Switch to the release 2019.10 branch and then do a git pull

3.2 Build

3.2.1 User Registration Web Services

In your settings.gradle file, find the commented out line with this text:

//include ":server:optionalModules:workflow"

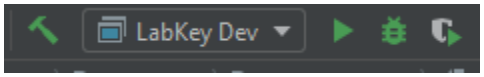
Underneath this line, add these two lines:

include ":server:modules:UserReg-WS"

include ":server:modules:UserReg-WS:distributions:Registration"

To generate a local build, use the below command:

· gradlew cleanBuild deployApp

Once the build is successful, click the run icon in your IDE 

Use this API to ping the local server after it is started with the Run action mentioned above, to verify if the web services are running locally: http://localhost:8080/labkey/fdahpUserRegWS/ping.api

To open the LabKey Portal of the (local) User Registration server, use http://localhost:8080/labkey/home/project-begin.view?

To generate a production build, use the following commands:

· gradlew deployApp -PdeployMode=prod

· gradlew -PdeployMode=prod :server:modules:UserReg-WS:distributions:Registration:distribution

Once the build is completed, you will find the distribution file in the path given below:

{LABKEY_HOME}/dist/Registration

LABKEY_HOME is the root folder where you have cloned the LabKey code

To deploy the UserReg-WS module to the production server please refer to

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

3.3 Multiple App support

MyStudies supports multiple apps with a single deployment of the platform. So in order to manage the data of different apps, the User-Reg server follows a specific folder structure for each app – an App folder and Study folder(s) within it - to house mobile application data

3.3.1 Folder Creation

The base project folder (App folder) will hold all the app level data and the subfolder (Study folder) will hold all study level data

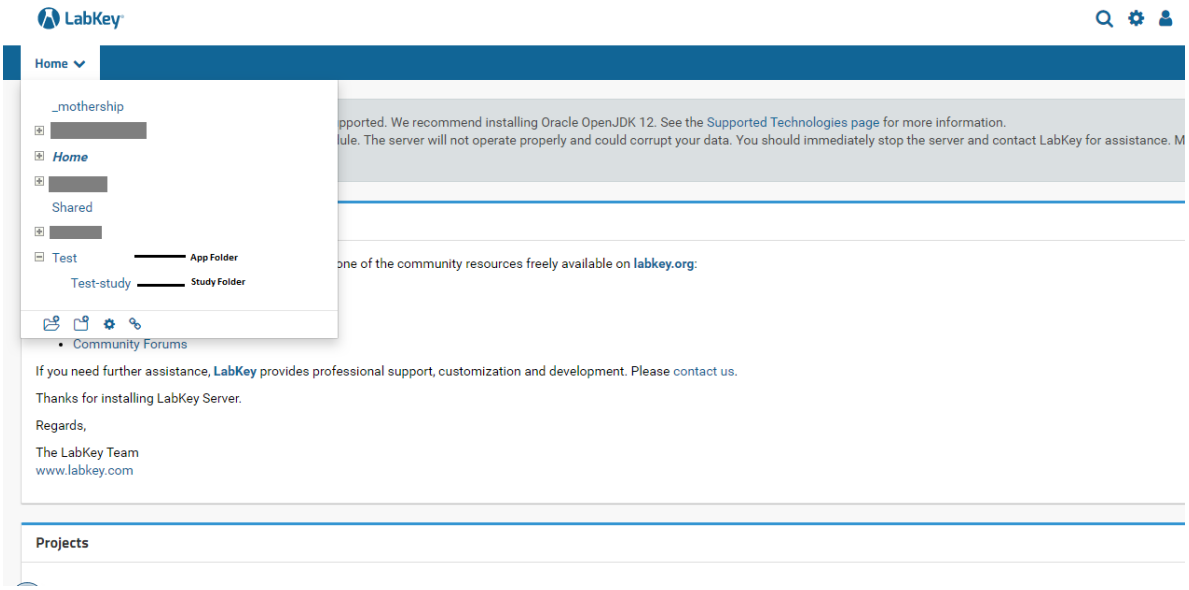
Note:

For the User-reg server to handle App & Study level data, the following steps need to be followed before publishing the study:

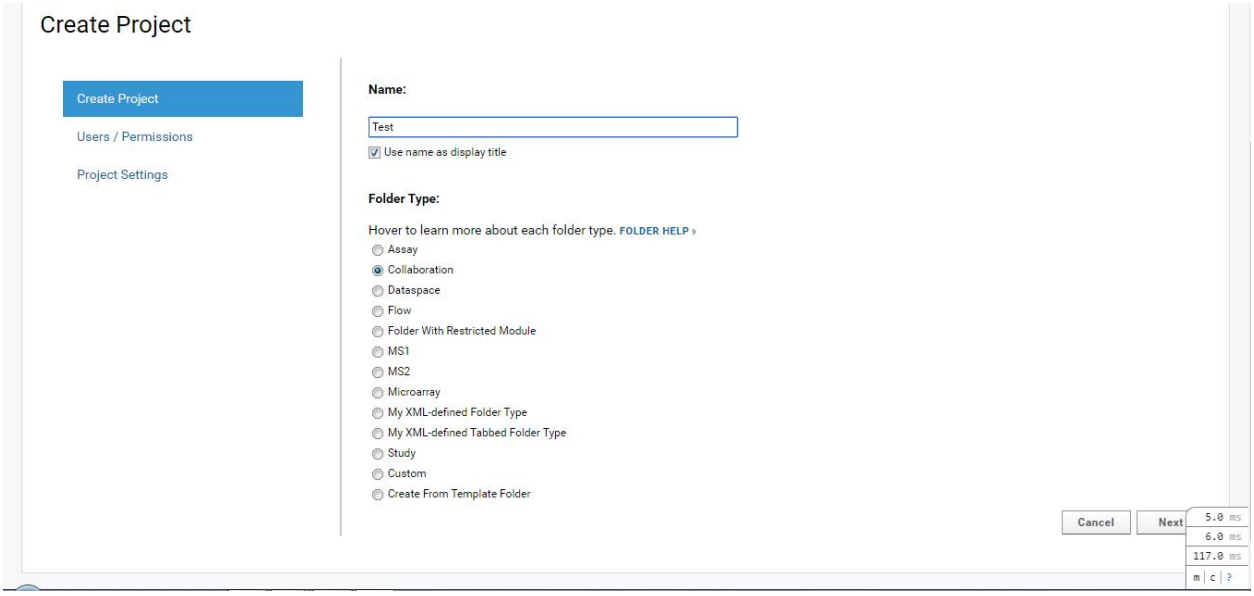
- If a study with a new AppId is created in WCP server, then the App Folder and Study Folder should be created on the User Registration server's Labkey Portal interface, with AppId and StudyId as the names respectively.
- If a study with an already existing AppId is created in WCP server, then only the Study Folder needs to be created.

For more on **AppId** and **StudyId**, refer to SECTION: 7.1

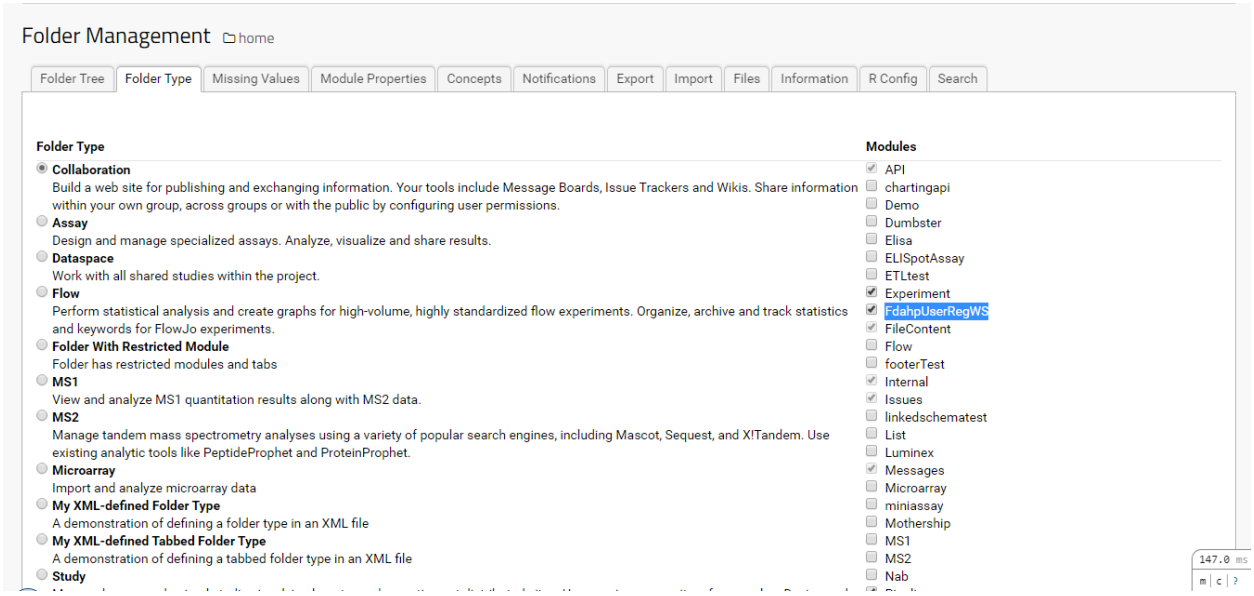
Following are the steps to create the folders in the User Registration server and steps to view the data on the server: (Note that for a production/live environment, access to data can be restricted as required by controlling access to the server and also with user permissions on the Labkey Portal.)



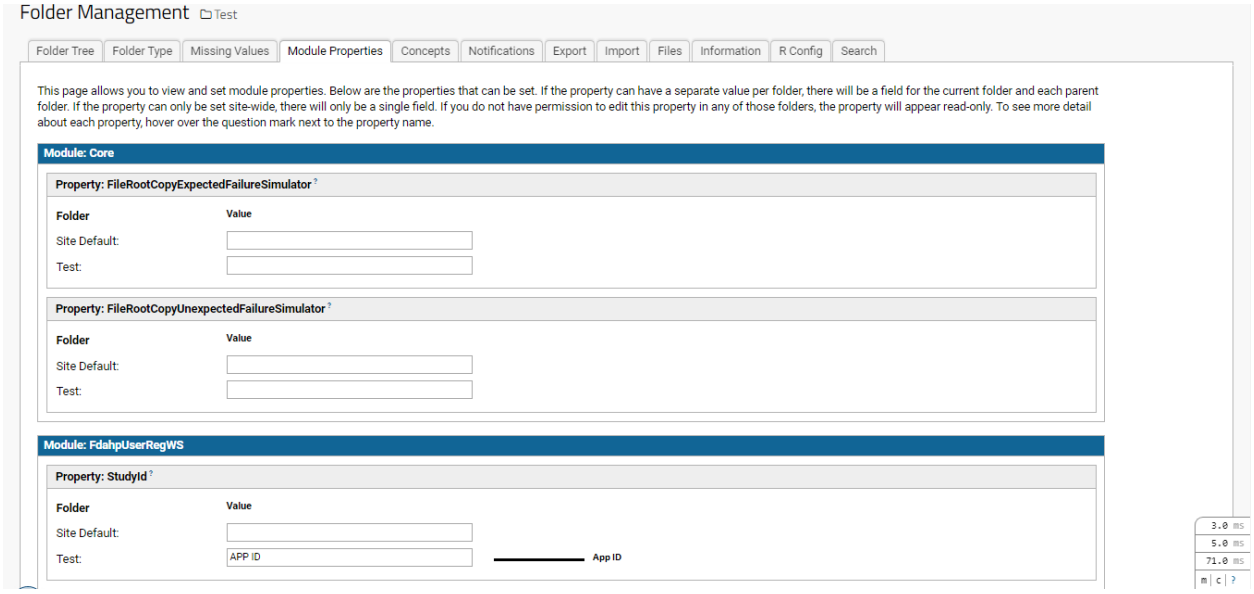
Create a project to capture all app level data



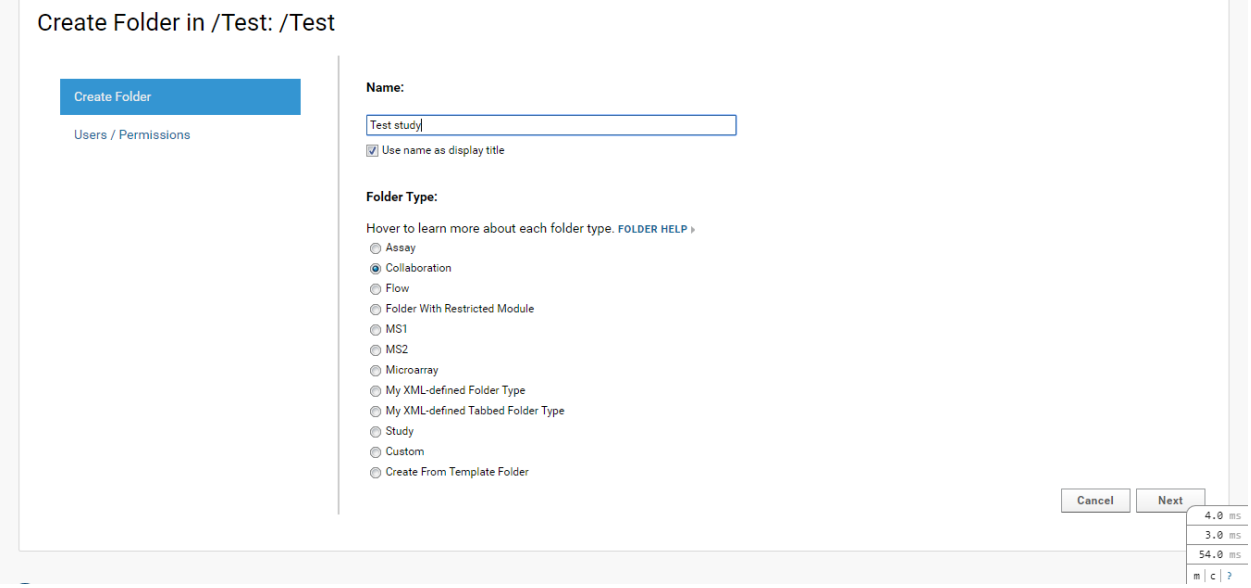
In the Folder Management section, make sure that “FdahpUserRegWS” module is checked



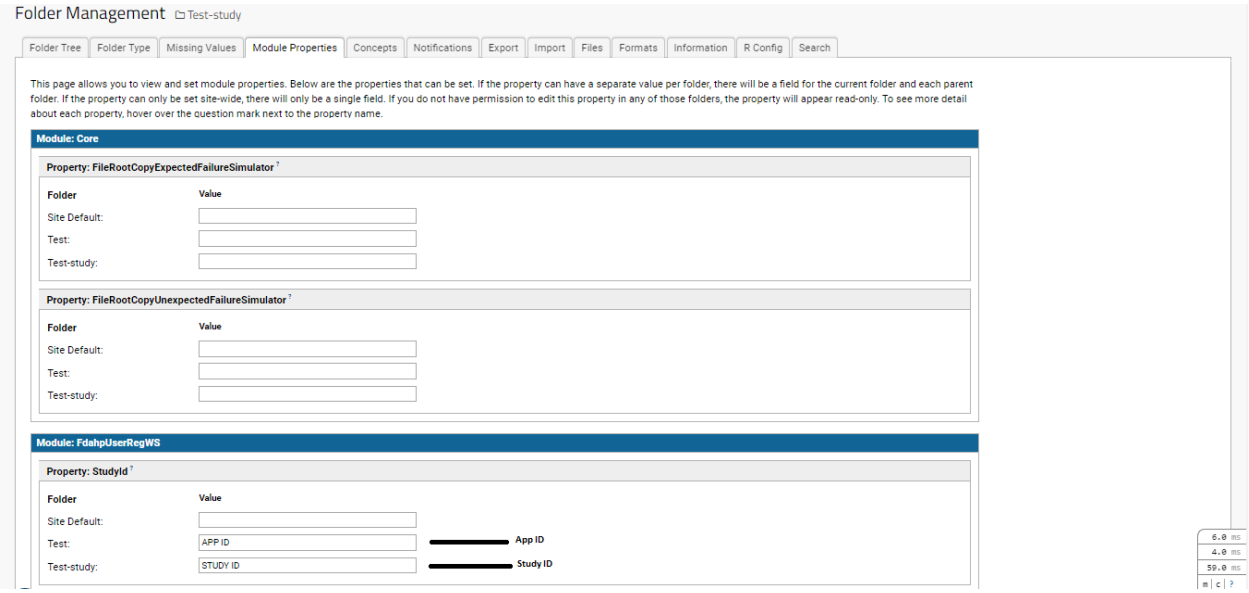
In module properties of folder management add the “APPID” of the application in the value of study



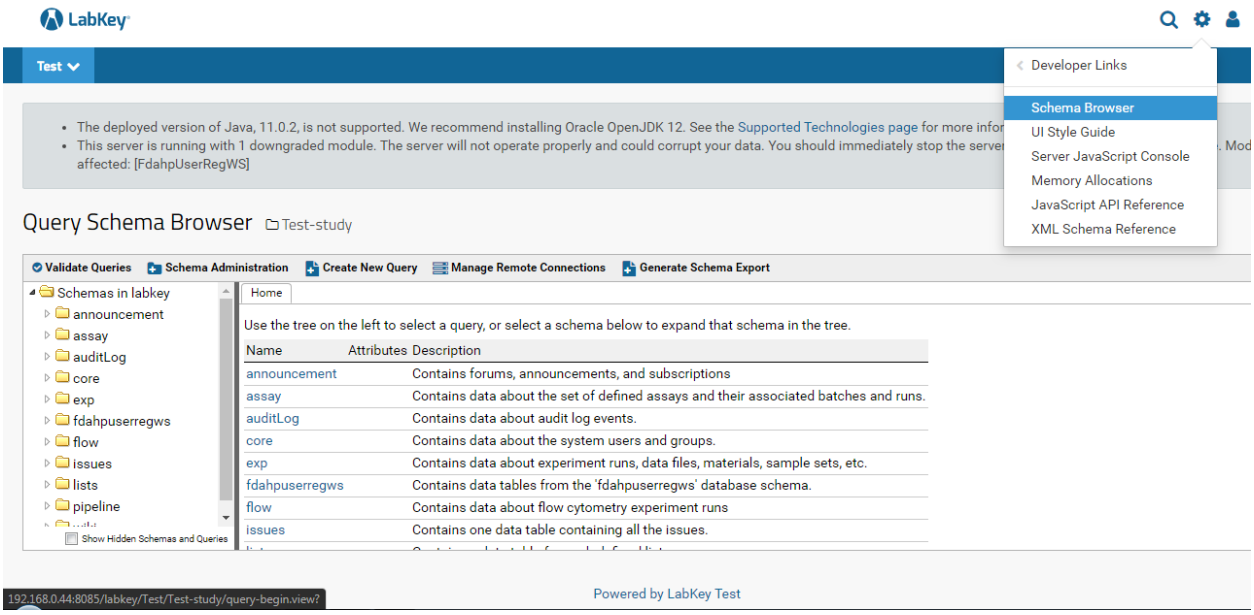
Then create a subfolder inside the project to hold all the study level data



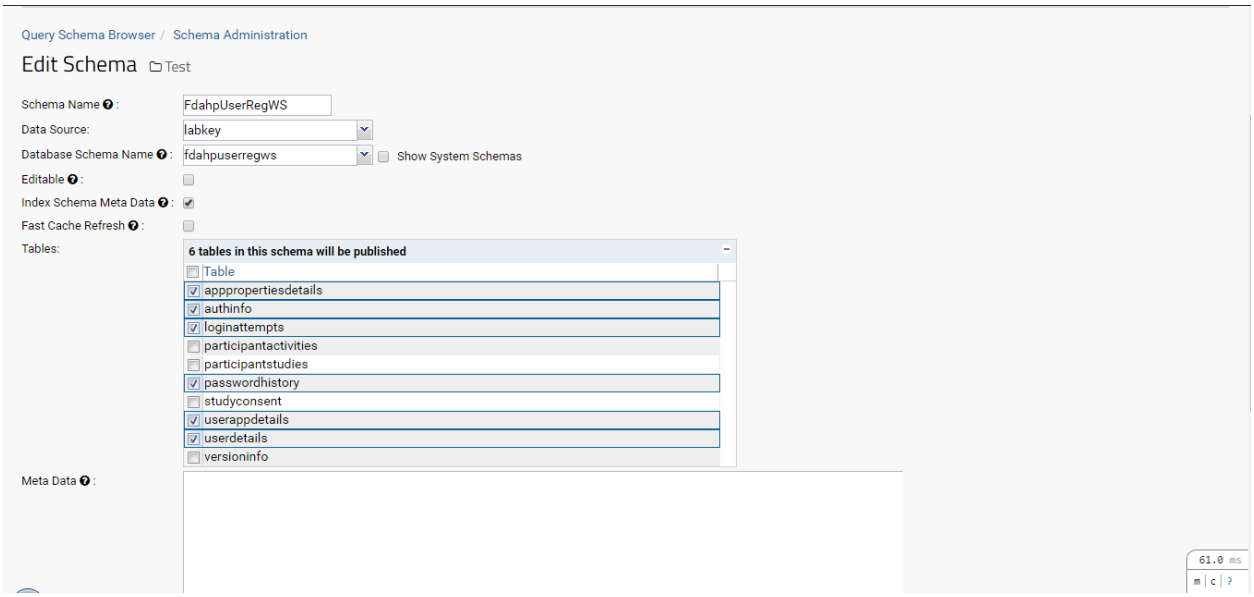
Make sure that “FdahpUserRegWS” module is checked in folder type and add ”Study ID” in the value of study in Module Properties



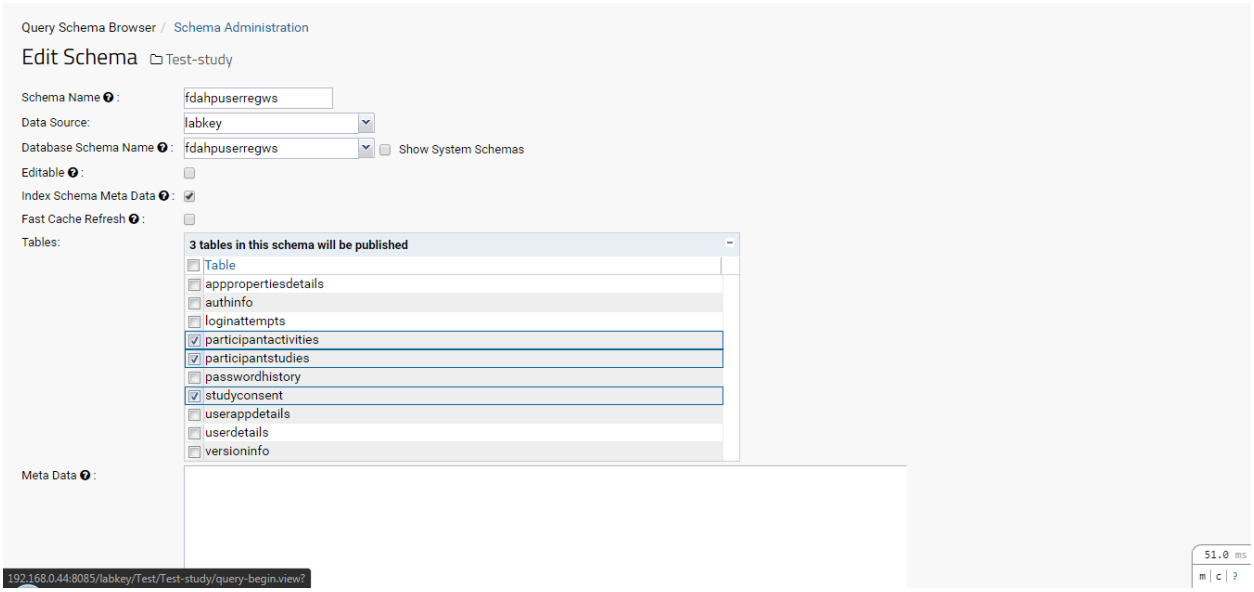
To view the data, create external schemas



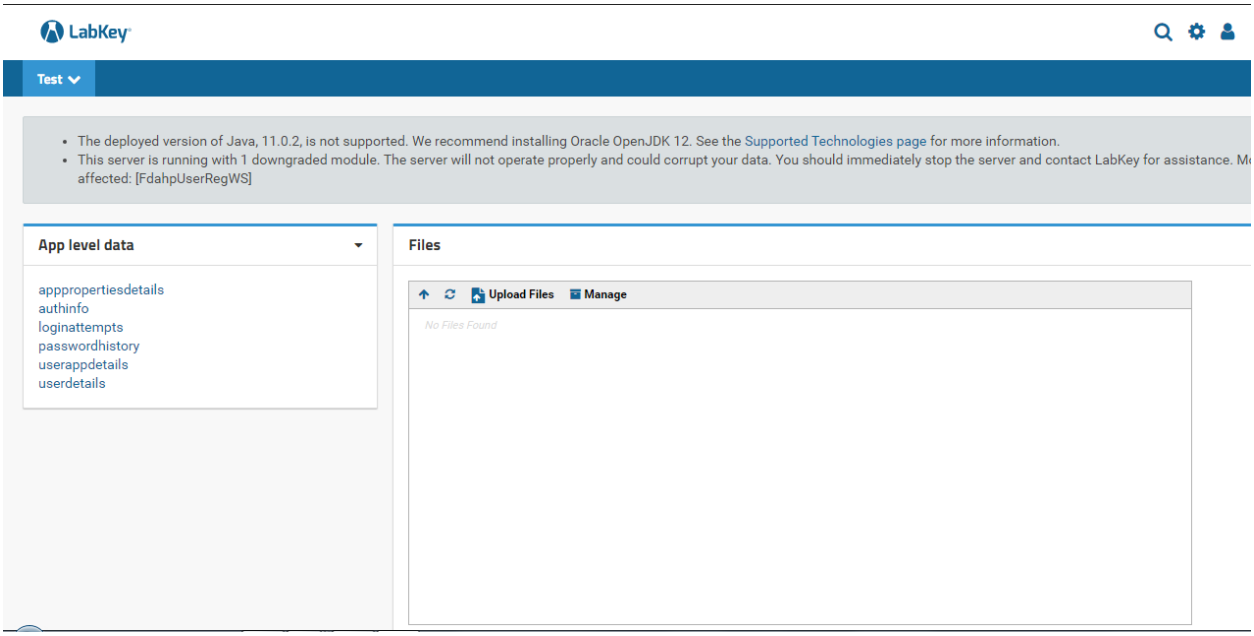
Enable the below table in the schema to view app level data

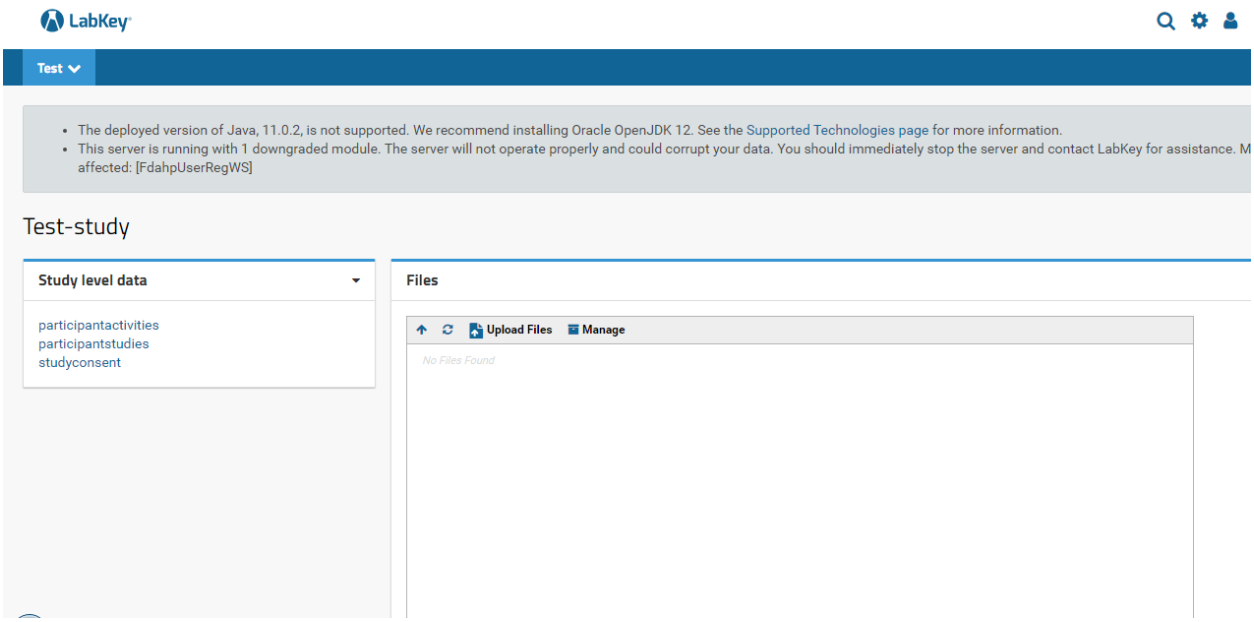


Enable the below table in the schema to view study level data



Add “Query” web part and choose the schema to view the data and add “Files” to view the files associated to them





3.3.2 App Properties API

If a new app is created in WCP server, then the following API should be called manually before publishing the study. This API helps populate the User Registration Server with app-specific data and files that it requires to operate the mobile apps. Please ensure the API is loaded with values as applicable to your app.

(Note that the platform may be enhanced in the future, to provide an interface in the WCP, for managing such app-level properties and content, and automating the transfer of these values to the User Registration server with the API.)

POST: {Base url of user-Reg-WS}/fdahpUserRegWS/appPropertiesUpdate.api

Content-Type: application/json

{

"appId": "", // app ID

"orgId":"OrgName", // org ID (correctly this value of the orgID has been hardcoded in the code base, so do not change this; this field may be made configurable via WCP in the future)

"androidBundleId":"", //android app package name

"androidServerKey":"", // android push notification(fcm) server key

"iosBundleId":"", // iOS app bundle id

"iosCertificate":"", // base64 format text of iOS push notification certificate

"iosCertificatePassword":"", //password of the certificate

"email":"", // email from which mails needs to be sent

"emailPassword":"", // password of the mail id (Not required for production environment)

"registerEmailSubject":"", // email subject for signup mail

"registerEmailBody":"<html><body> Hi,

Thank you for registering with us! We look forward to having you on board and actively taking part in
research studies conducted by xxxxxx.

Your sign-up process is almost complete. Please use the verification code provided below to
complete the Verification step in the mobile app.

Verification Code: <<< TOKEN HERE >>>

This code can be used only once and is valid for a period of 48 hours only.

Please note that registration (or sign up) for the app is requested only to provide you with a
seamless experience of using the app. Your registration information does not become part of
the data collected for any study housed in the app. Each study has its own consent process
 and no data for any study will not be collected unless and until you provide an informed consent
 prior to joining the study

For any questions or assistance, please write to <a>Contact Email Address

Thanks,
The xxxxxx Team

PS - This is an auto-generated email. Please do not reply. </body></html>", // email subject for signup mail, replace 'xxxxxx' with your organization's name that is offering the app, or other suitable text.

"forgotPassEmailSubject":"", // email subject for Password Help email

"forgotPassEmailBody":"<html><body> Hi,

Thank you for reaching out for password help.

Here is a temporary password which you can use to sign in to the (app name) App.
 You will be required to set up a new password after signing in.

Temporary Password: <<< TOKEN HERE >>>

Please note that this temporary password can be used only once and is valid for a period of 48 hours only.

For any questions or assistance, please write to <a> Contact Email Address

Thanks,
The xxxxxx Team

PS

- This is an auto-generated email. Please do not reply. In case you did not request password help, please visit the app and change your password as a precautionary measure. </body></html>" // email Body for Password Help email, replace 'xxxxxx' with your organization's name that is offering the app, or other suitable text.

}

Important Notes:

The body of the emails need to be in HTML format and the <<< TOKEN HERE >>> part represents identifier for the verification code or temporary password dynamically generated for that email.

All fields in the API are mandatory.

After setting up the folder structure and calling the API as described above, publish the study from the WCP application, and start using the mobile app.

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

4.2.2 iOS

Application is supported only on iOS 11 and above versions.

4.3 Xcode Setup

After successful installation of xcode follow below steps

4.3.1 Setup Developer Credentials

- Open Xcode and go to **Preferences**.
- Click on **Accounts** on top menu.
- Click on + icon and Choose **Apple ID.**
- Sign In with Apple developer account.

4.3.2 Change Bundle Identifier

- Enter a new bundle identifier for your application.
- Choose Code Signing to "Automatically manage signing" and Xcode will take care of registering bundle identifier.

4.3.3 Enable for Push Notification

- Create push notification certificates for newly created Application.
- Encode the .p12 file to Base64 test and send this in App Properties API.(REFER SECTION 3.3.2)
- For more info Visit Apple Official Page for Establishing a Certificate-Based Connection to APNs

Note: To know more on Xcode and above setup Refer to Apple official guide to Xcode Setup

4.4 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.

4.5 How to change Server URLs

Note: Once your Registration, WCP & Response Server are setup please follow below steps.

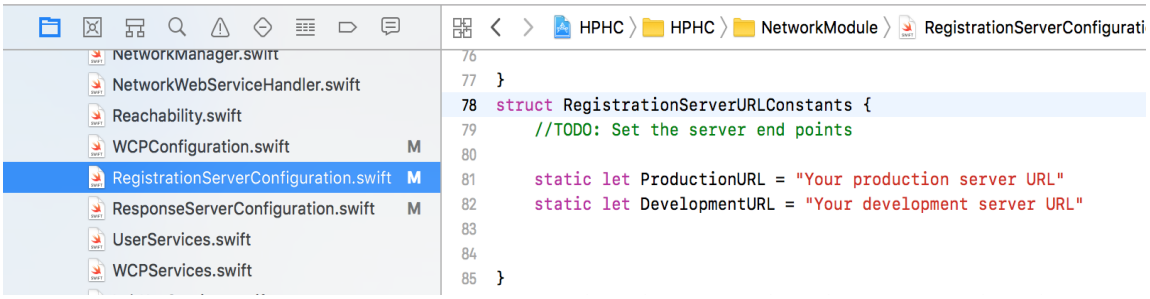
4.5.1 Setup study configuration

After an application is setup on WCP server and after creating the study.(REFER SECTION: 7.1)
You will need to add your "Application Identifier" into info.plist file.
Replace the value for **ApplicationID** in info.pist file

4.5.2 Registration Server

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

Add your Production and Development Server URLs.



4.5.3 WCP Server

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

Add your Production and Development Server URLs.

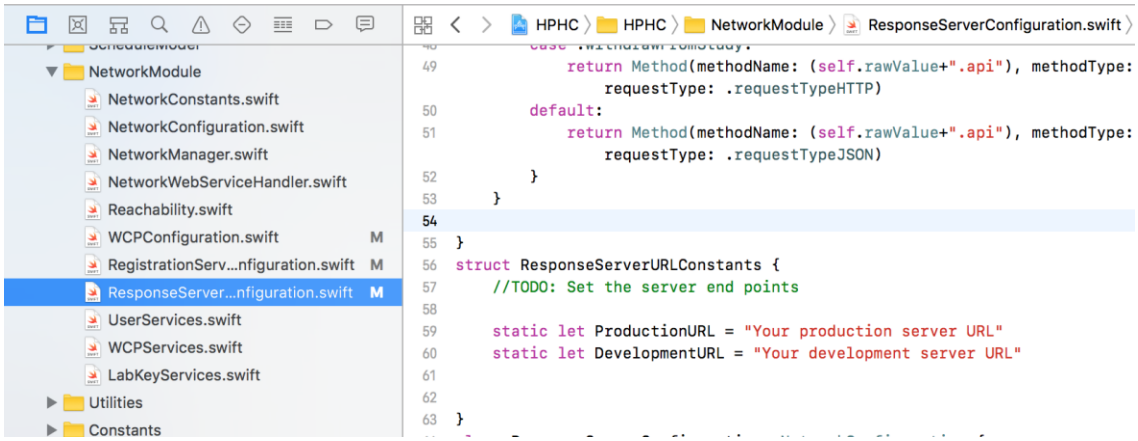
- Update your Username (represented as bundle id) and AuthToken (represented as appToken) to call WCP Server API. Please refer to (REFER SECTION: 2.2.3)

```
56 struct Credentials {
57
58     static let username: String = "username"
59     static let authToken: String = "authToken"
60
61     static var token: String {
62         return username + ":" + authToken
63     }
64 }
```

4.5.4 Response Server

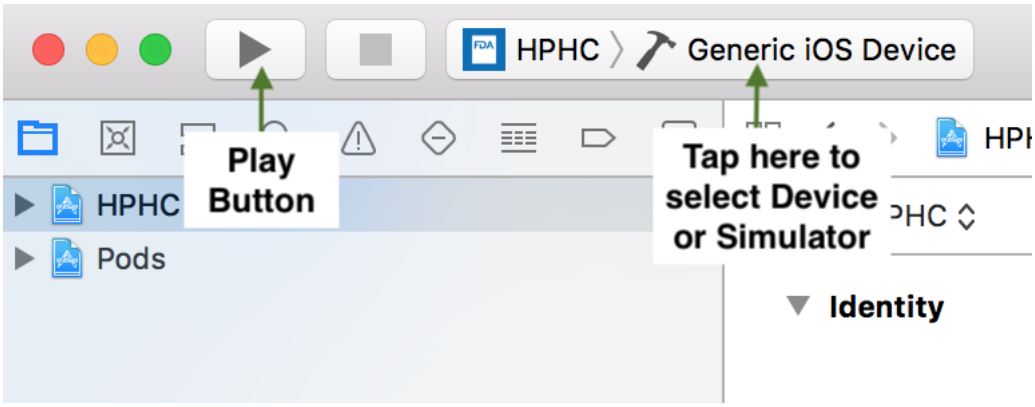
Look for "**ResponseServerConfiguration.swift**" file in Navigator Section and tap on it.

Add your Production and Development Server URLs.



4.6 How to Build and Run

Application can be run on iPhone Simulator OR iPhone Device.



4.6.1 Run on Simulator

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

4.6.2 Run on Device

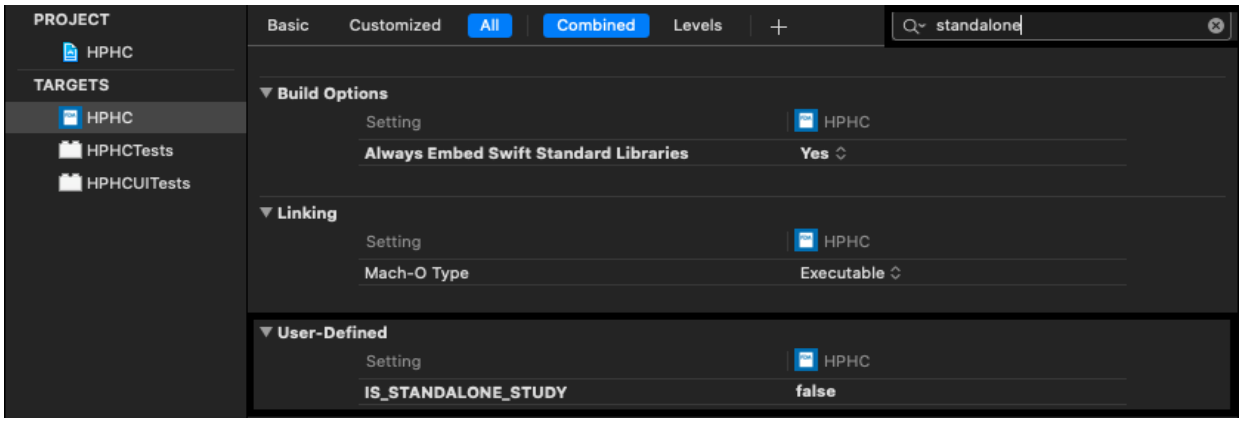
To build and run application on your iPhone device, connect your phone with power cable to mac machine.

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

4.7 How to setup Standalone Study App

Note: You need to create the standalone study on WCP server first & get the studyID. Once standalone study setup is finished please follow below steps (REFER SECTION: 7.1)

1. Open the project workspace in Xcode.
2. Replace the StandaloneStudyId value with studyID in Info.plist
3. Make sure OrganizationID & ApplicationID is same in the Info.plist from the same WCP server.
4. Go to main target Build settings & Search for "standalone"
5. Under User-Defined, set the "IS_STANDALONE_STUDY" value as ***true*** for both **debug** and **release.**



6. Build and run the project.

4.8 Apply Your Branding

- **AppIcon & Launch Image**
  Replace your AppIcon and Launch Images into Assets.xcassets under the AppIcon & LaunchImage respectively.
- **Change Display Information**
  There are some informational content items that can be directly changed at file level, and not required to be changed at the code level. Look for file Branding.plist and change information appropriate to your application.
- **App Introduction Changes**
  App Introduction screen can also be changed at file level.
  Look for GatewayOverview.plist file and change information appropriate to your application.

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 Initial Setup

5.4.1 App Setup

Go to **com.harvard** package in **fda** directory and open the **AppConfig.java** file. Do the following steps:

a. To build the app as **Standalone** update following variable as (REFER SECTION: 7.1)
public static String AppType = Standalone;
public static String StudyId = "STUDY ID PROVIDED IN WCP";
b. To build the app as **GateWay** update following variable as (REFER SECTION: 7.1)
public static String AppType = GateWay;
public static String StudyId = "NOT REQUIRED FOR GATEWAY APP(CAN LEAVE IT AS EMPTY)";
c. Update **APP_ID_VALUE** variable with the **APP ID** provided in WCP. (REFER SECTION: 7.1)

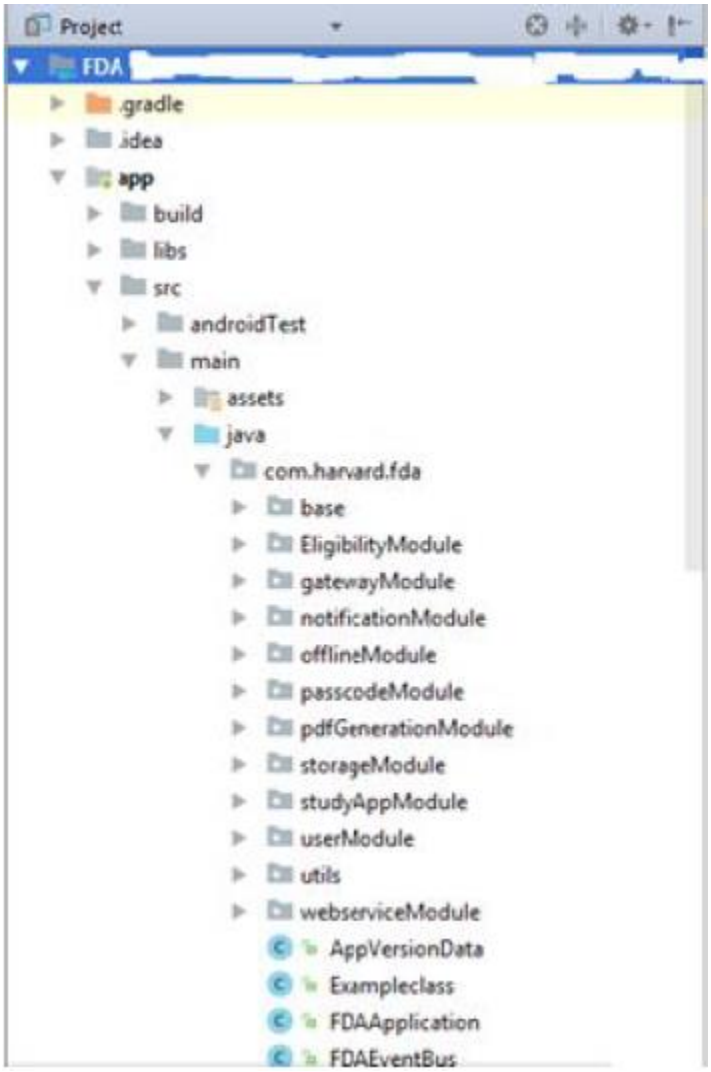
d. To authenticate the client to make API calls to WCP server, update the value of **API_TOKEN** with the **<value of android.bundleid>:<value of android.apptoken>**.(REFER SECTION: 2.2.3)

5.4.2 Push Notification Setup

a. Go to your Firebase project
b. Set up Push Notification for Android
c. Download the json file and replace the **google-services.json** file in **app/src/fda** directory.
d. Send the Server Key (from Cloud Messaging section of Firebase) in App Properties API.(REFER SECTION 3.3.2)

5.4.3 Update the Map key(com.google.android.maps.v2.API_KEY) in Android Manifest file in app/src/main directory and app/src/fda directory

5.5 Steps to change API URL



Go to **utils** package from base package **com.harvard** in **main** directory 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.

5.6 Apply Your Branding

i. **AppIcon & Launch Screen**

To update these, the following changes have to make in src/fda directory:

a) Replace **ic_launcher.png** in mipmap-hdpi, mipmap-mdpi, mipmap-xhdpi, mipmap-xxhdpi, mipmap-xxxhdpi directories with respective resolutions for App icon updates.

b) Replace **fda_logo1.png, fda_logo2.png** in drawable-560dpi, drawable-xhdpi, drawable-xxhdpi, drawable-xxxhdpi directories with respective resolutions for updating launch screen logos and update the **activity_splash.xml** file in layout directory for launch screen UI.

ii. **Change Display Information & App Introduction Changes**

There are some informational content items in the app that can be directly changed at file level, and not required to be changed at the code level. Look for file **strings.xml** in values directory and change information appropriate to your application including App Introduction screen text.

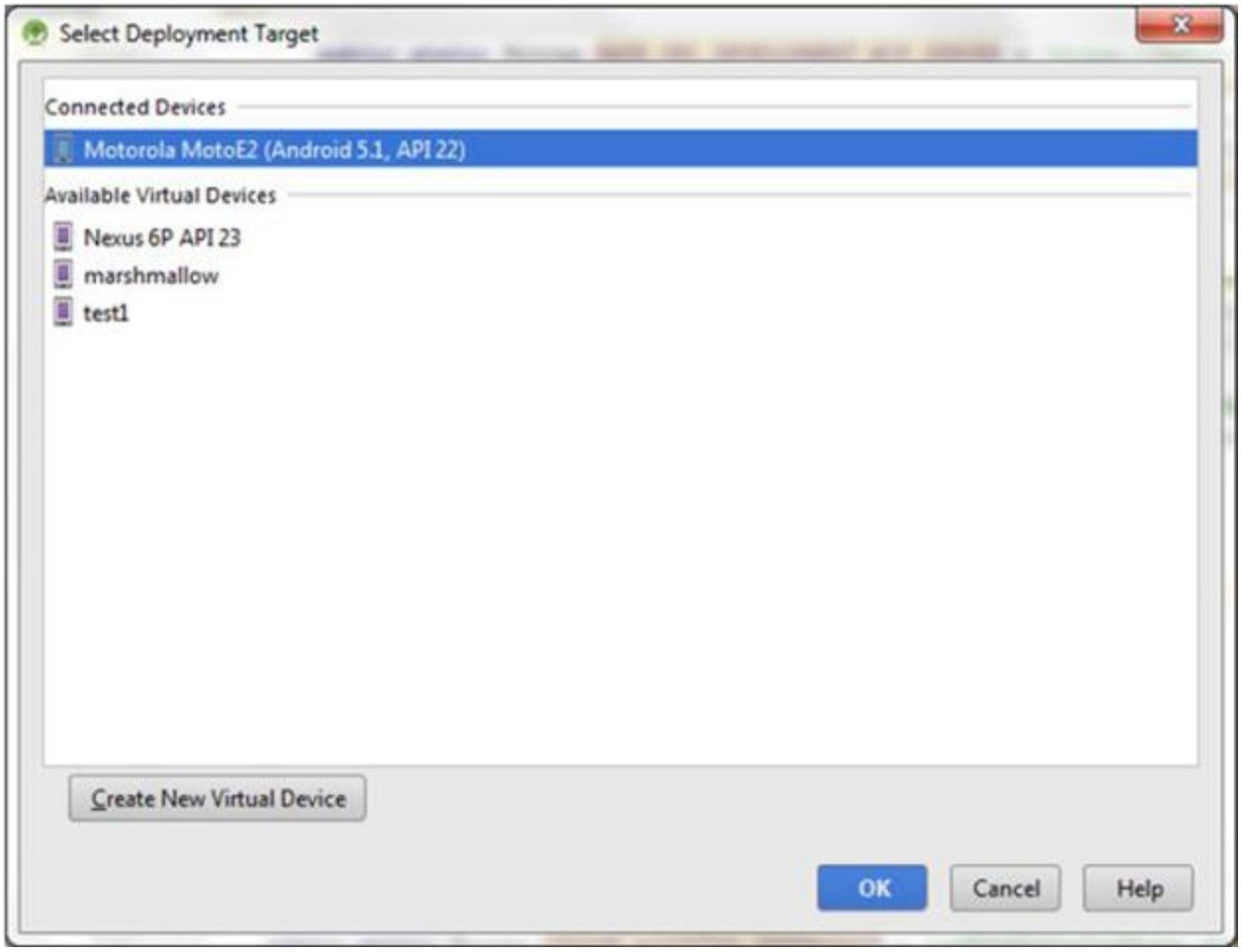
5.7 Steps to install Android app

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)

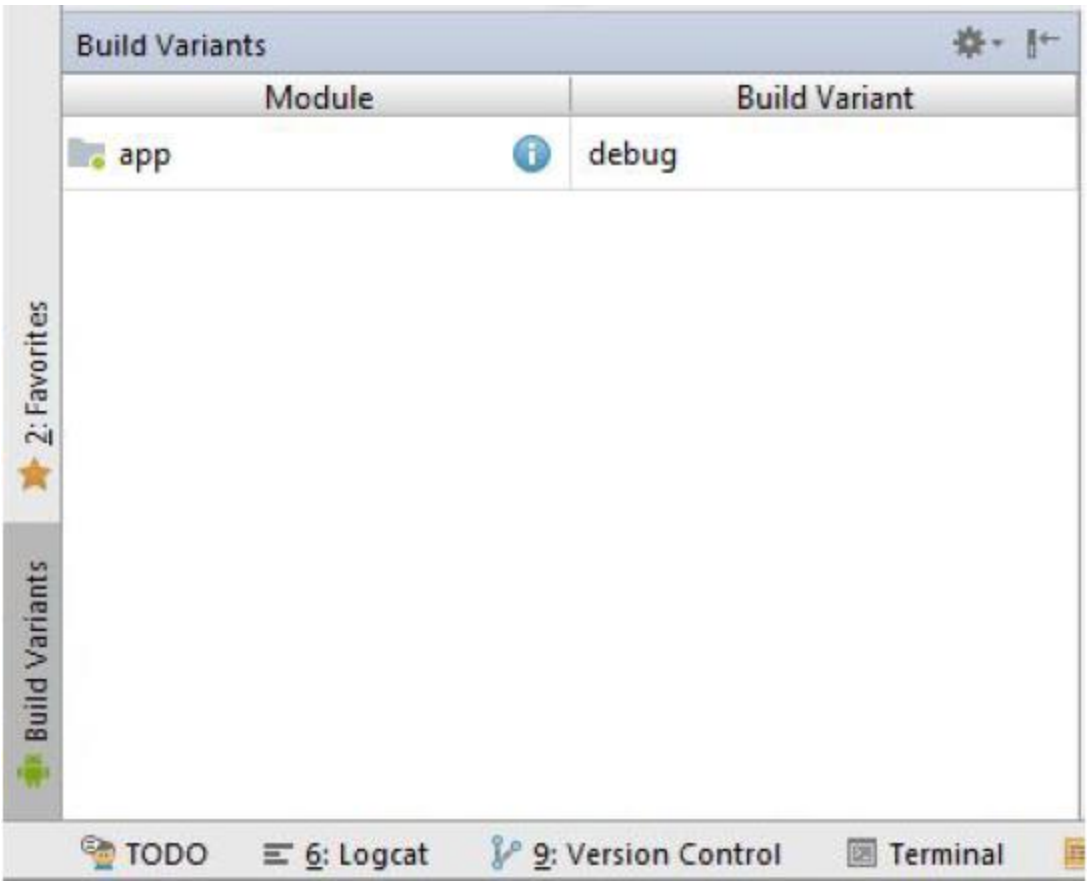
image2

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

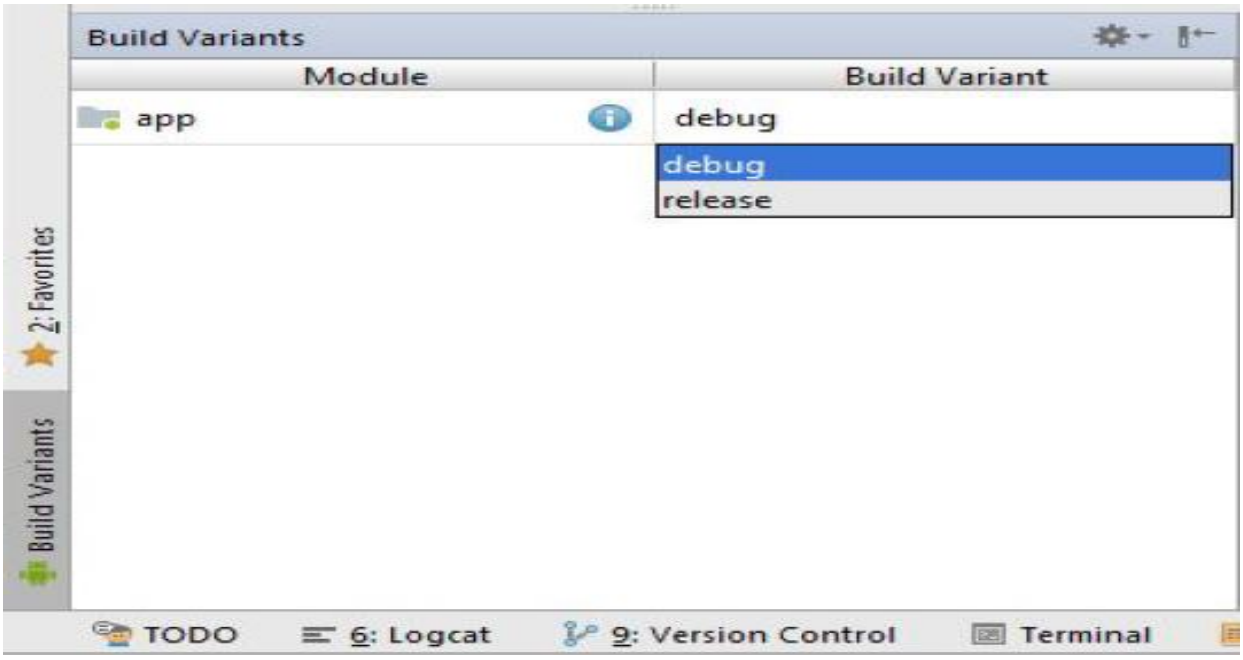


5.8 Creating the Android app build

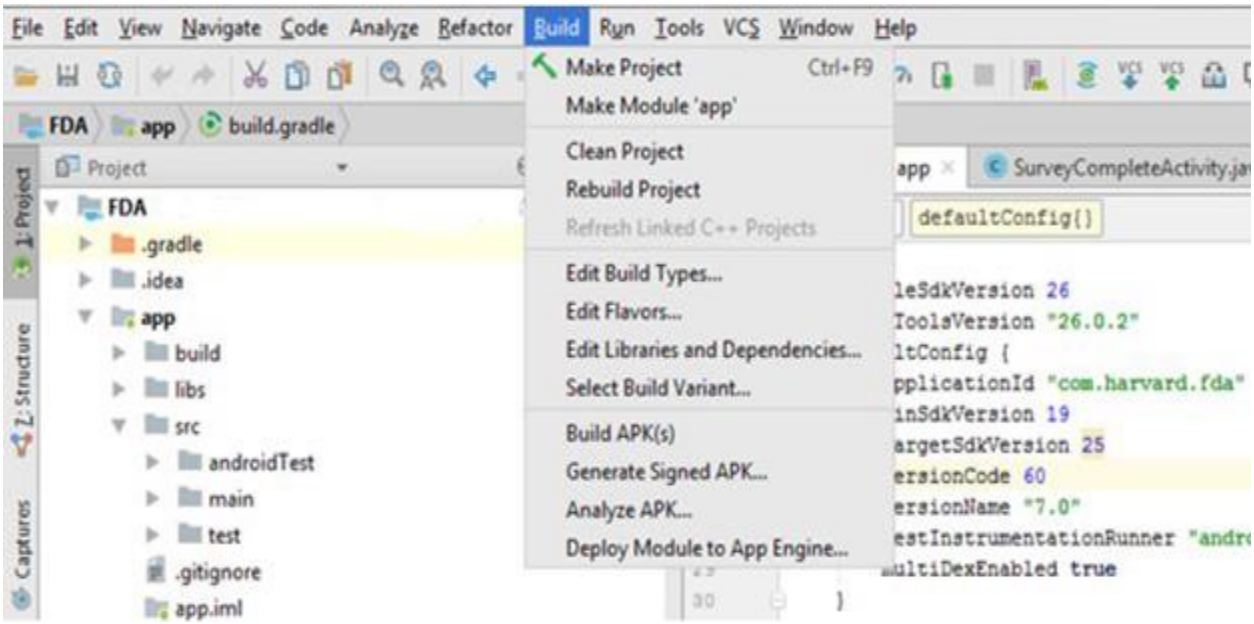
a. First increment the **versionName** and **versionCode** in **build.gradle** file in App Directory from Project Explorer.
b. Click on **Build Variants** and in Android Studio and click on the area where **debug** text is displayed.



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

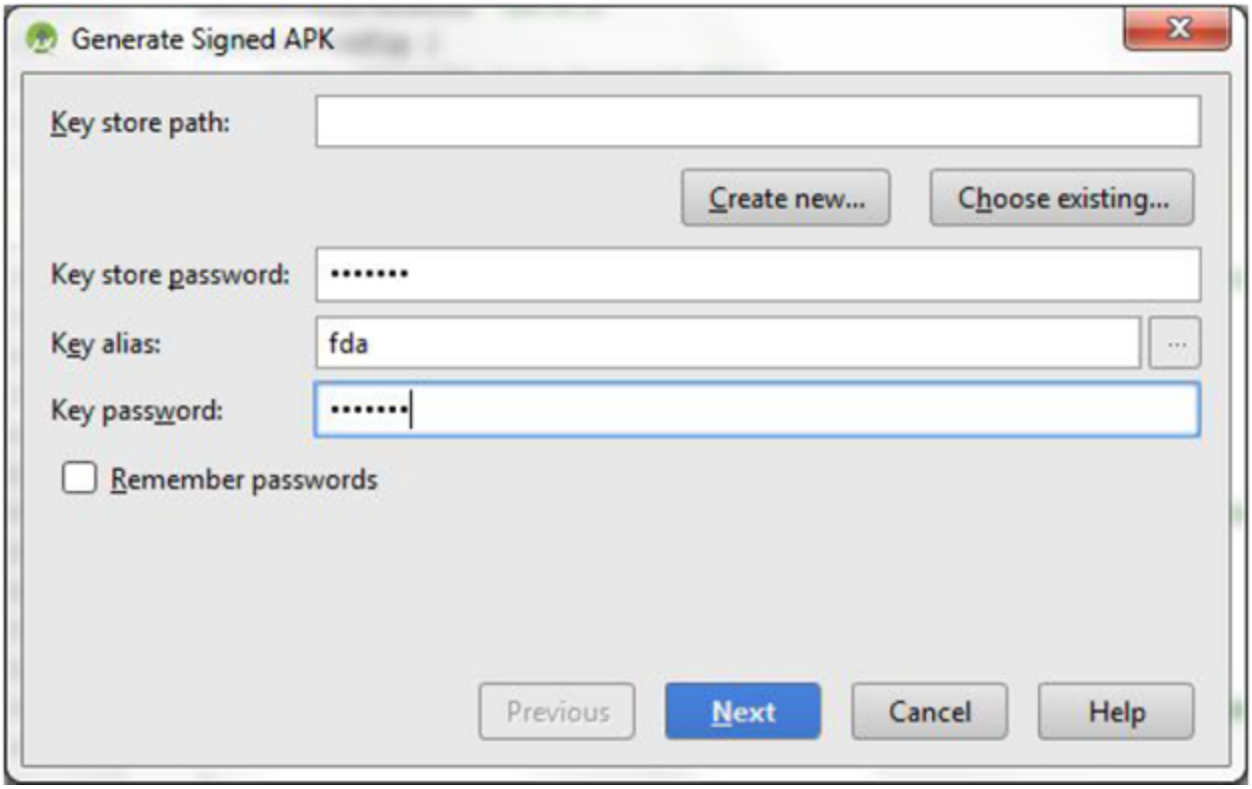


d. Click on **Build** from the menu bar and select **Generate Signed APK**.



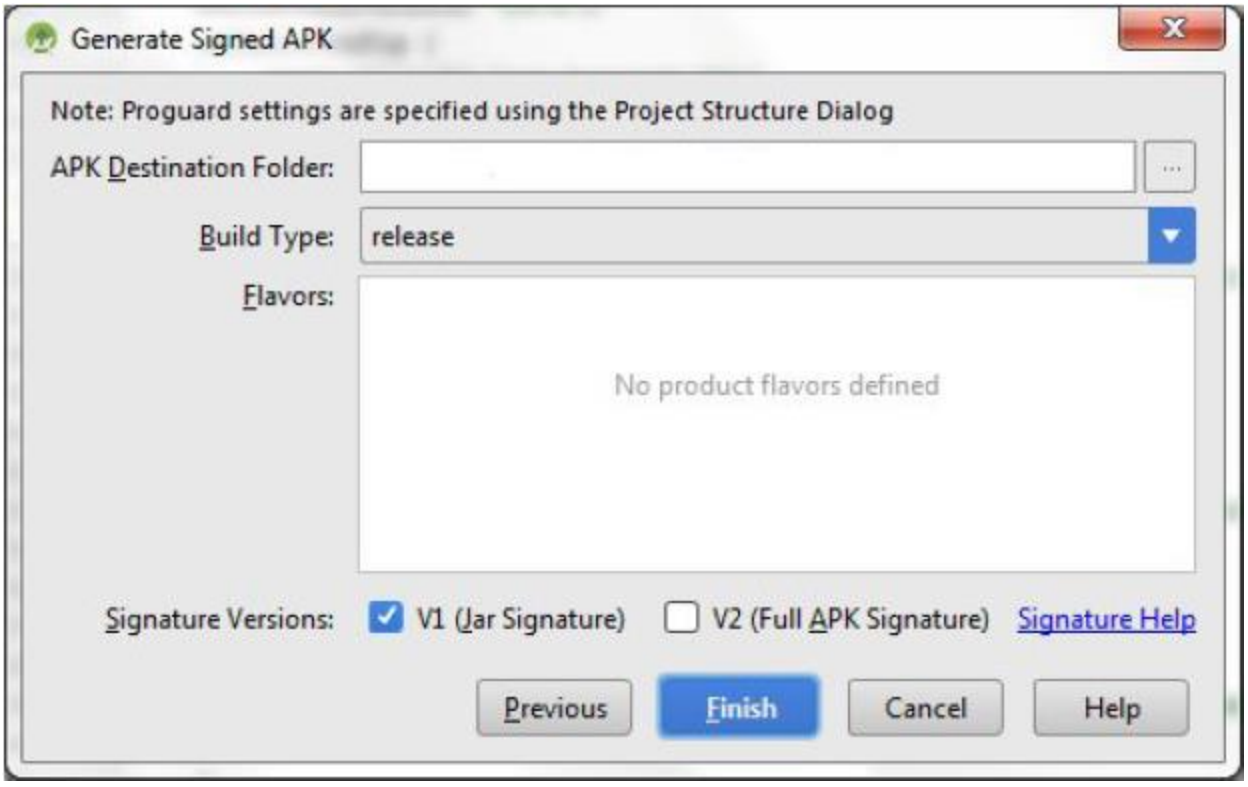
e. Download the **keystore.jks** from the following link <Keystore Location>

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.

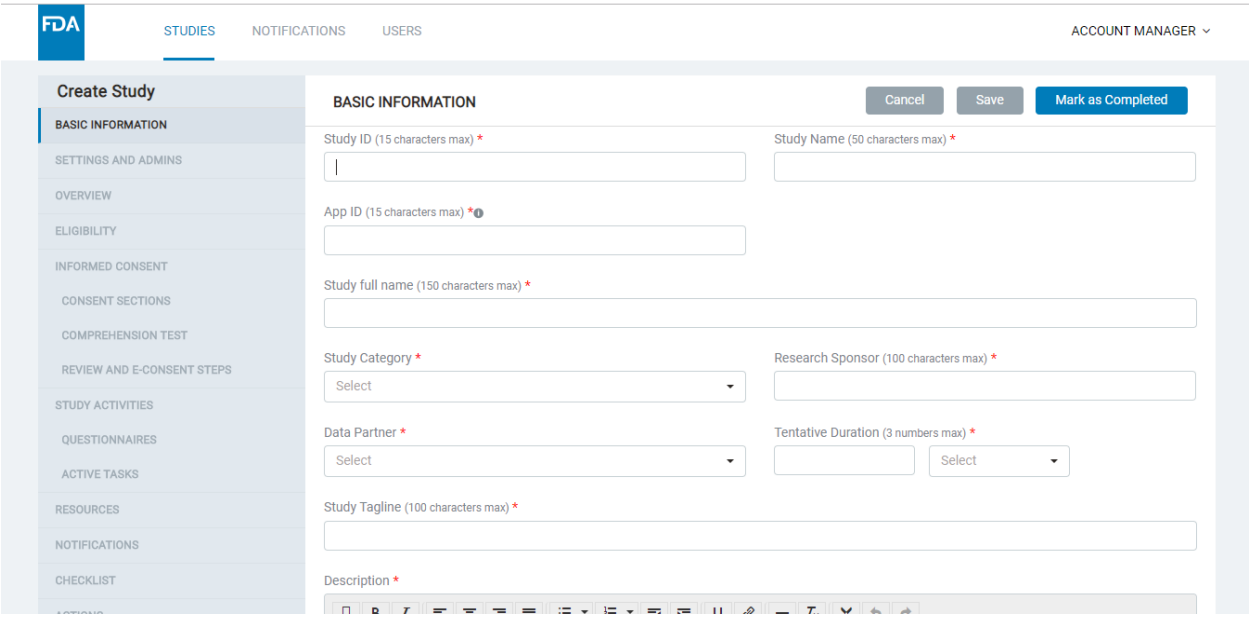
7.1 Create the study in WCP

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)

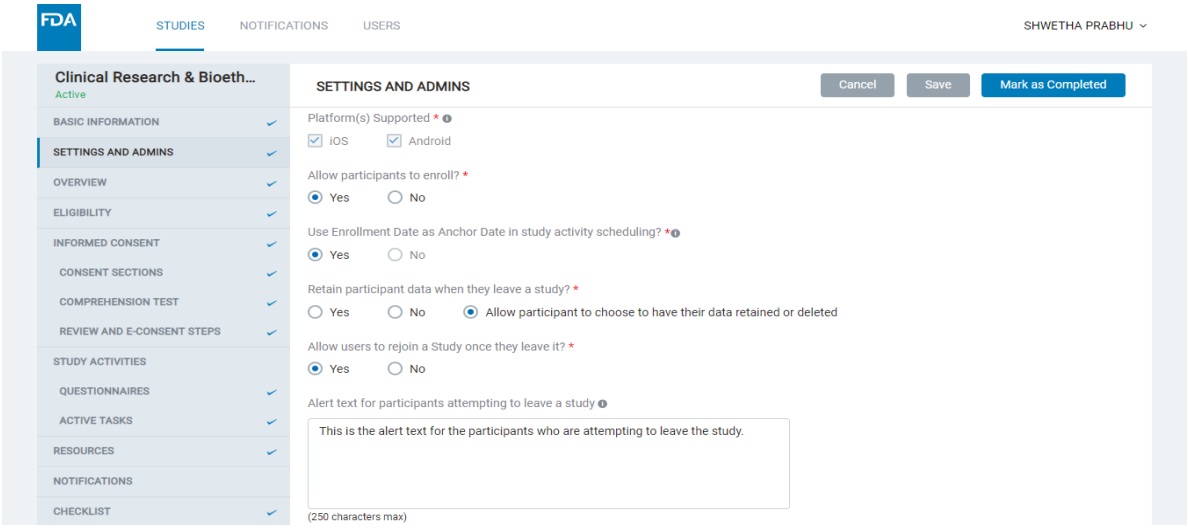
7.1.1 Basic information

- Here, the Admin should enter a Study ID (which should be unique for each study) App ID, 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.)
- To have a gateway app, create multiple studies under a single AppId and all of those studies will be visible in the mobile app that has that AppId
- To have a standalone app, create a single study for a unique AppId and the corresponding mobile app will correspond to that one study only.
- OrgId (to tie the app to an Organization name) is not supported to be configured via WCP UI as of now, this value has been hardcoded to 'OrgName' in the code base for now, and can be changed directly in the code, if necessary. However, in the future, the WCP UI may be enhanced to make this value configurable by the Admin.
- If Admin chooses Study Type as Gateway, a Study Thumbnail Image should be uploaded as well.



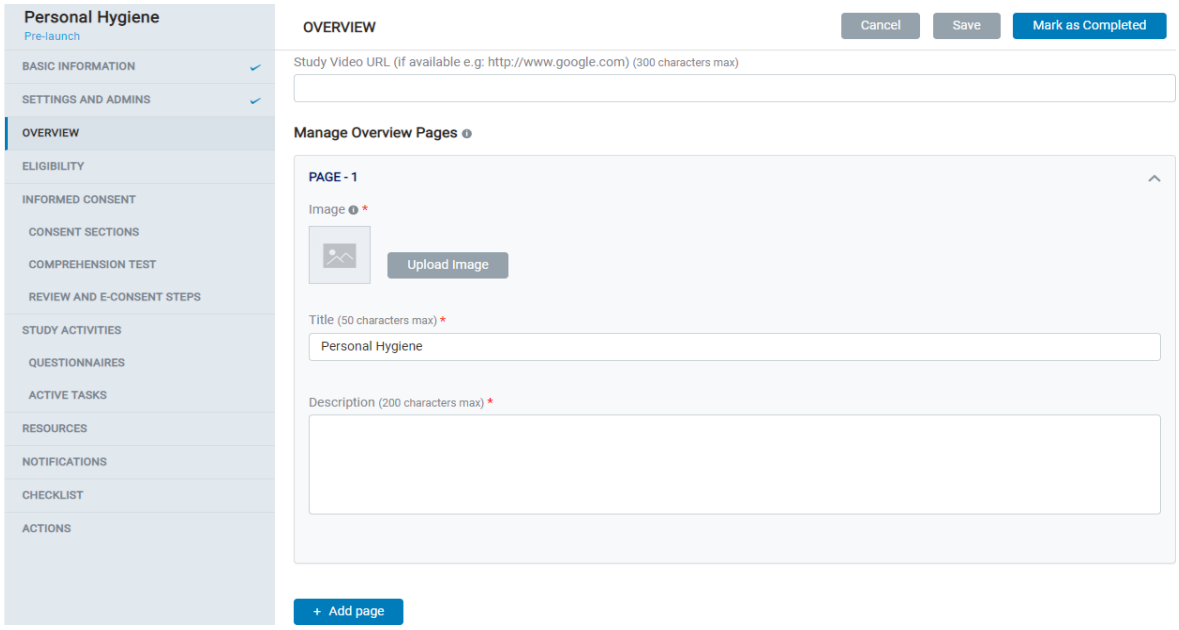
7.1.2 Settings & Admins

- 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.



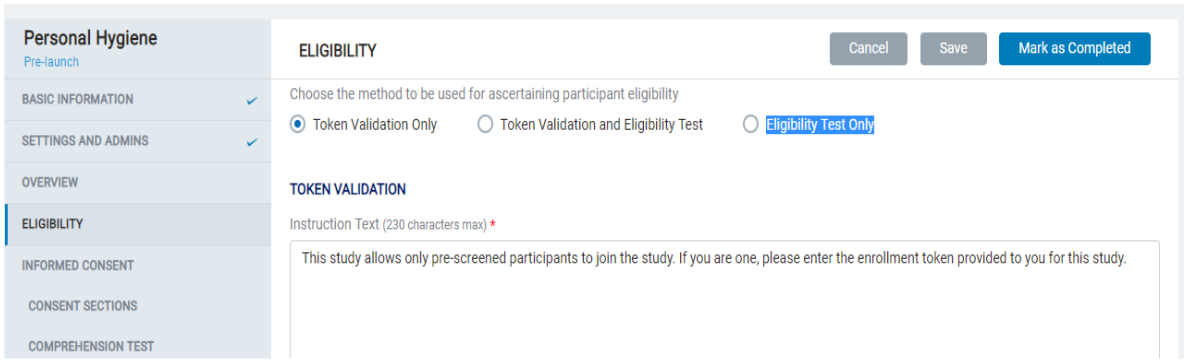
Overview

- 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.



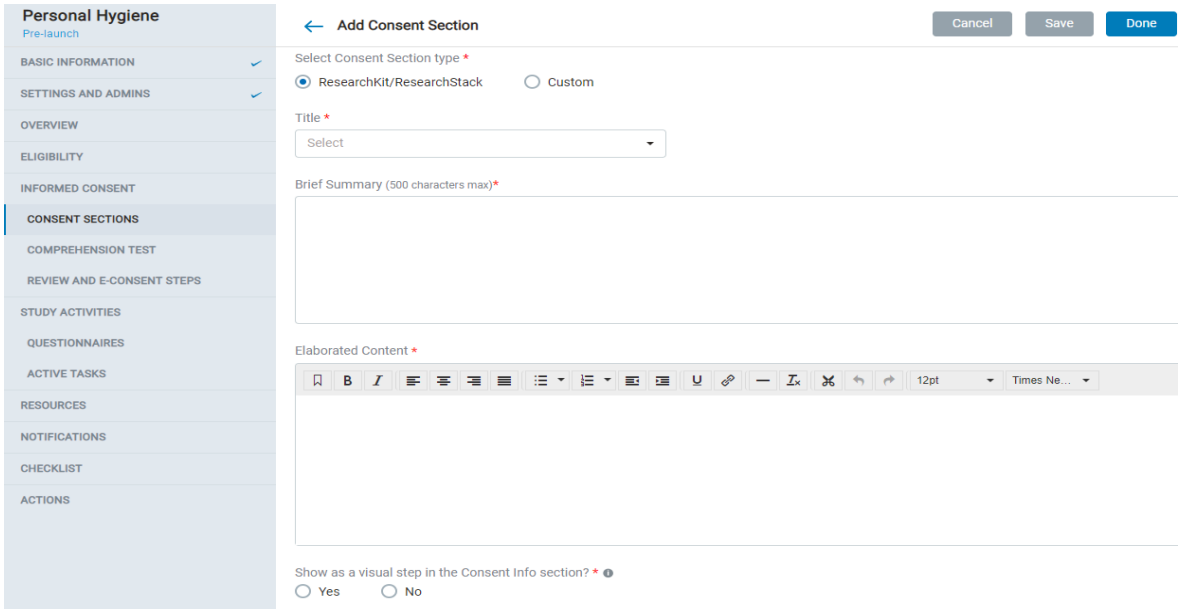
7.1.3 Eligibility

- 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

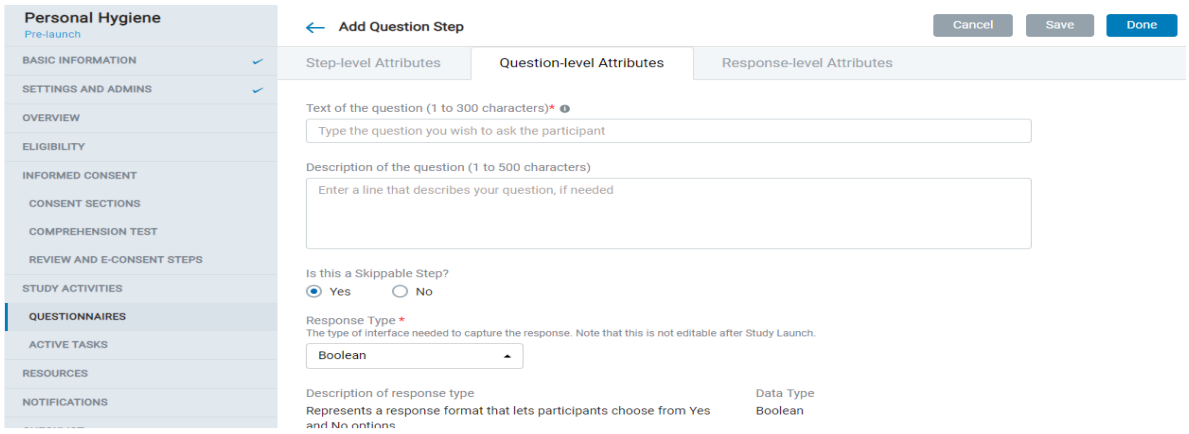
- In Consent Sections, the Admin can add ResearchKit/ResearchStack based (pre-formatted mobile UI) or Custom consent section types and fill in content accordingly.
- Each consent section contains Title, Display Title, Summary and Elaborated content.
- The admin can also choose to display the Consent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

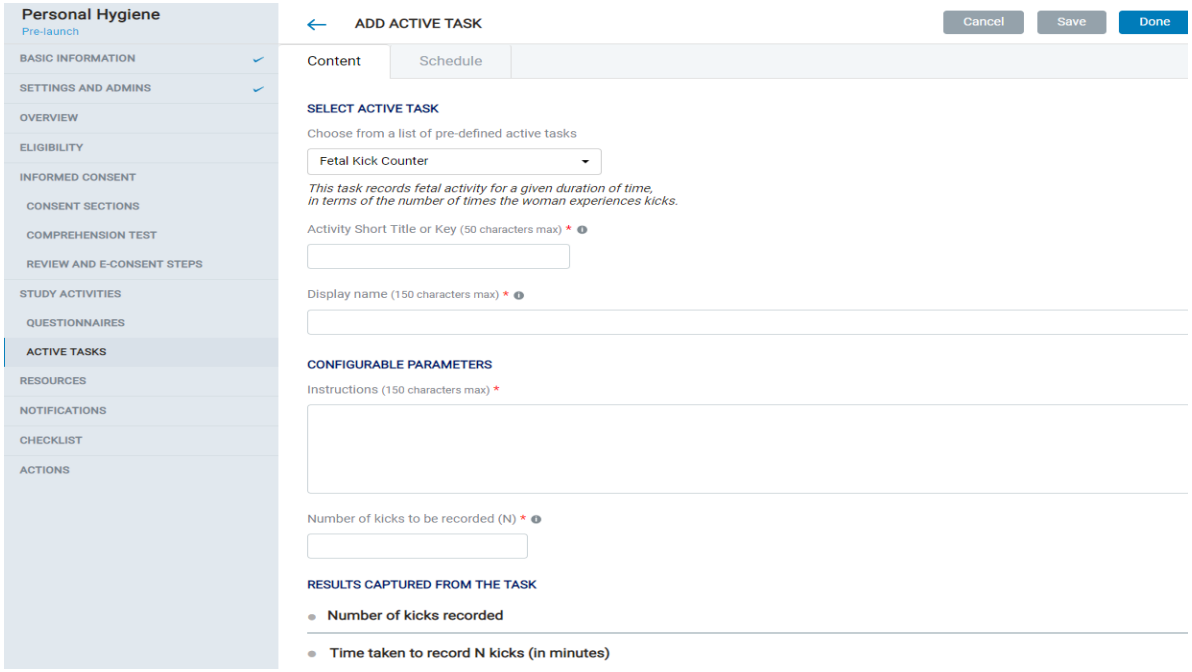
7.1.5 Study Activities – Questionnaires

- 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.



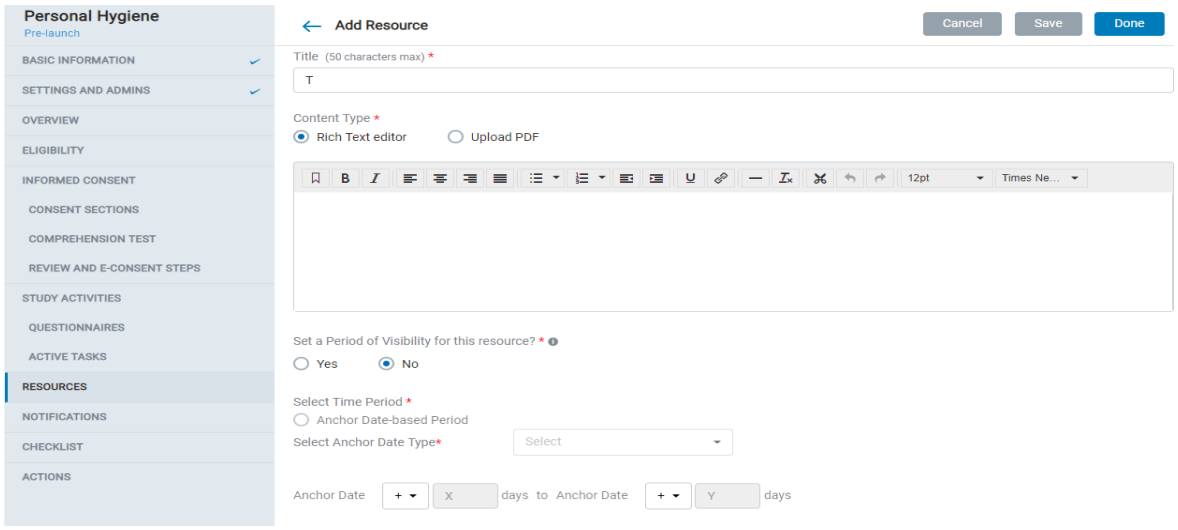
7.1.6 Study Activity – Active Tasks

- 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.



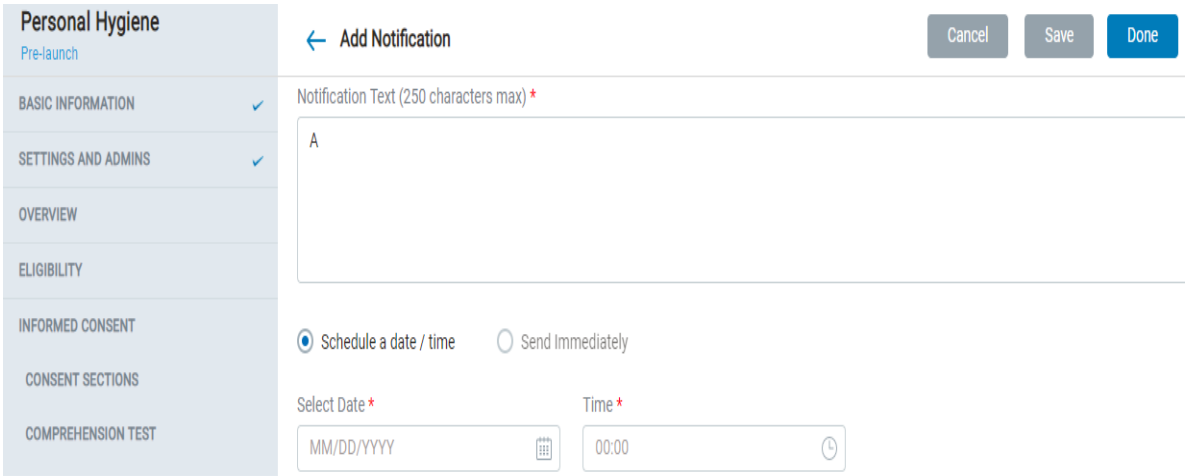
7.1.7 Resources

- 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.



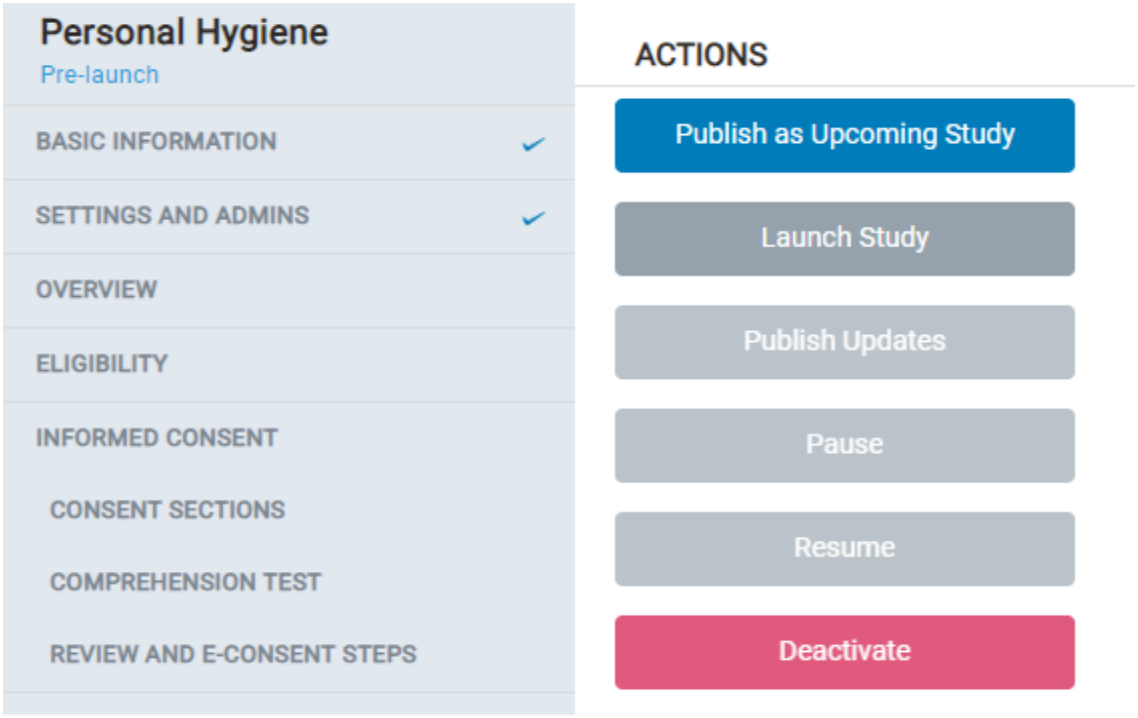
7.1.8 Notifications

- 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 App and Study Folder in User-Reg Server

Create App and Study folders for your app on the User Registration Server (REFER SECTION 3.3).

7.3 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)

7.4 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 (Note that mobile app users would need to sign up separately for each of the apps created using the platform.)
- 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 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.