An Introduction to FDA MyStudies: An Open-Source, Digital Platform to Gather Real World Data for Clinical Trials and Research Studies

May 9, 2019

Welcome

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The US FDA, Harvard Pilgrim Health Care Institute, LabKey Software,
Boston Technology Corporation

AN INTRODUCTION TO FDA MYSTUDIES: AN OPEN-SOURCE, DIGITAL PLATFORM TO GATHER REAL WORLD DATA FOR CLINICAL TRIALS AND RESEARCH STUDIES

Speakers

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Agenda

Topic	Presenter	Time
Welcome and administrative announcements	SBIA	10:00 – 10:05
Introduction to the FDA MyStudies Mobile App System	David Martin	10:05 – 10:15
A live demonstration of the FDA MyStudies Mobile App System: Patient and Researcher experiences	Zachary Wyner	10:15 – 11:30
Break	-	11:30 – 11:40
Responses to submitted questions	MyStudies Team	11:40 – 12:00
Break	-	12:00 – 12:30
Technical Overview: Mobile Application, Web Configuration Portal	Shyam Deval, Ranjani Rao	12:30 – 1:10
Response Server Technical Overview	Adam Rauch	1:10 – 1:30
Break	-	1:30 – 1:45
Responses to submitted questions	MyStudies Team	1:45 – 2:10
Deploying the MyStudies System in a Compliant Manner	Stuart MacDonald	2:10 – 2:30
Responses to submitted questions	MyStudies Team	2:30 – 2:50
MyStudies closing thoughts and resources	MyStudies Team	2:50 – 2:55

David Martin

INTRODUCTION TO THE FDA MYSTUDIES MOBILE APP SYSTEM

Disclosure and Disclaimer

- David Martin received funding from the Patient Centered Outcomes Research Trust Fund to develop the FDA MyStudies Mobile App
- No conflicts of interest to disclose
- The views expressed are those of the author and should not be construed as FDA's views or policies
- The mention of commercial products, their sources, or their use in connection with material reported herein is not to be construed as either an actual or implied endorsement of such products by the Department of Health and Human Services

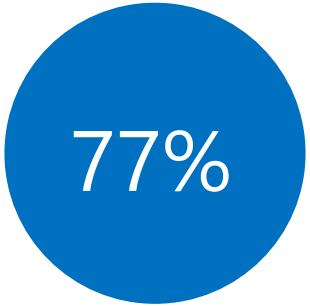
01

WHY CONSIDER MOBILE NOW?

Evolution of RWD Collection from Patients

www.fda.gov

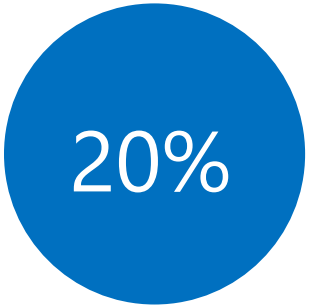
Smartphone use among U.S. adults is increasing[1]



now own Smartphones (35% in 2011)

Fewer (73%) own a laptop or desktop

Growth of "smartphone only" internet use[2]



of US adults do not rely on traditional home internet service for access

Variation in "smartphone only" internet use[3]

Reliance on smartphones for online access is especially common among younger adults (<50), non-whites and lower-income Americans.

FDA

It's time to leverage the power of mobile technologies to aid research

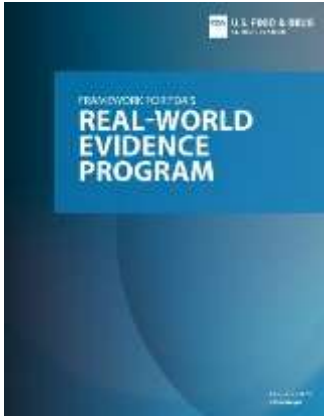
www.fda.gov

Real World Data and Evidence

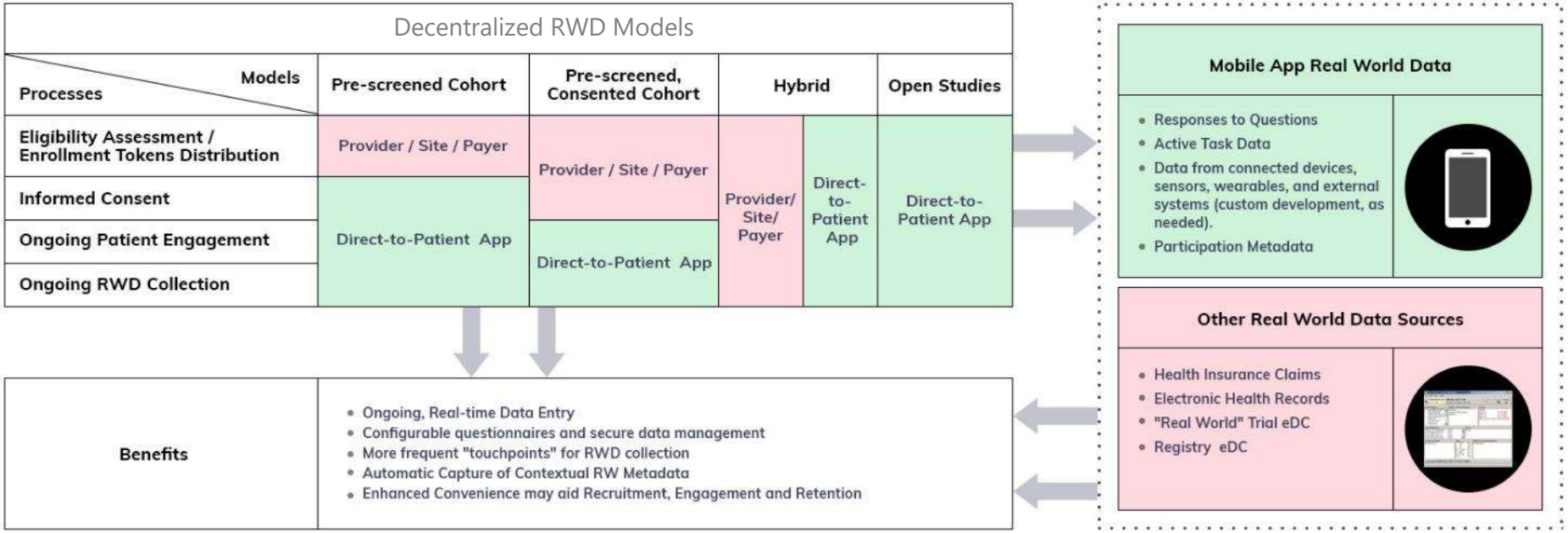
- Real-World Data (RWD) are data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources.

- RWD includes data derived from electronic health records (EHRs), claims and billing data, data from product and disease registries, patient-generated data including in home-use settings, and data gathered from other sources that can inform on health status, such as mobile devices

- Real-World Evidence (RWE) is the clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of RWD.



Decentralized RWD Models – 4 Examples



02

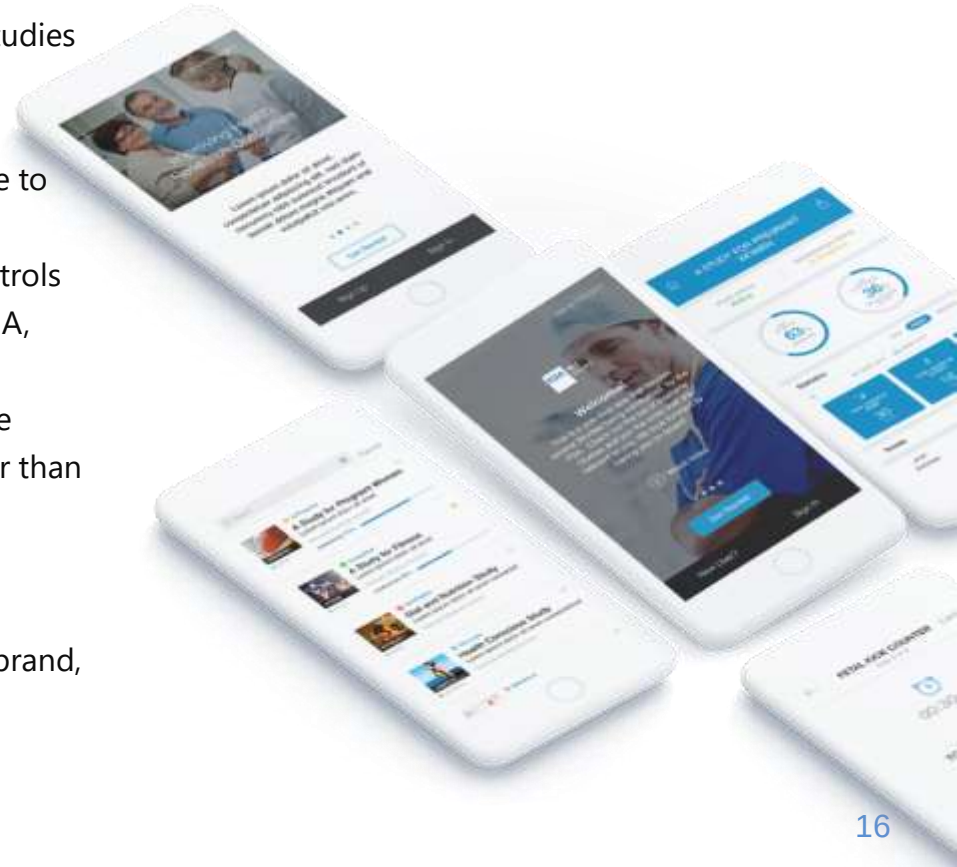
INTRODUCTION TO MYSTUDIES

FDA MyStudies

- **Mobile App**
  - Standard frameworks - ResearchKit (iOS), ResearchStack (Android)
- **Web-based Configuration Portal (WCP)**
  - Enables support of multiple types of medical product effectiveness and safety studies with minimal software development
- **Secure Storage Environment**
  - Generates secure tokens
  - Separates registration information and responses
  - Partitioned for multisite, decentralized, or distributed models

Key System Attributes

- **Scalable**: Capability to simultaneously support multiple studies for a research organization
- **Modular**: Various modular components of the platform can be integrated with external/3rd party system of choice to create a tailored solution for your organization.
- **Secure**: Partitions all data and provides robust access controls
- **Compliant**: Can be deployed to comply with HIPAA, FISMA, and 21 CFR Part 11
- **Customizable**: All study content as seen in the app can be authored and updated via the WCP web application rather than through new software development per study or app
- **Tested**: FDA and PCORI sponsored clinical research demonstration projects
- **Open-source** and ready for research organizations to re-brand, publish, and use!

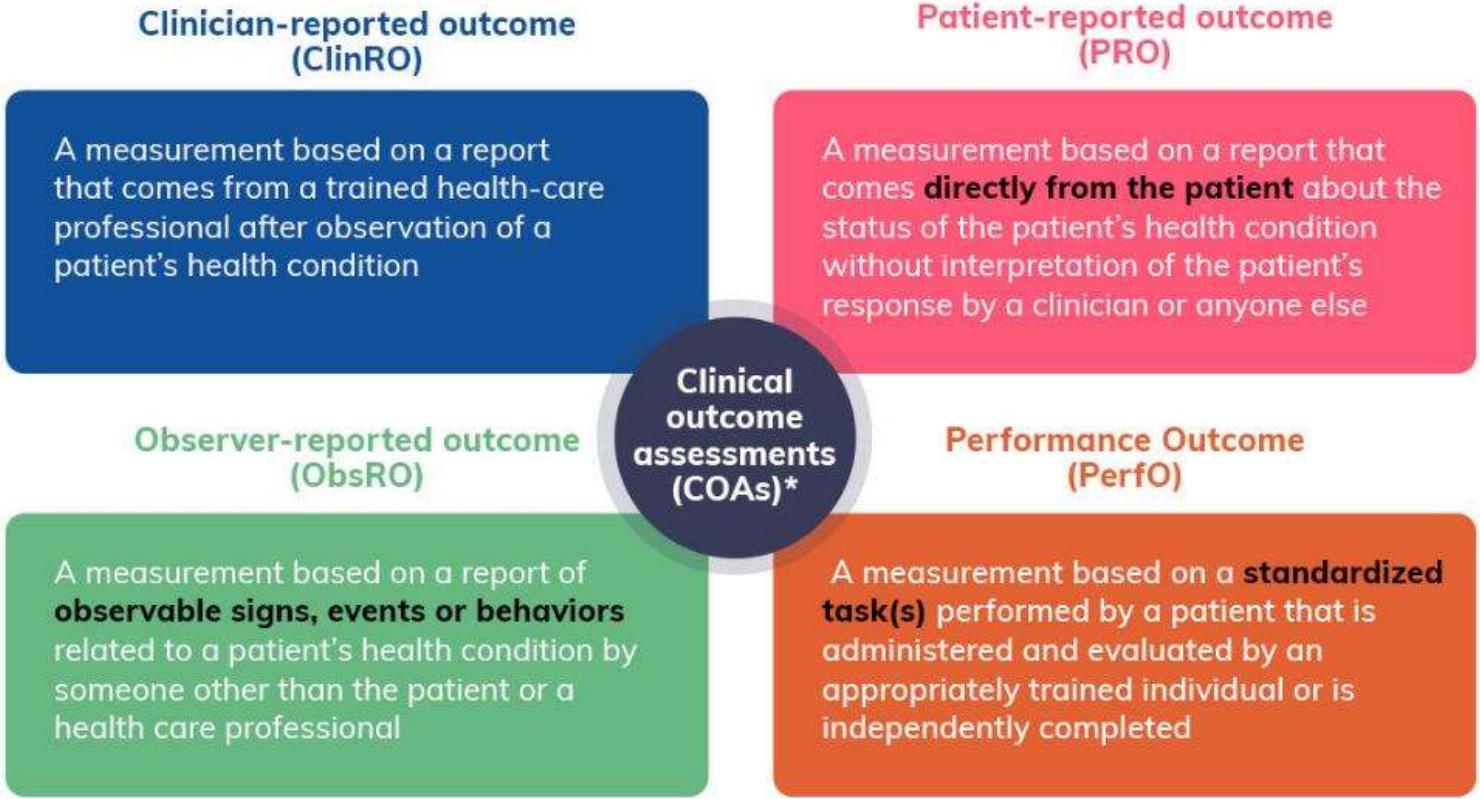


03

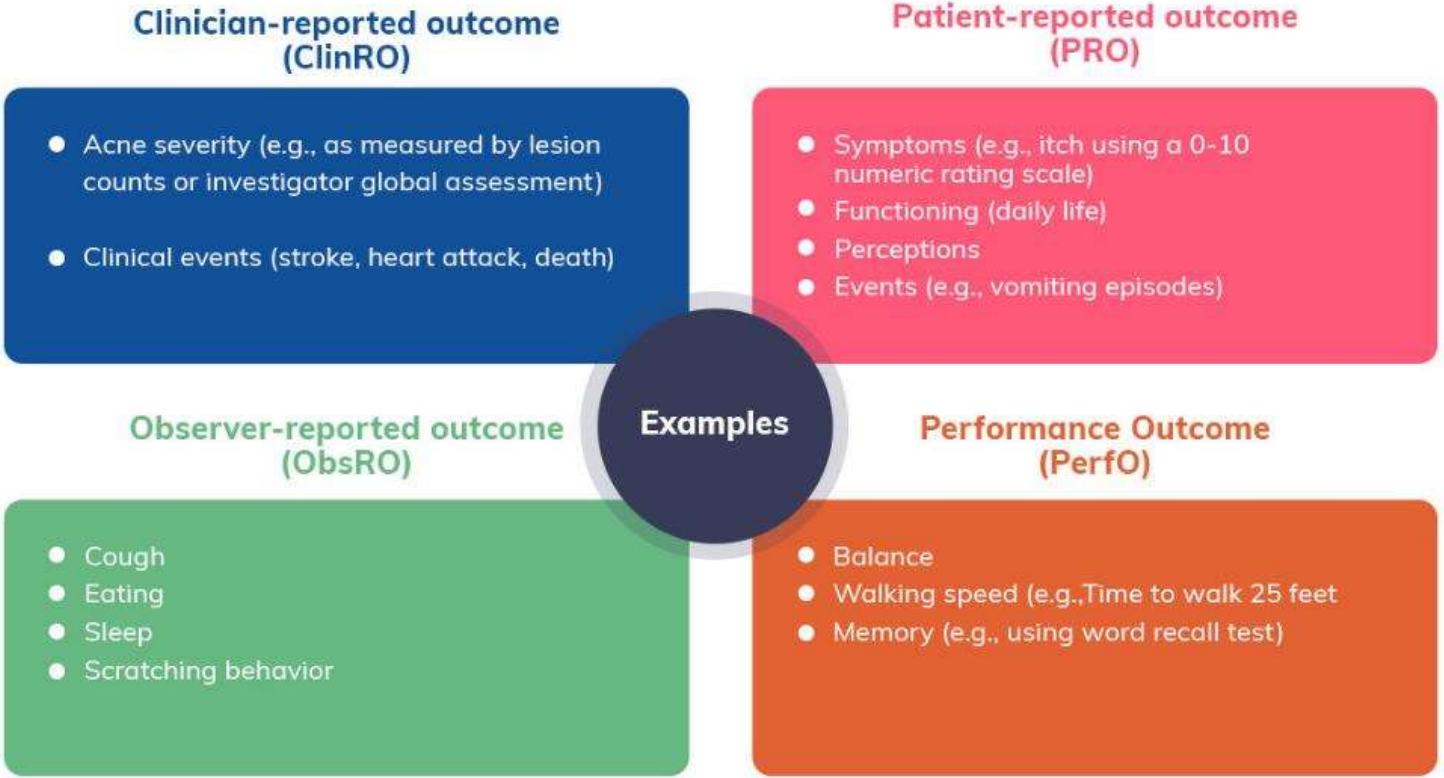
REGULATORY CONTEXT

Endpoints in FDA Registrational trials 2007-2015

Type of Endpoint	% of NDA	Examples of Endpoints Measured
Chemistry data	11	HBA1c, pregnancy test, GFR
Hematology	6	Severe neutropenia Apheresis yield > 5 million CD34+ cells/kg
Pathology	2	Increase/decrease of parabasal cells; biopsy proven acute rejection, clearing of anterior chamber cells
Microbiology	6	Sustained virological response, plasma viral load, conversion to negative sputum
Imaging +/- (survival, clinical signs)	17	Bone mineral density; vertebral fractures, spleen volume, progression free survival
Physiological/ functional measurement	9	6 minute walk, normal sinus rhythm, FEV1, sleep studies
Clinical event /clinical sign	19	Death, hospitalization, MACE, MS relapse, Lice free head
CRO/PRO	30	Toronto western spasmodic torticollis rating scale, Hamilton depression rating scale, Rheumatology scale ankylosing spondylitis scale, psoriasis severity index, seizures, sleep, prostate symptom score



*Digital health technology (e.g., mobile and wearables) can also be used to collect clinical outcomes.



Digital health technology (e.g., mobile and wearables) can also be used to collect clinical outcomes.

How does FDA review COAs?

- FDA evaluates an instrument in the context of its intended use (clinical trial design, patient population, desired labeling claim)
- In other words, there is no such thing as instrument validation for all purposes
- FDA PRO Guidance (2009)* describes good measurement principles applicable to all COA types

*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM193282.pdf

Configuring questionnaires

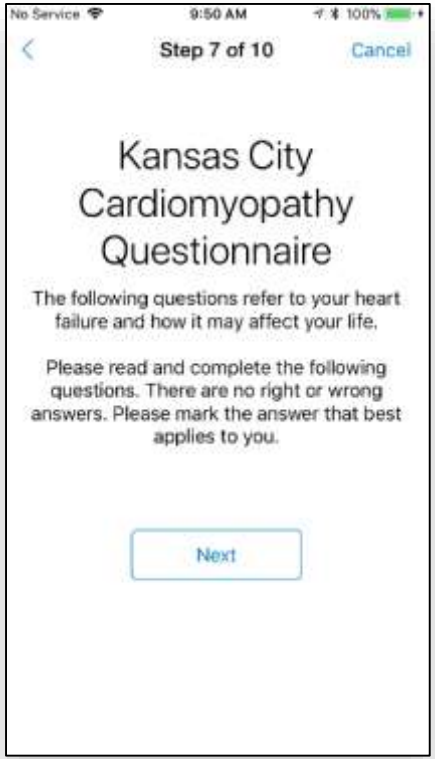
Kansas City Cardiomyopathy Questionnaire (KCCQ-12)

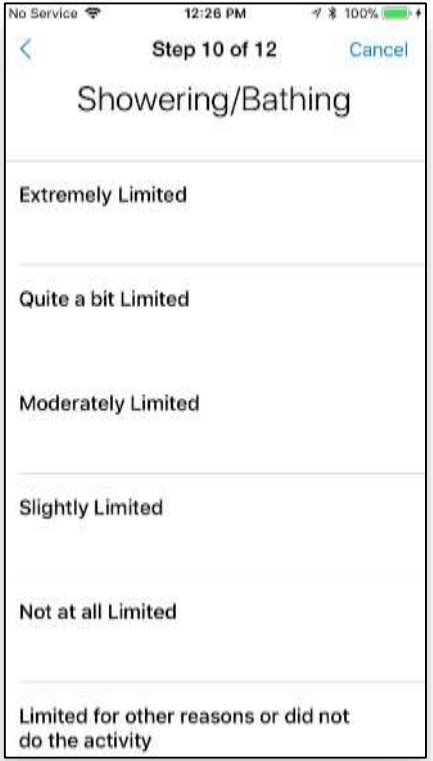
The following questions refer to your **heart failure** and how it may affect your life. Please read and complete the following questions. There are no right or wrong answers. Please mark the answer that best applies to you.

1. **Heart failure** affects different people in different ways. Some feel shortness of breath while others feel fatigue. Please indicate how much you are limited by **heart failure** (shortness of breath or fatigue) in your ability to do the following activities over the past 2 weeks.

Activity	**Extremely** Limited	**Quite a bit** Limited	**Moderately** Limited	**Slightly** Limited	**Not at all** Limited	Limited for other reasons or did not do the activity
a. Showering/bathing	O	O	O	O	O	O

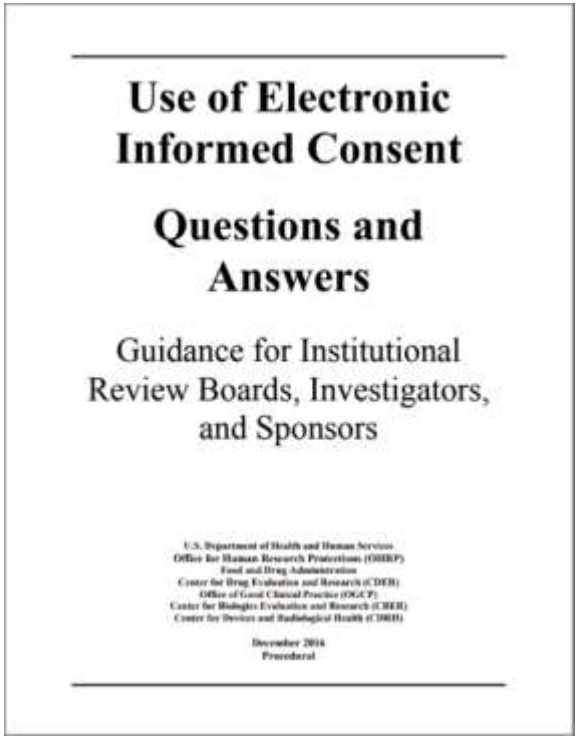
Translation to Mobile





Informed Consent

- Can be obtained from patient remotely
- Method needed to ensure the person signing the consent is the person in the study
- May use audio visual presentation
- Must have a process to address patient's questions
- Must provide a suitable record to patient
- FDA needs to be able to inspect it


Use of Electronic Informed Consent

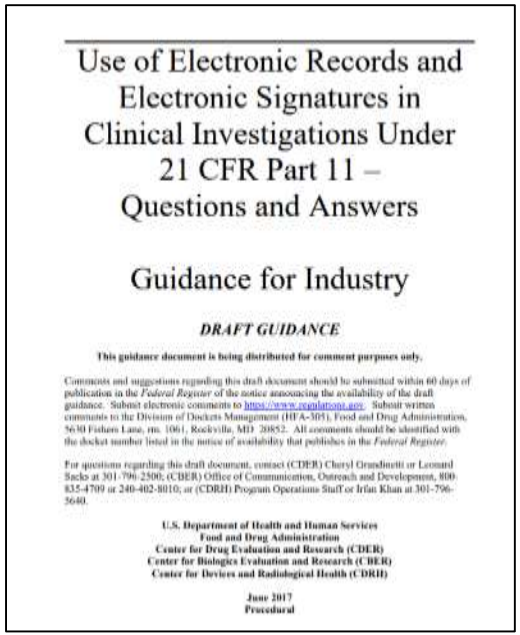
Questions and Answers

Guidance for Institutional Review Boards, Investigators, and Sponsors

U.S. Department of Health and Human Services
Office for Human Research Protections (OHRP)
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Office of Good Clinical Practice (OGCP)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)

December 2016
Procedural

21 CFR Part 11 and Mobile Technology



Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11 – Questions and Answers

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (CDER) Cheryl Grundhofer or Leonard Sacks at 301-796-2500; (CBER) Office of Communication, Outreach and Development, 800-835-4709 or 240-402-8010; or (CDRH) Program Operations Staff or Irfan Khan at 301-796-5640.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)

June 2017
Procedural

- Goals: Ensure authenticity, integrity, and confidentiality
- Refers to portable electronic technology used in clinical investigations that allows for off-site and remote data capture from study participants
    - Includes mobile platforms, mobile applications, wearable biosensors and other remote and ingestible sensors, and other portable and implantable electronic devices
- The recommendations apply to technology that is provided by the sponsor or owned by the study participant

04

ACCESSING THE SYSTEM

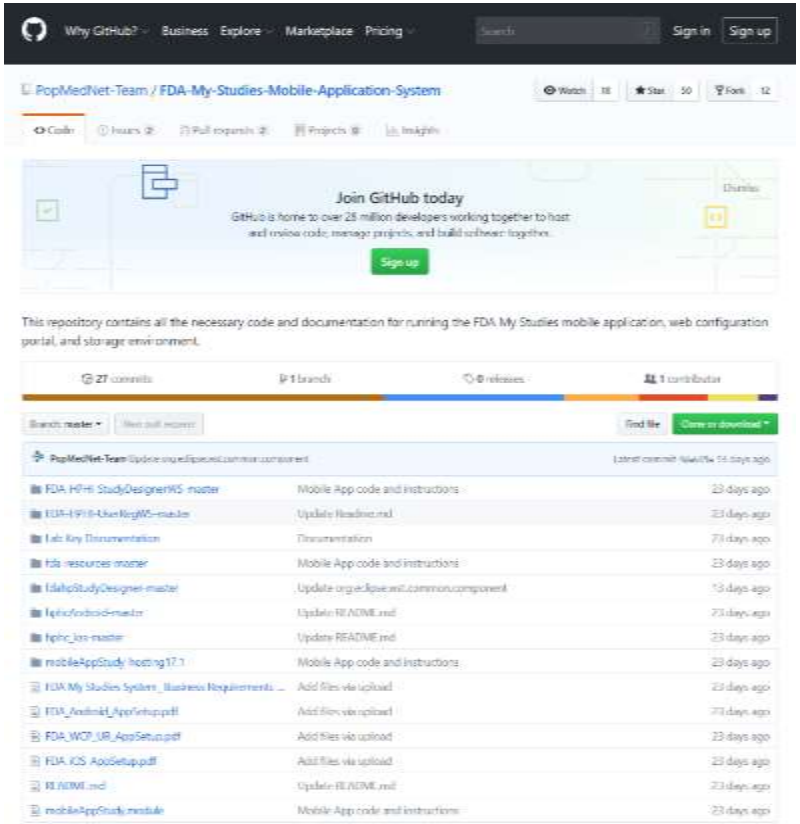
FDA MyStudies: Now Open-Source

— https://www.fda.gov/NewsEvents/Newsroom/FDAInBrief/ucm625228.htm

— https://www.fda.gov/Drugs/ScienceResearch/ucm624785.htm

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

GitHub Repository



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Harvard Pilgrim Health Care Institute
Zachary_wyner@harvardpilgrim.org

A DEMONSTRATION OF THE FDA MYSTUDIES MOBILE APP SYSTEM: PATIENT AND RESEARCHER EXPERIENCES

Disclosure and Disclaimer

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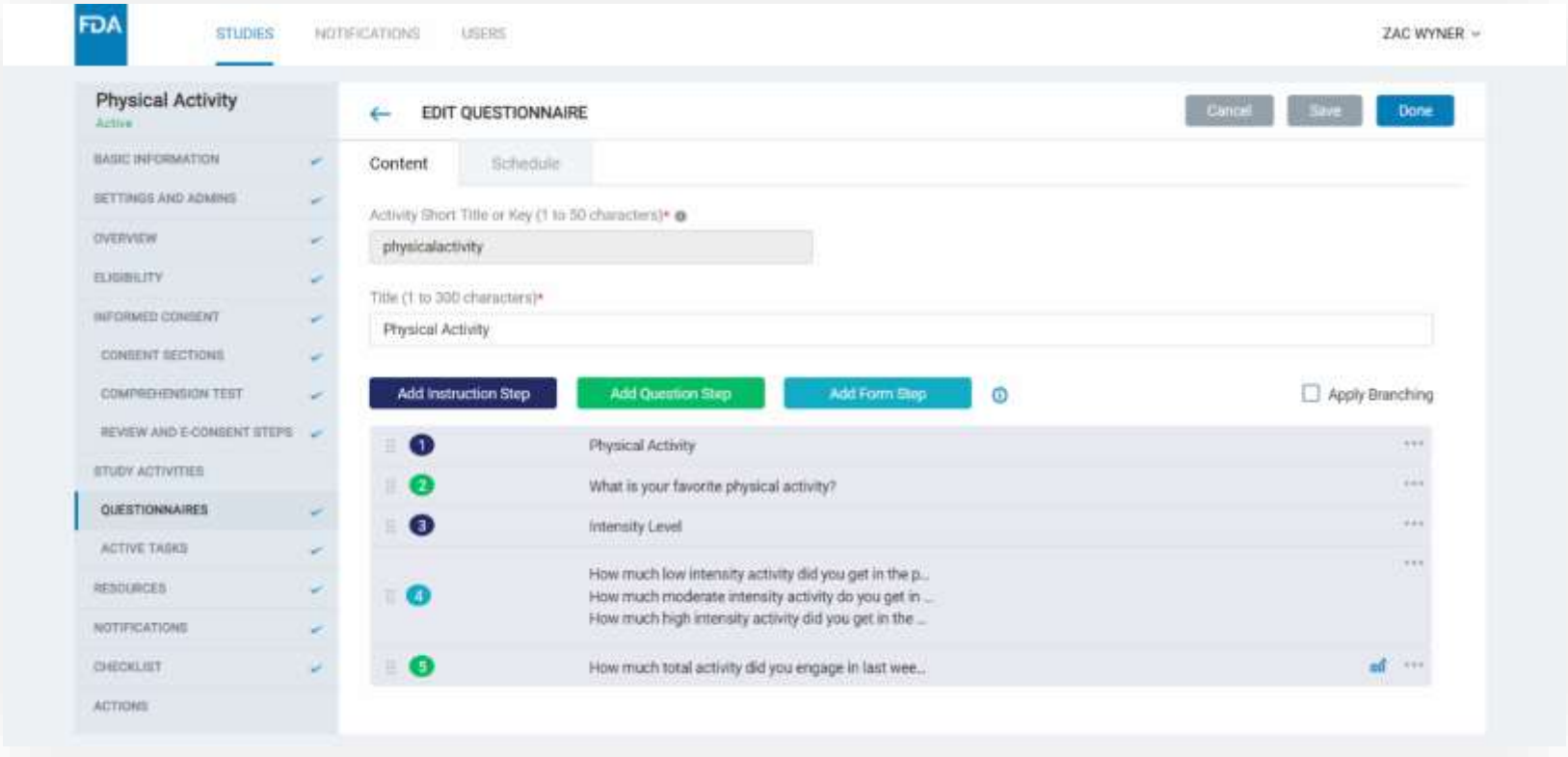
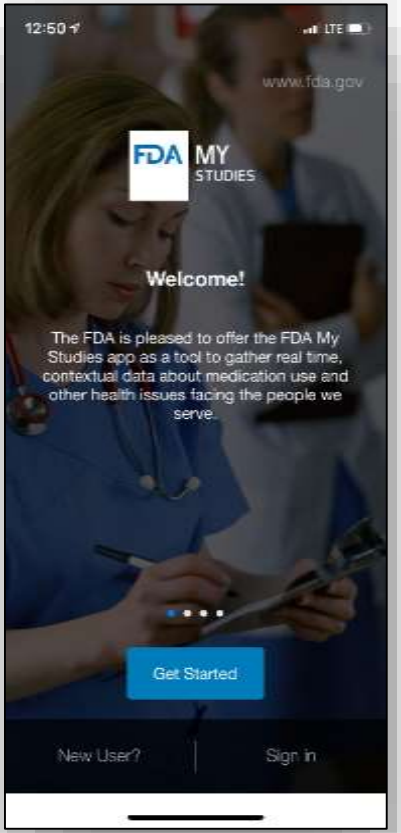
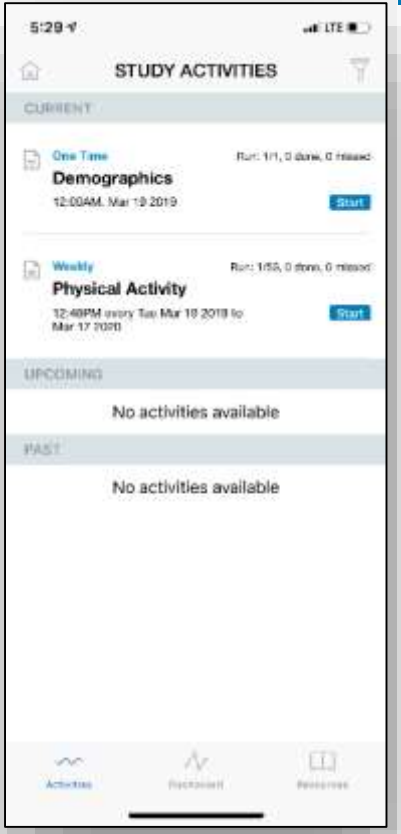
Web Configuration Portal (WCP)



Mobile App


12:50
LTE
www.fda.gov
FDA MY STUDIES
Welcome!
The FDA is pleased to offer the FDA My Studies app as a tool to gather real time, contextual data about medication use and other health issues facing the people we serve.
Get Started
New User?
Sign in


12:50
LTE
FDA My Studies
In Progress
Study A
Study A
FDA
COMPLETION 66%
In Progress
Study B
Study B
FDA
COMPLETION 83%
Yet To Join
Physical Activity
This is a study on physical activity
FDA
COMPLETION 0%
Yet To Join
A Study for Pregnant Women
A study on exposures during pregnancy
FDA
COMPLETION 0%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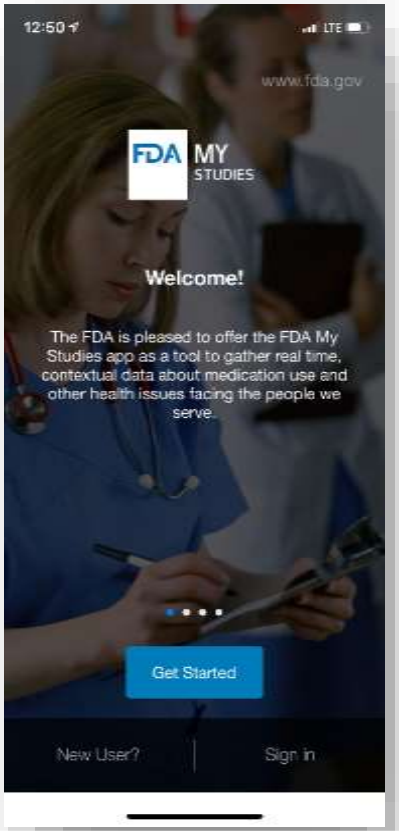
STUDY ACTIVITIES
CURRENT
One Time
Demographics
12:00AM, Mar 10 2019
Start
Weekly
Physical Activity
Start
UPCOMING
No activities available
PAST
No activities available

Mobile App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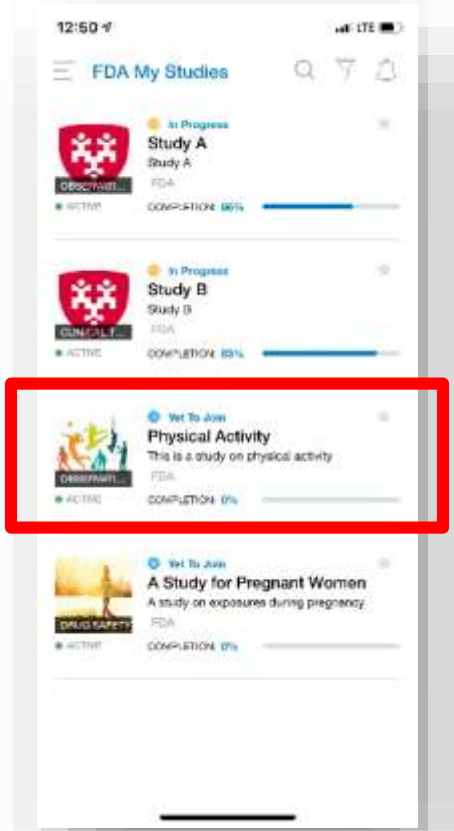
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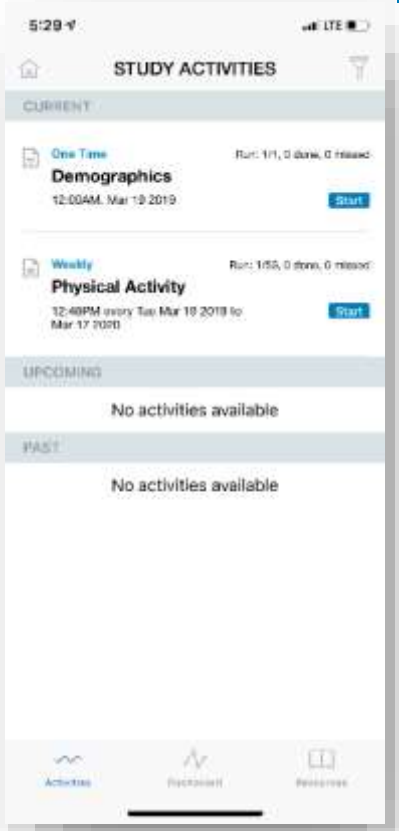
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Weekly
Physical Activity
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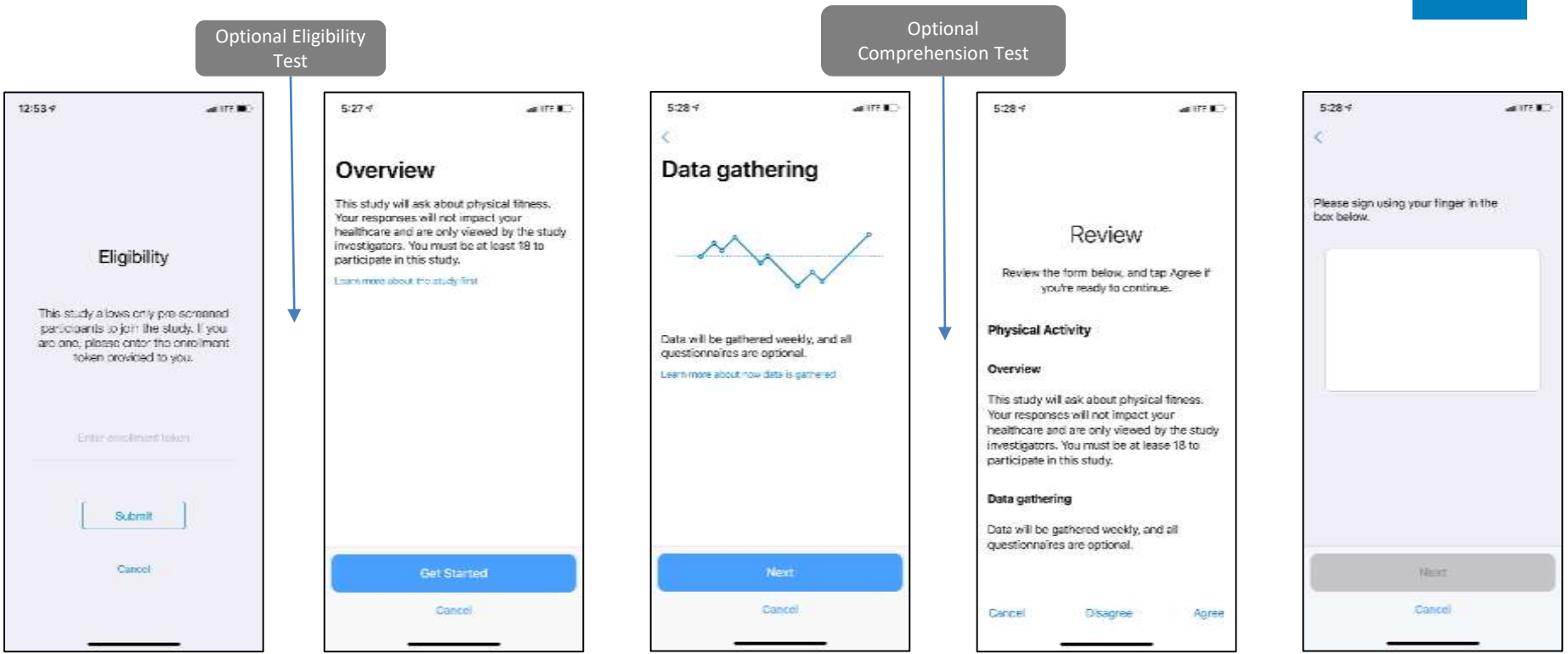
UPCOMING
No activities available
PAST
No activities available

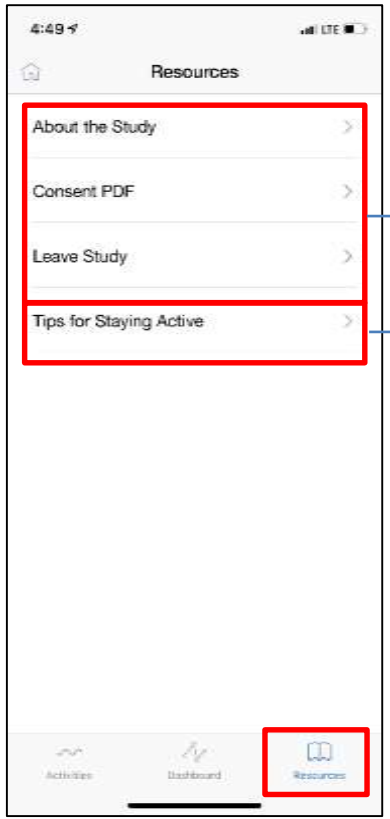
Enrollment and Consent



Patient Engagement

DASHBOARD

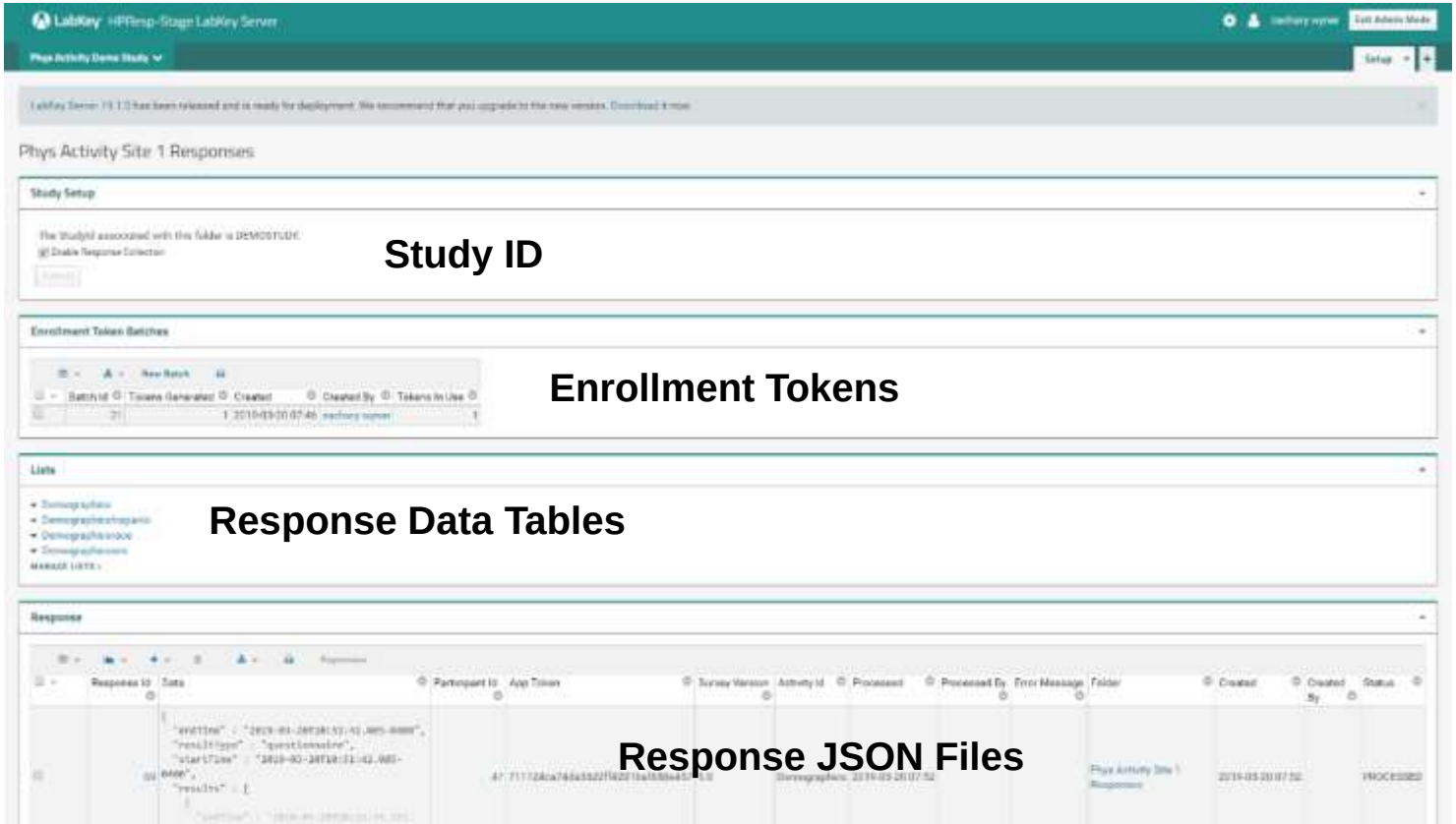
RESOURCES



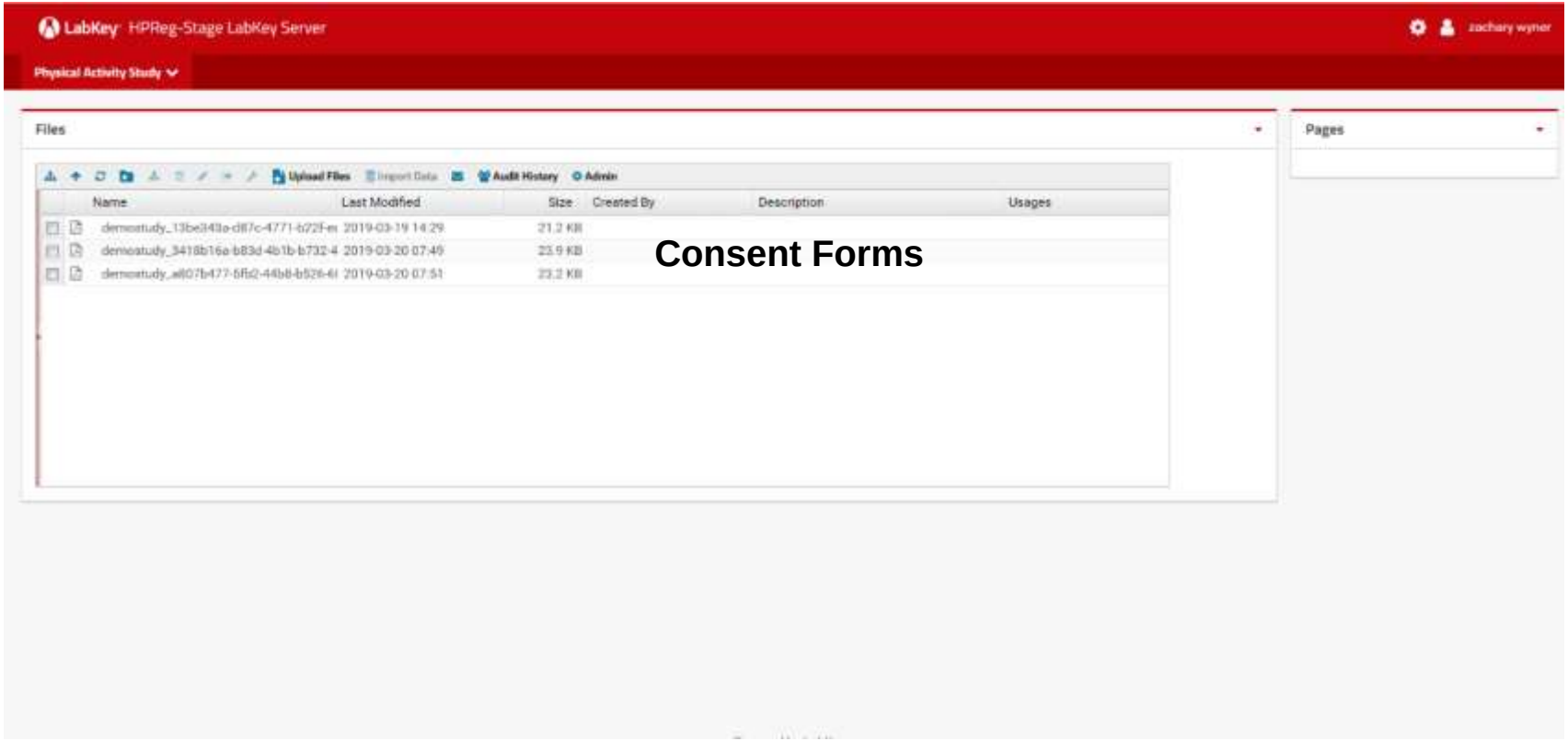
Default

Custom

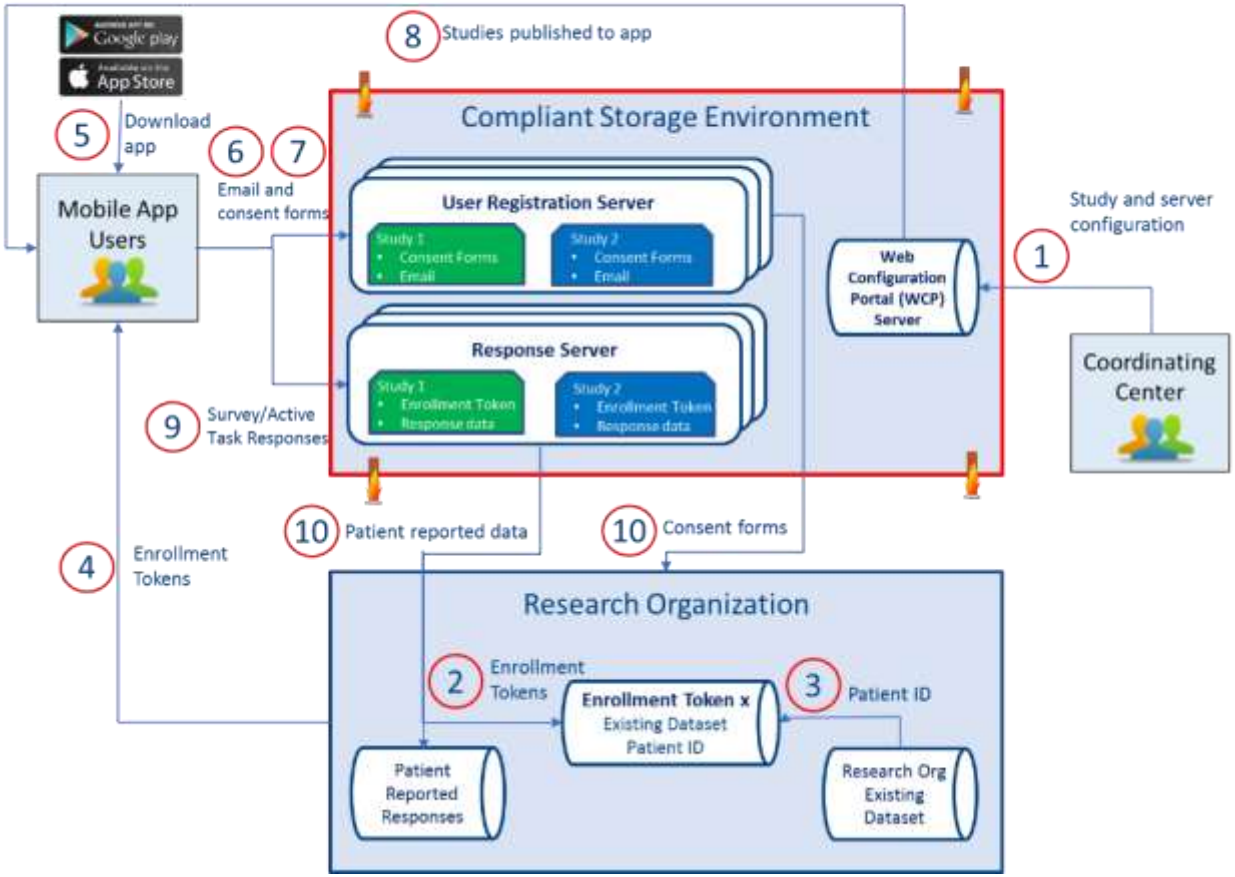
Storage Environment – Response Server



Storage Environment – Registration Server



Data Flow


Google play
App Store
8 Studies published to app
5 Download app
6 7 Email and consent forms
Mobile App Users
Compliant Storage Environment
User Registration Server
Study 1
Consent Forms
Email
Study 2
Consent Forms
Email
Response Server
Study 1
Enrollment Token
Response data
Study 2
Enrollment Token
Response data
Web Configuration Portal (WCP) Server
1 Study and server configuration
Coordinating Center
9 Survey/Active Task Responses
10 Patient reported data
10 Consent forms
4 Enrollment Tokens
Research Organization
2 Enrollment Tokens
Enrollment Token x
Existing Dataset
Patient ID
3 Patient ID
Patient Reported Responses
Research Org Existing Dataset

Live Demo

- Web Configuration Portal (WCP)
  - Creating and publishing a study
- Mobile Application
  - Registration, enrollment, and submission of responses
- Response and Registration Servers
  - Configuring a study
  - Viewing responses and registration information


BREAK

Q&A and Resources

Click for:

- https://www.fda.gov/NewsEvents/Newsroom/FDAInBrief/ucm625228.htm
- https://www.fda.gov/Drugs/ScienceResearch/ucm624785.htm
- https://github.com/PopMedNet-Team/FDA-My-Studies-Mobile-Application-System
- https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-electronic-informed-consent-clinical-investigations-questions-and-answers
- https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-electronic-records-and-electronic-signatures-clinical-investigations-under-21-cfr-part-11
- http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM193282.pdf
- https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence

- Additional questions on the webinar?

  Email: CDERSBIA@fda.hhs.gov

Open Q&A begins shortly – type in your questions now.

Learn about other resources from CDER Small Business & Industry Assistance:
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FDA

MOBILE APPLICATION(S), WCP, USER REGISTRATION SERVER: TECHNICAL OVERVIEW

 Shyam Deval  Ranjani Rao

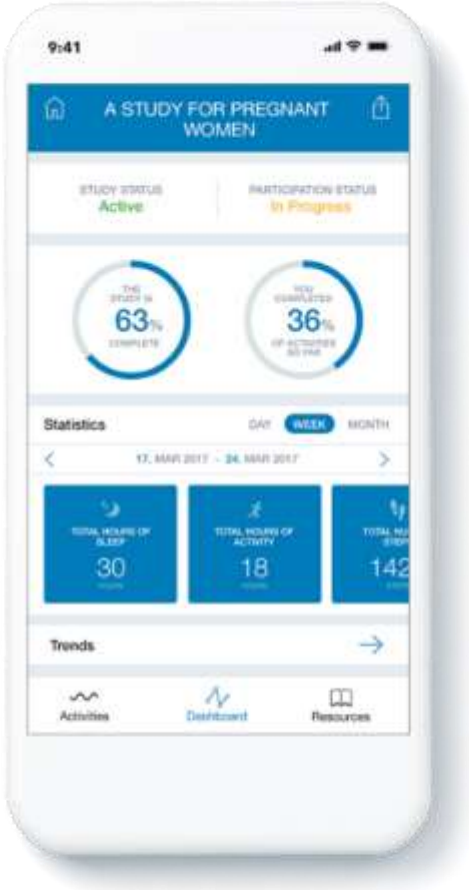
Boston Technology Corporation
Shyamd@boston-technology.com, Ranjanir@boston-technology.com

Mobile Application: Usability

- User interface that's intuitive, convenient and adopts an 'appy' look and feel
  - Use of 'Mobile First' design practices
  - Comprehensive UI/UX design methodology
  - Key considerations
    - Users (who, when, where and why)
    - Form factors
    - Screen loading times
    - Faster response times for user actions
    - Optimized user action flows
- Rapid proto-typing and continuous user testing during design

Mobile Application: Usability

- Offline capability
  - Ability for participants to take study activities even when offline
  - Secure local storage of responses
  - Auto-sync of response data with server, when connected
  - Design of network calls done to ensure no data is lost due to network failures or server downtime

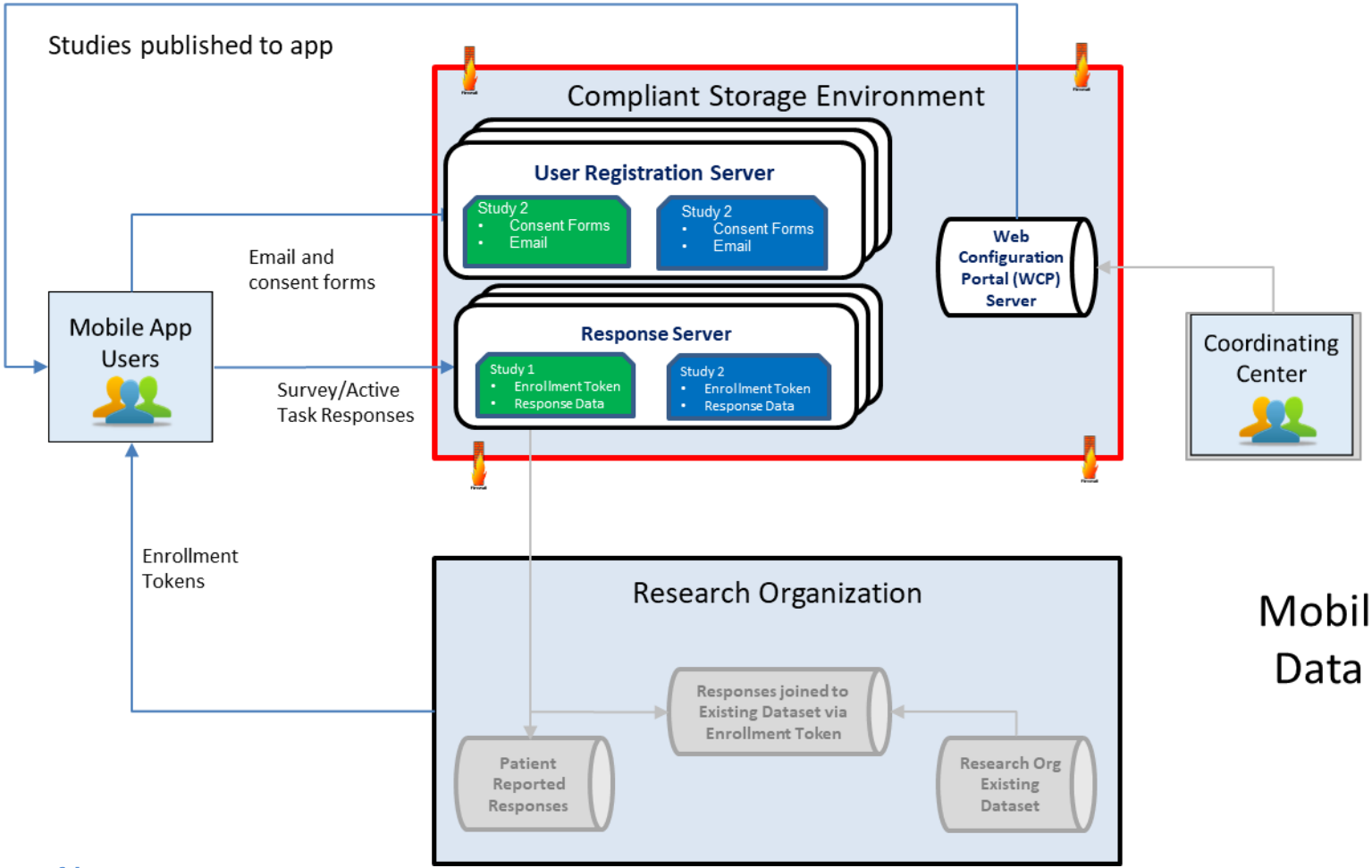


Usability Features: A few more examples

- Easy to navigate study overview with provision to have a video (helps participants easily understand the app/study)
- Helpful links to study website, protocol document, and relevant resources.
- Ability to tailor content and images to suit your target audience
- Ability to white-label/ apply branding to the app as required
- Customizable push notifications to participants
- Timely and useful reminders and notifications when study activities are due to be taken
- Participant-managed preferences for app settings
- Ability to set up activities with clear and custom instruction steps for participants
- All survey screens are easy to navigate through and answer, irrespective of question type
- Option to allow the app to read a question's numeric response from HealthKit
- Study activities prominently marked with completion status and arranged by date
- Provisions for Feedback and Contact Us forms

Mobile Application: Compliance / Security Support

- Secure user registration and sign in
- Passcode and Touch ID based access
- Data encrypted at rest and in transit
- Secure session-handling/session management
- No participant identifiable information is transacted to the Response server when responses are saved in or fetched back from it



Mobile App Data Flow

Mobile App Architecture and Tech Stack

- The mobile app interacts with the User Registration Server, WCP & Response Server via RESTful services.
- The app uses AES-256 for encryption of data.
- Study metadata and activity/survey information is stored for offline usage.
- Data is stored locally using Realm Database (an open-source database framework)
- Application stores users response data locally, and in cases of network failure, attempts to resubmit the data to the response server when network is available
- The app is not allowed to be used on jailbroken or rooted phones

- The iOS app is built using Swift language
- Runs on the latest Swift 5.0 and Xcode 10.2.
- Makes use of Apple ResearchKit, UIKit, Foundation,
- CoreLocation,HealthKit,AVFoundation,UserNotification
- The app also uses UserNotification framework to schedule local notification/reminders for study activities
- The app follows the Apple-recommended MVC Design Pattern

- Development and Build Tools: Android Studio 3.3.2 & Gradle 3.3.2
- Event Bus Architecture is used for communicating with modules
- Researchstack modules are used for base Enrollment, Informed Consent and Survey functionality.
- Multiple extensions have been developed to the existing ResearchStack framework to support additional functionality

ResearchKit

- ResearchKit 2.0 is used
- iOS uses Apple ResearchKit Framework to provide a framework with Enrollment, Informed Consent, Surveys and Active Tasks
- BTC extended the ResearchKit framework to add the following:
  - A custom Active Task 'Fetal Kick Counter' that is built on ResearchKit framework
  - An enrollment token verification step as part of ascertaining eligibility to participate in the study
  - A 'Repeatable Form Step'
  - The response data captured using ResearchKit, is converted into a JSON format and sent to Response Server

ResearchStack

FDA

- ResearchStack 1.1.1 is used
- BTC developed the following extensions to the ResearchStack framework
  - Image choice support for Eligibility module
  - Custom Consent module including support for two types of Consent Documents, signed consent PDF generation and review.
  - Survey module to support the following steps:
    - Multiple-select for Image Choice question type
    - Multiple-select Text Choice question type, to support mutually exclusive option as well as to support question Description
    - Single-select Text Choice question type, to support question description
    - New Question Steps for Value Picker, Scale, Text Scale, Continuous Scale, Location, Height, Time Interval, Email

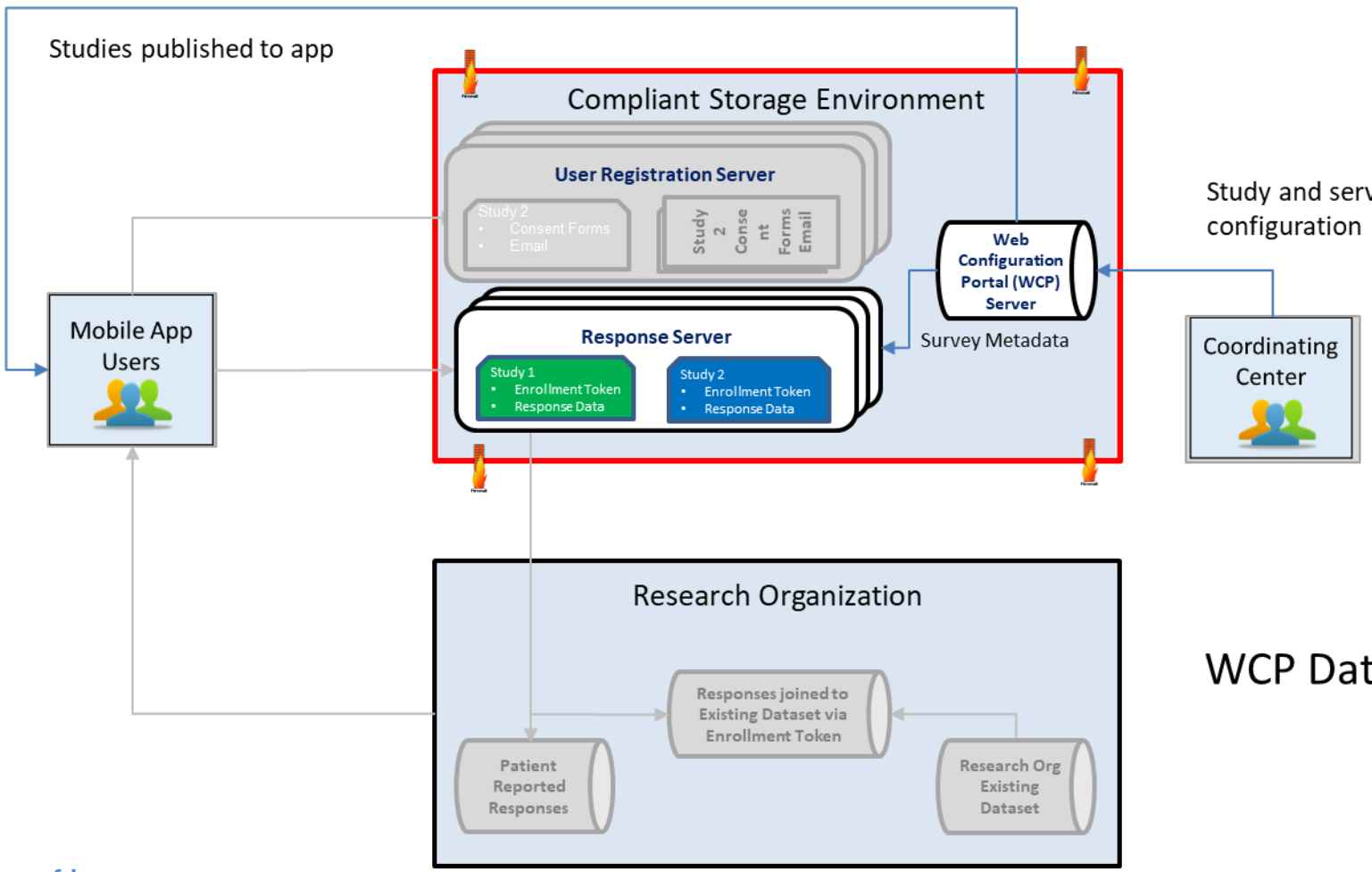
ResearchStack

FDA

- More Extensions
  - Created custom steps to support the Fetal Kick Counter Active Task
  - Extended Text Choice question type, to support Regular Expression
  - Extended Integer question type, to support units
  - Extended Decimal question type, support units
  - Extended Date question type, to support multiple date/time response formats
  - Extended Form Step to achieve ‘Repeatable Form’ behavior

WCP Characteristics

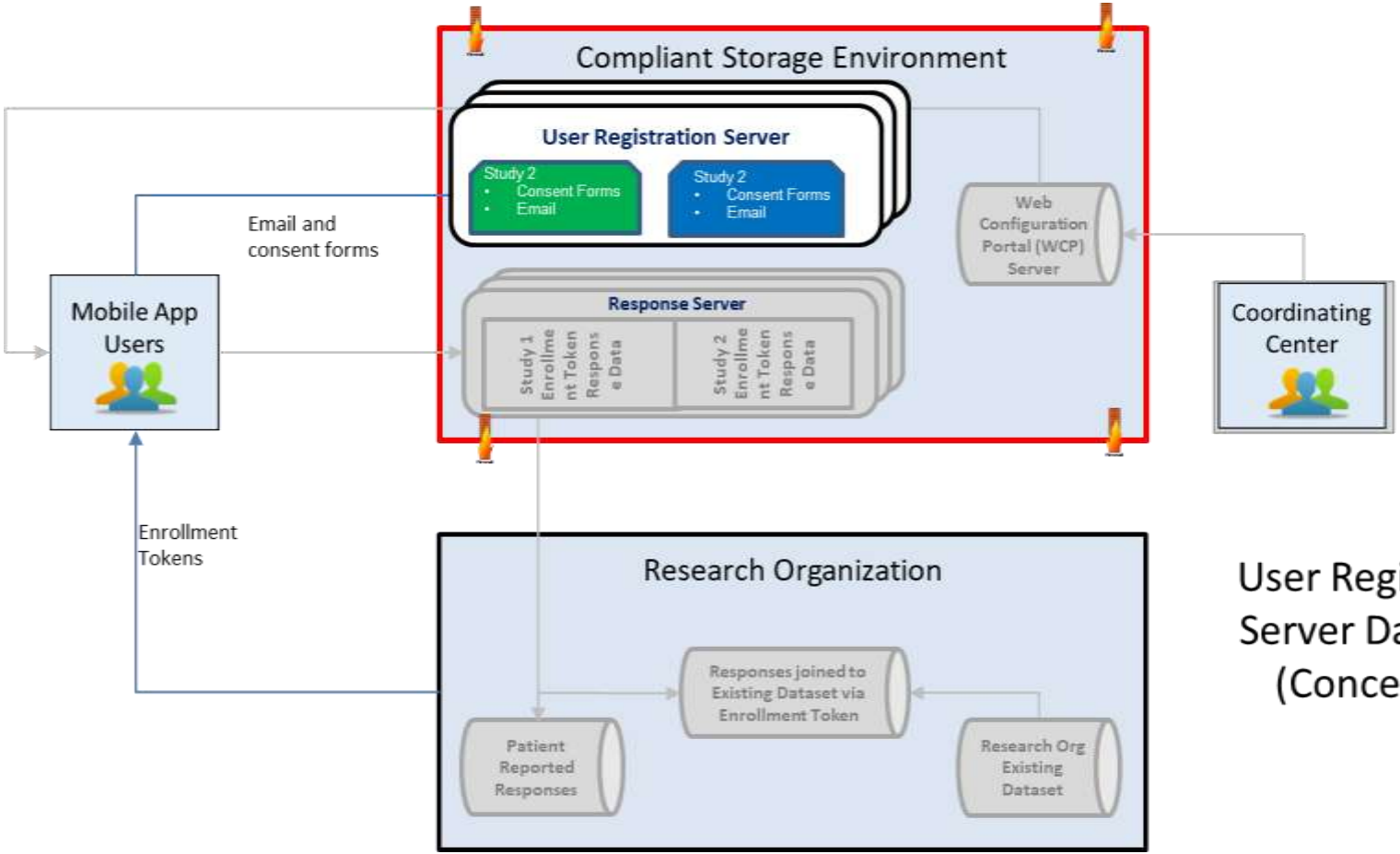
- Flexible
  - Choose components that work for your unique research study requirements
  - Run suite of studies in one gateway app or have a standalone app per study
- Customizable
  - Configure study workflows be it eligibility, consent or surveys
  - Tailor app content as required for your study
- Extensible
  - Extend the platform to offer more functionality and features
  - Add more active tasks, or new question types
- Scalable
  - Run multiple studies in concurrence with large teams of administrators and participants
  - Recruit for and manage long-running studies across diverse populations
  - Engage in large-scale collection of data using surveys and active tasks



WCP Data Flow

WCP and Web Services Tech Stack

- Web application and web services
  - Java (V 1.8)
  - Spring (V3)
  - JQuery
  - Hibernate ORM 3 for web application
  - Jersey RESTful web services
  - Tomcat 8
  - Operating System: Linux (Ubuntu)
  - Database: MySQL Database 5.6



User Registration Server Data Flow (Conceptual)

User Registration Server: Primary Role

- The User Registration server is used to support mobile app functionality and user flows.
- It is accessed via web services by the mobile app
- This server is only used to store only user profile information, preferences and study-related statuses as well as used for push notifications
- No user response data is stored on this server

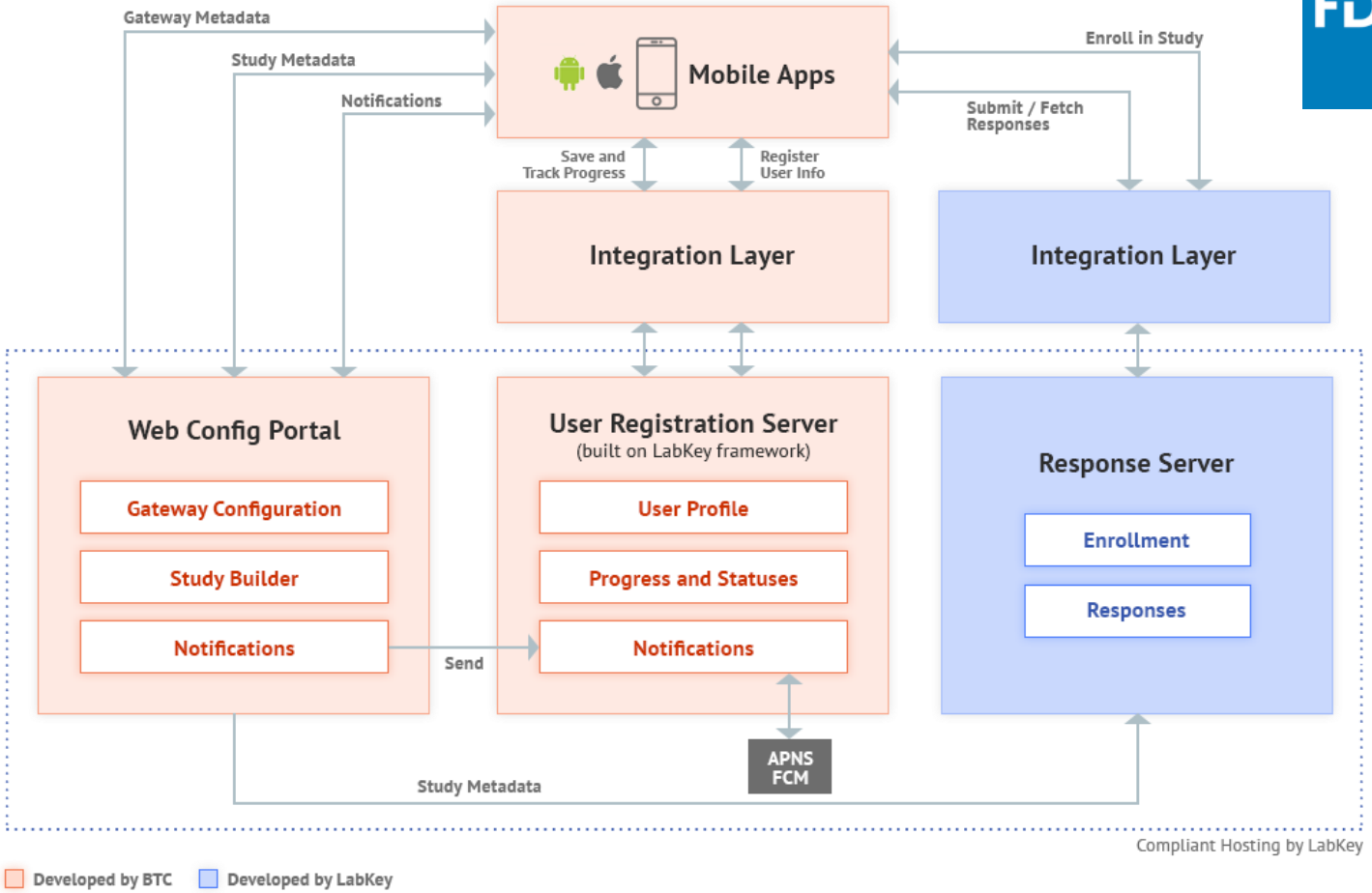
User Registration Server Architecture and Tech Stack

- The web service for the User Registration server are built on the LabKey platform
- Access is limited to users registered on the platform. Each user is assigned a unique user ID and access token
- Access token expiry is set within application configuration on the registration server.
- Access token is required in the web service header to transmit data to/from the registration server
- The User Registration server is built using LabKey framework as well
- It leverages LabKey's User and Registration modules to provide registration services for the users of the mobile app.
- Features:
    - User registration & session management
    - User profile and preferences
    - User progress and activity status
    - Stores study-specific user information such as Participant ID and Enrollment Date/Time

User Registration Server Architecture and Tech Stack

- LabKey Platform (open-source, Apache 2.0 licensed)
- Java and JavaScript for the web application
- Apache Tomcat
- PostgreSQL database
- Gradle script to build the application
- JSON format for the web services used by the mobile app

Overall Architecture



GitHub Repository

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

- iOS Source Code :
  Download the code OR clone it and run the 'HPHC.xcworkspace'

  To rebrand, change App Icon, Launch Image, Logos and Bundle ID (a unique ID registered on the Apple Developer portal for each application).

- Android Source code:
  Download the code OR clone it and open the source code in Android Studio

  To rebrand, change App Icon and other assets from 'Resources', and the Package name. Update changes to styles for Researchstack Theme, as required.

Adam Rauch
LabKey Software
adam@labkey.com

LABKEY RESPONSE SERVER TECHNICAL OVERVIEW

Response Server: Primary Role

Process and store all mobile app survey and active task responses, then provide secure access for data analysis purposes

Response Server Architecture

Built on LabKey Server, which is:

- Open-source (Apache 2.0 licensed) platform designed to integrate, analyze, and share complex biomedical data
- Originally developed at Fred Hutchinson in Seattle
- Expanded and supported by spin-off LabKey Software
- Open-source project, support, docs: www.labkey.org
- Company info: www.labkey.com

Response Server Architecture

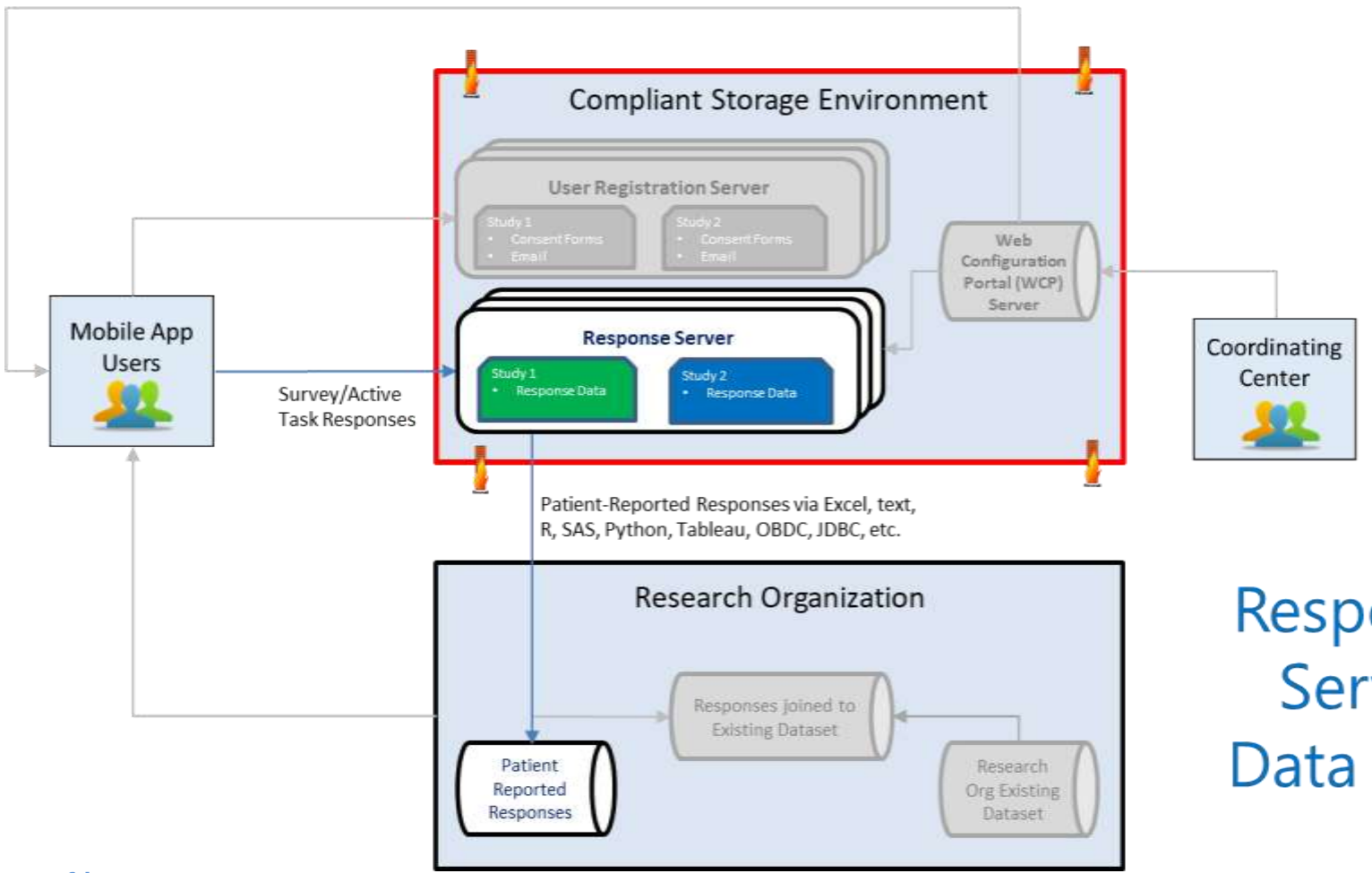
- Web application written in Java and JavaScript
- OpenJDK
- Apache Tomcat servlet container
- PostgreSQL database back-end
- Scaled down version of LabKey Server
  - Security, administration, compliance, query, reporting, lists
  - Response server functions implemented by mobileAppStudy LabKey module

Response Server: Processing Responses

- Receives responses from mobile app
  - JSON (JavaScript Object Notation) format
- Performs basic validation
  - Valid, existing participant ID for an enrolled participant
- Queues processing job and sends response to mobile app
- Parses JSON and stores responses in database tables
  - All data partitioned by study and restricted to authorized users
- Provides many ways to analyze and retrieve data

```
{
  "startTime": "2019-03-14T12:26:00.000-0700",
  "endTime": "2019-03-15T12:26:00.000-0700",
  "results": [
    {
      "resultType": "textChoice",
      "key": "ethnicity",
      "startTime": "2019-03-14T16:11:59.824-0400",
      "endTime": "2019-03-14T16:12:05.212-0400",
      "skipped": false,
      "value": [
        "HispanicLatino"
      ]
    },
    {
      "resultType": "textChoice",
      "key": "country",
      "startTime": "2019-03-14T16:12:09.347-0400",
      "endTime": "2019-03-14T16:12:17.175-0400",
      "skipped": false,
      "value": [
        "US"
      ]
    },
    {
      "resultType": "textChoice",
      "key": "IBDcurrentmed",
      "startTime": "2019-03-14T16:12:49.987-0400",
      "endTime": "2019-03-14T16:12:53.976-0400",
      "skipped": false,
      "value": [
        "Yes"
      ]
    },
```


Sample Response JSON



Response Server Data Flow

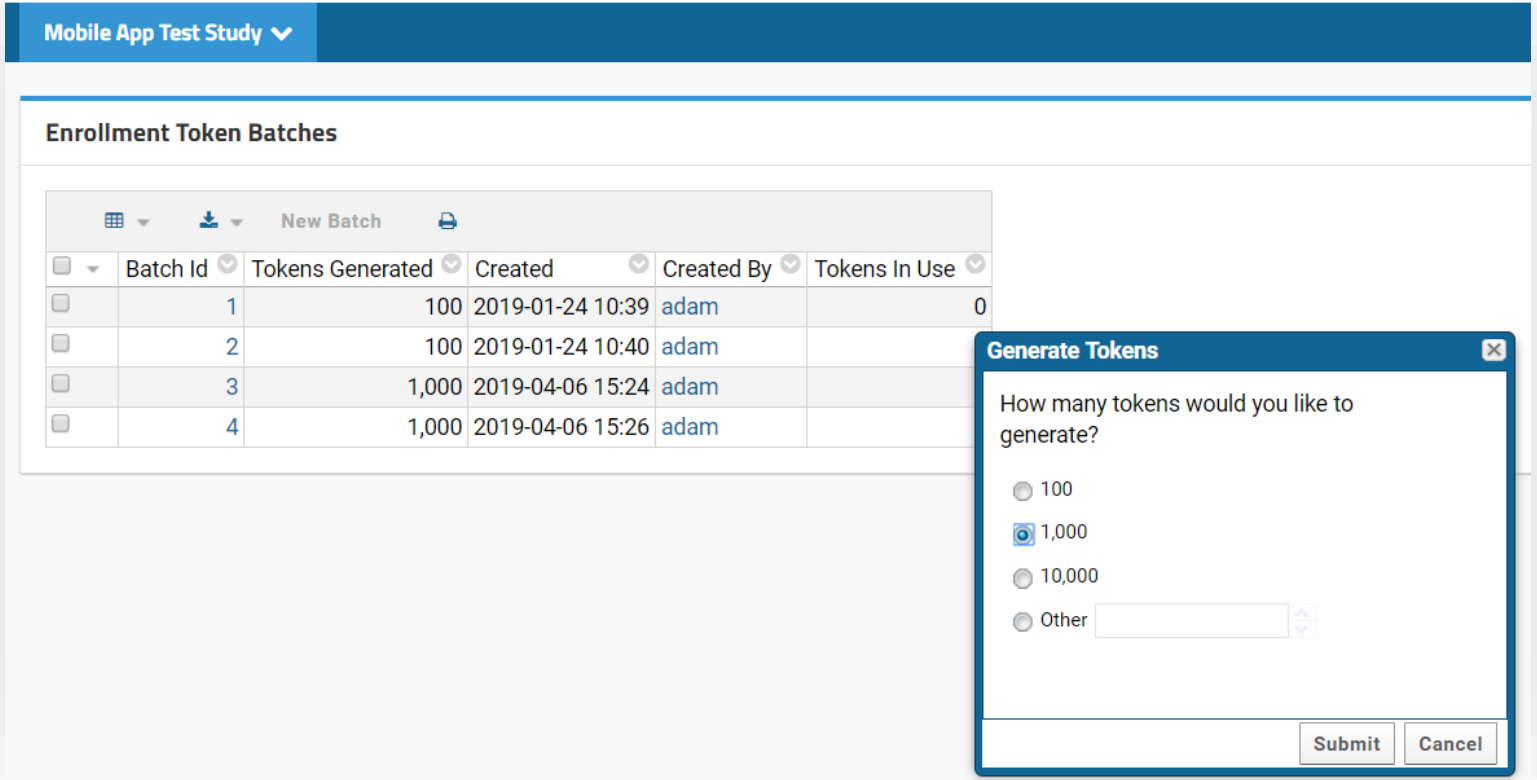
Response Server: Other Duties

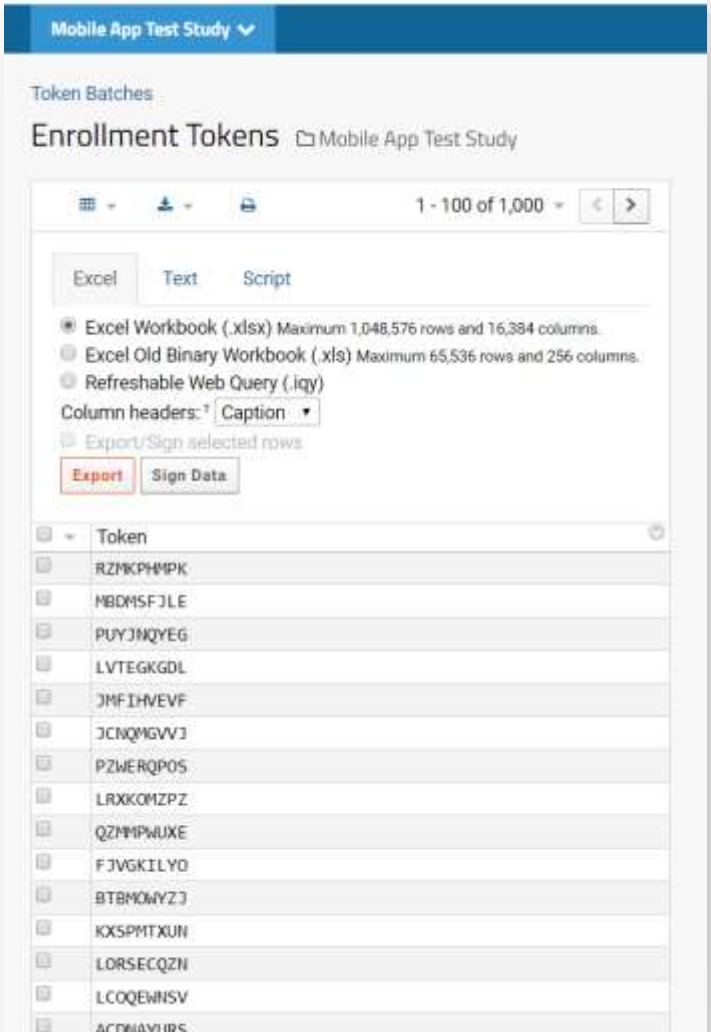
- Issues enrollment tokens to research organizations
- Enrolls and unenrolls participants
- Creates database schemas that match each study's design and updates them as studies change
- Provides limited querying of data by mobile app
- Enables web analytics, querying, reporting, and visualizations through manual and programmatic methods
- Forwards responses to external system (optional)

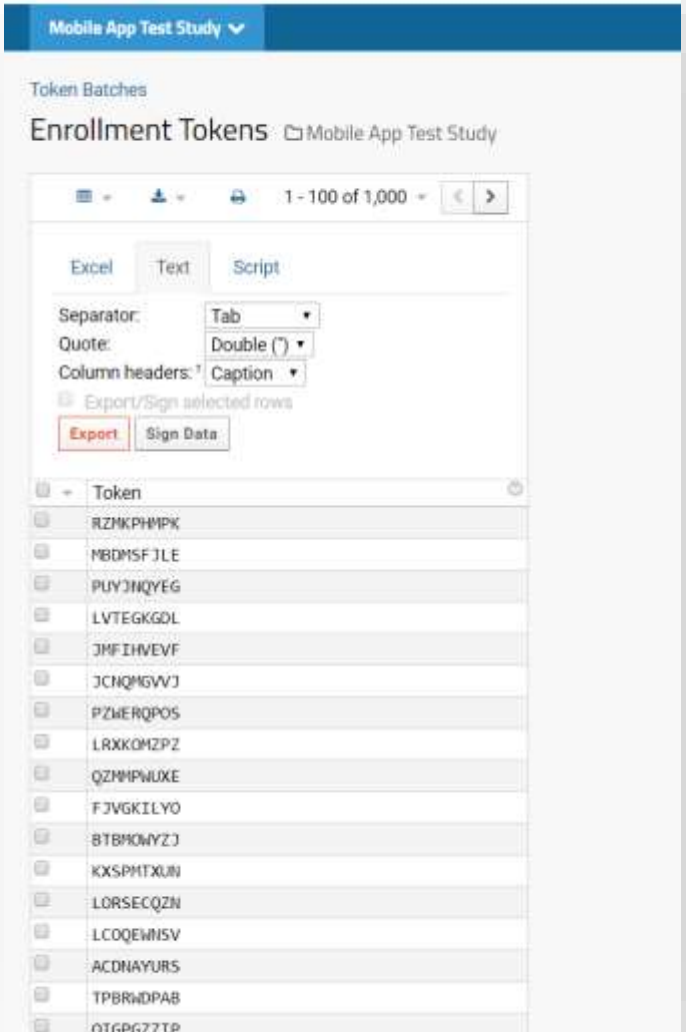
Enrollment Token

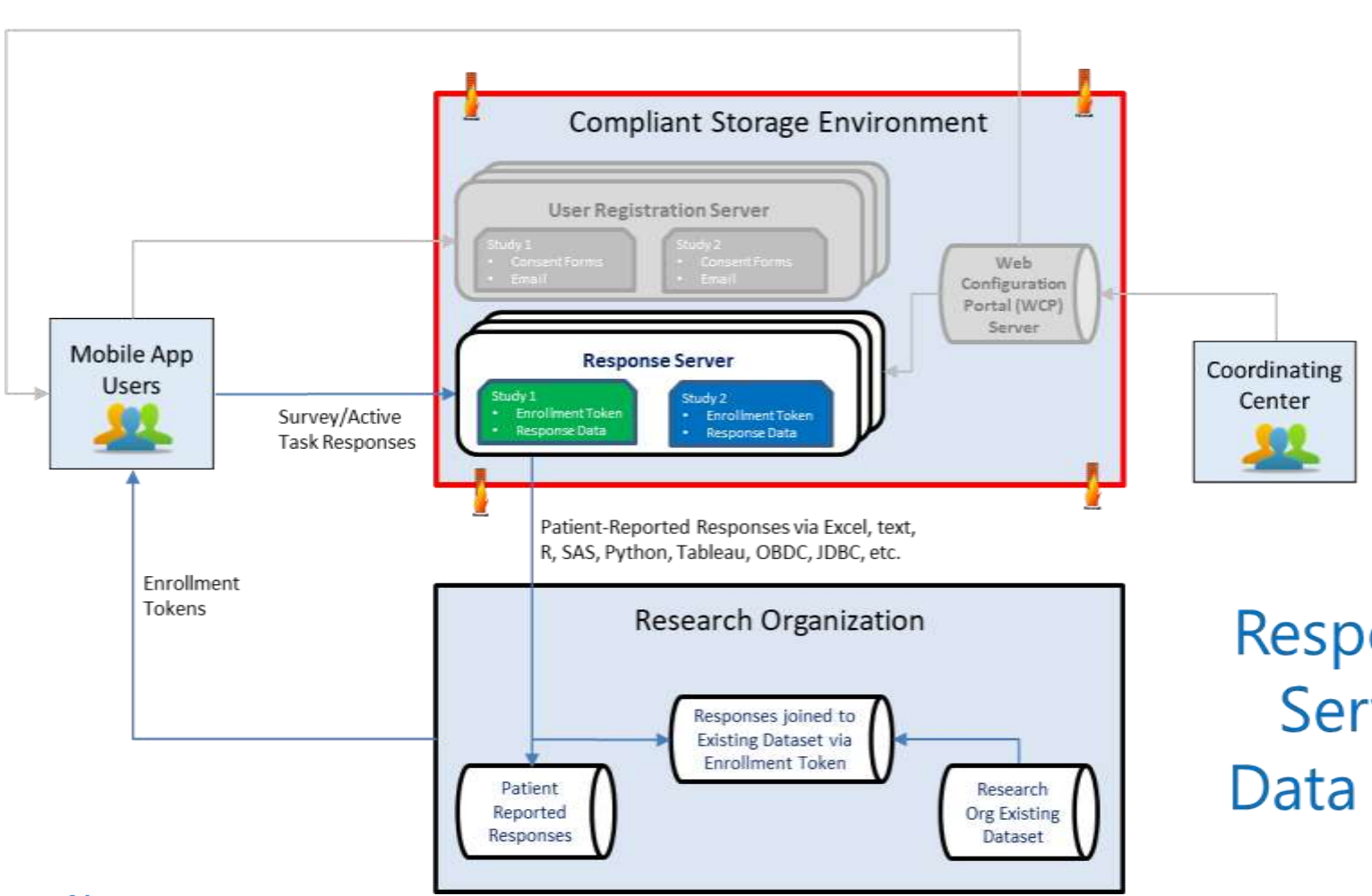
- Purpose
  - Uniquely identifies a participant and authorizes that person to enroll in a specific study
  - Links a participant's data to records maintained by the research organization
  - Provides option of keeping PII (Personally Identifiable Information) out of Response server

- Process
  - Token: randomly generated, one-time-use code that's 8 letters plus a checksum (e.g., "EZMKPHMPK")
  - Research organization requests tokens from a specific study on the Response server
    - Typically in batches of 100, 1000, etc.
    - Export via Excel and text formats, retrieve via API call, etc.
  - Research organization assigns tokens to prospective participants, stores with participant records, sends with invitations
  - Participant enrolls in study via the mobile app
    - Participant enters enrollment token into mobile app UI
    - Mobile app calls Response server to validate enrollment token and exchange for secure participant ID used for subsequent authorization
  - Later, research organization retrieves response data and joins it to participant records via enrollment token


Mobile App Test Study
Enrollment Token Batches
New Batch
Batch Id
Tokens Generated
Created
Created By
Tokens In Use
1 100 2019-01-24 10:39 adam 0
2 100 2019-01-24 10:40 adam
3 1,000 2019-04-06 15:24 adam
4 1,000 2019-04-06 15:26 adam
Generate Tokens
How many tokens would you like to generate?
100
1,000
10,000
Other
Submit
Cancel


Mobile App Test Study
Token Batches
Enrollment Tokens
Mobile App Test Study
1 - 100 of 1,000
Excel
Text
Script
Excel Workbook (.xlsx) Maximum 1,048,576 rows and 16,384 columns.
Excel Old Binary Workbook (.xls) Maximum 65,536 rows and 256 columns.
Refreshable Web Query (.iqy)
Column headers:
Caption
Export/Sign selected rows
Export
Sign Data
Token
RZMKPHMPK
MBDMSFJLE
PUYJNQYEG
LVTEGKGDL
JMFIHVEVF
JCNQMGVVJ
PZWERQPOS
LRXKOMZPZ
QZMMPWUXE
FJVGKILYO
BTBMOWYZJ

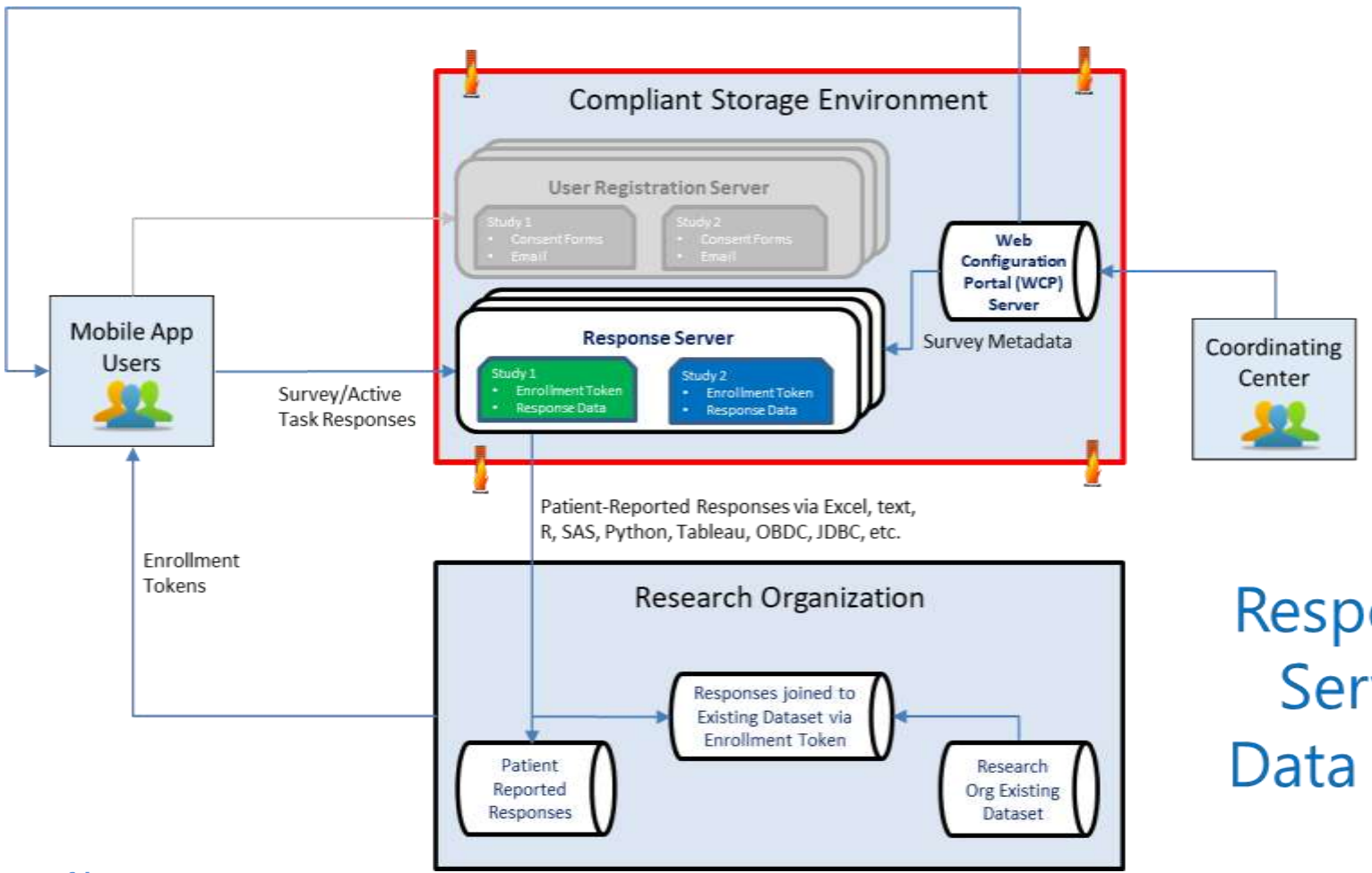

Mobile App Test Study
Token Batches
Enrollment Tokens
Mobile App Test Study
1 - 100 of 1,000
Excel
Text
Script
Separator:
Tab
Quote:
Double (")
Column headers:
Caption
Export/Sign selected rows
Export
Sign Data
Token
RZMKPHMPK
MBDMSFJLE
PUYJNQYEG
LVTEGKGDL
JMFIHVEVF
JCNQMGVVJ
PZWERQPOS
LRXKOMZPZ
QZMMPWUXE
FJVGKILYO
BTBMOWYZJ
KXSPMTXUN
LORSECQZN
LCOQEWNSV
ACDNAYUR5
TPBRWDPAB



Response Server Data Flow

Response Schema Management

- Studies are designed via the WCP (Web Configuration Portal) web application
- Response server provisions a custom, independent database schema for each study based on WCP-provided metadata
- Update to study design triggers Response server schema changes, for example:
  - Study administrator uses WCP to add a new question to a survey
  - Response server adds a new column to corresponding table



Response Server Data Flow

Data Analytics Options

- Standard Community Edition
  - Built-in web analytics, querying, reporting, visualizations
  - Export responses in Excel, text, XML formats
  - APIs: R, SAS, Python, Java, JavaScript, Perl, JSON
  - Configure real-time “response forwarding” (in testing)

- Premium
  - Support for HIPAA-compliant PHI handling and logging
  - Support for FISMA and 21 CFR Part 11 compliance
  - Tableau Desktop, MS Access, SSRS, JMP, and other ODBC clients
  - Spotfire and other JDBC clients
  - RStudio, Rserve, sandboxed R instances

GitHub Repository: Response Server Module

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

Subversion Repository: LabKey Server Platform

https://svn.mgt.labkey.host/stedi/branches/release19.1-SNAPSHOT

Documentation and Support for Building & Deploying LabKey Server

https://www.labkey.org/home/project-begin.view


BREAK

Q&A and Resources

Click for:

- https://www.fda.gov/NewsEvents/Newsroom/FDAInBrief/ucm625228.htm
- https://www.fda.gov/Drugs/ScienceResearch/ucm624785.htm
- https://github.com/PopMedNet-Team/FDA-My-Studies-Mobile-Application-System
- https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-electronic-informed-consent-clinical-investigations-questions-and-answers
- https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-electronic-records-and-electronic-signatures-clinical-investigations-under-21-cfr-part-11
- http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM193282.pdf
- https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence

- Additional questions on the webinar?

Email: CDERSBIA@fda.hhs.gov

Open Q&A begins shortly – type in your questions now.

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Stuart MacDonald
LabKey Software
stuartm@labkey.com

DEPLOYING THE MYSTUDIES SYSTEM IN A COMPLIANT MANNER

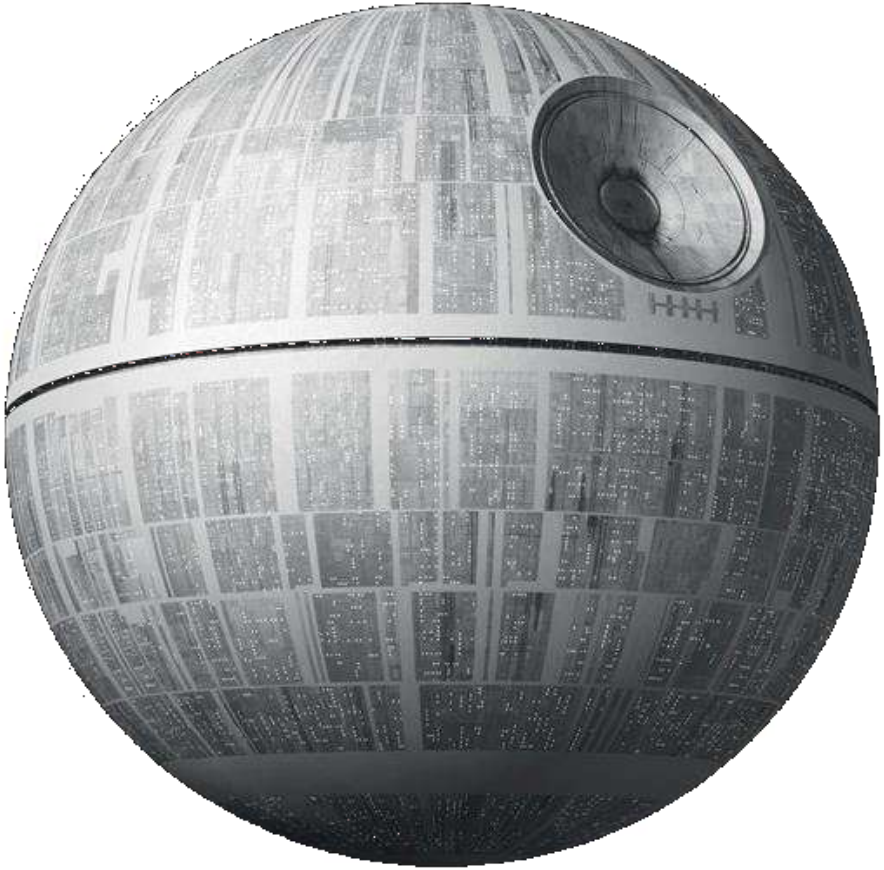
Numerous Compliance Requirements

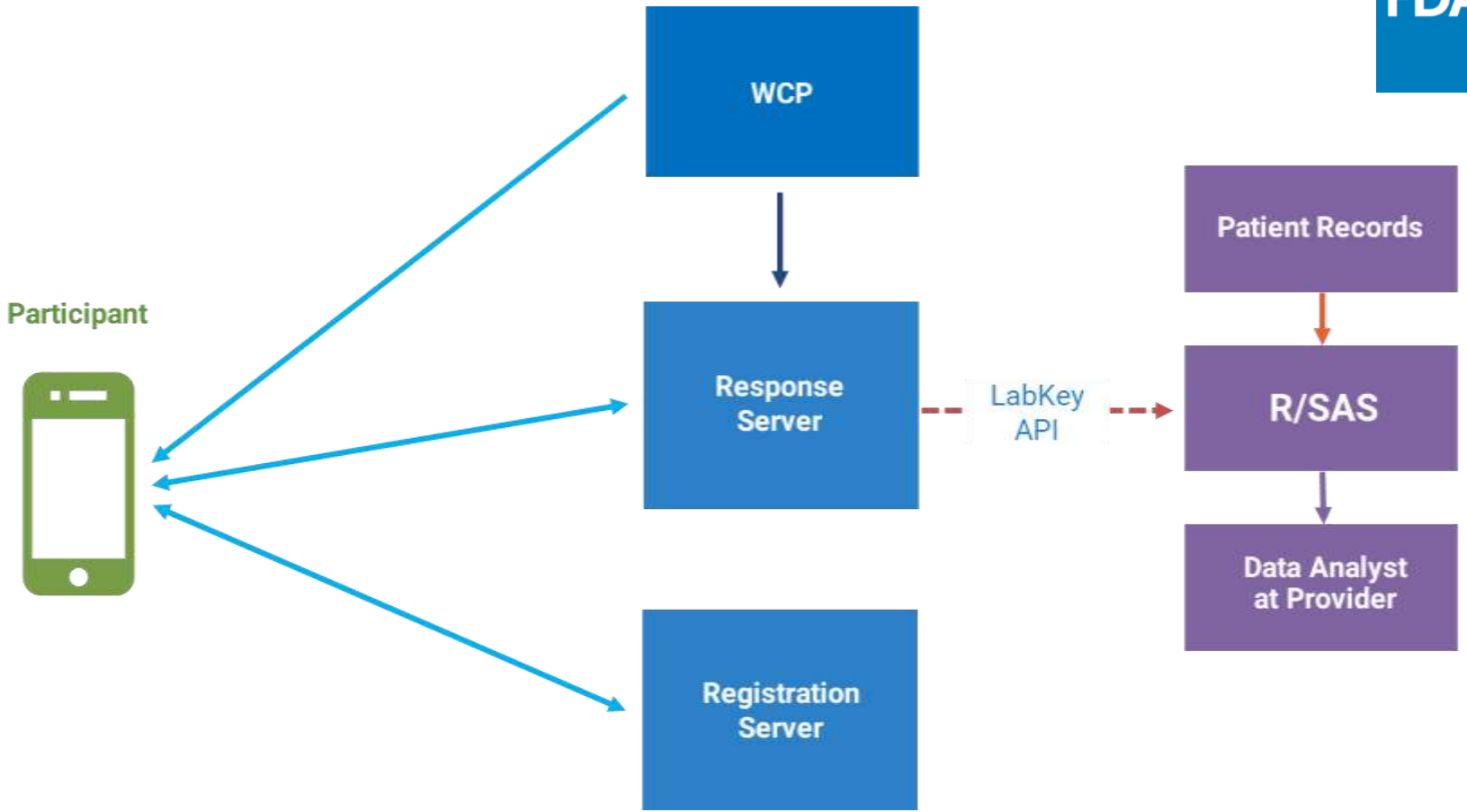
- HIPAA
- FISMA
- CFR-Part 11
- NIST SP 800-53

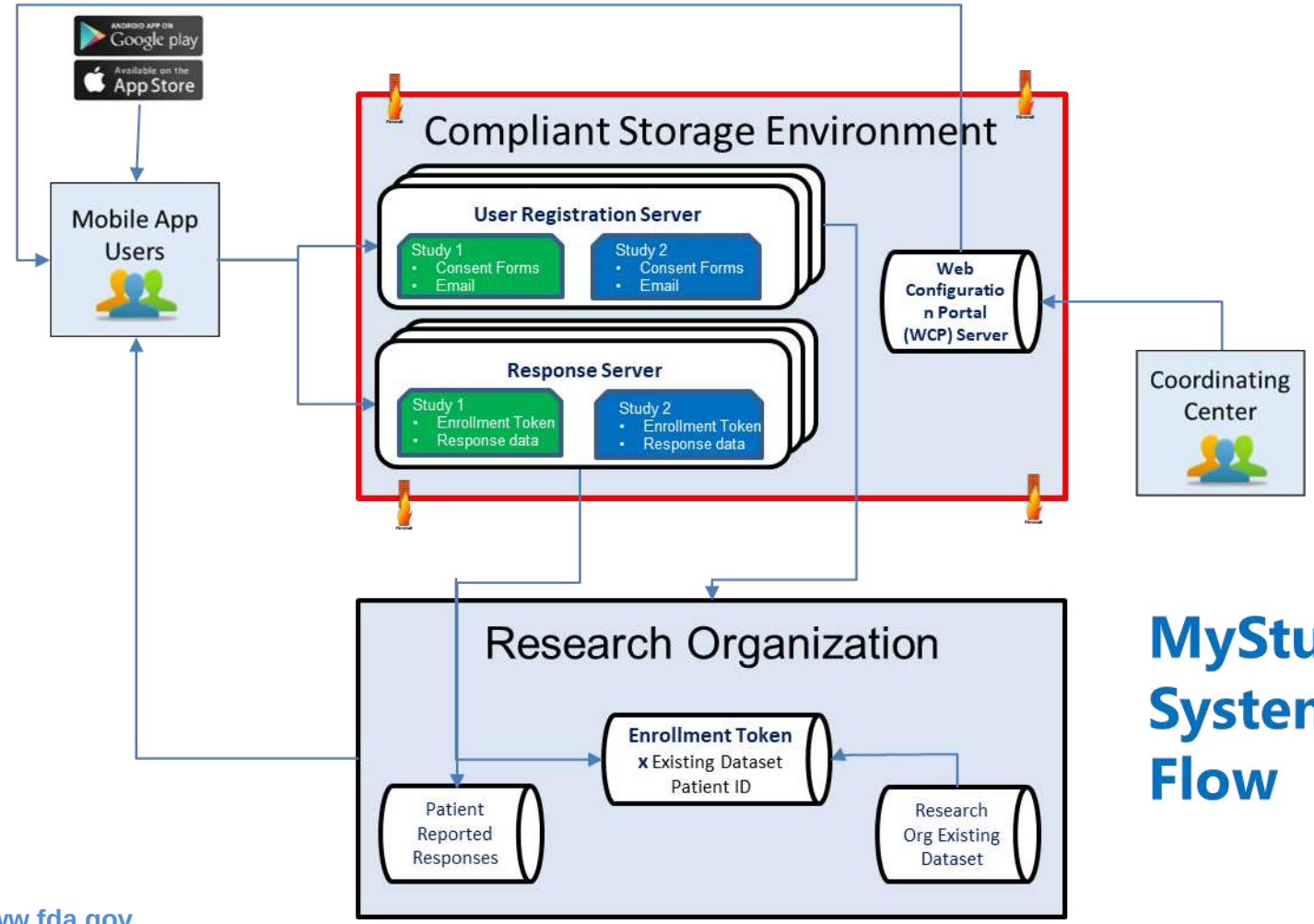
Compliance – not as easy as…

… it looks more like this

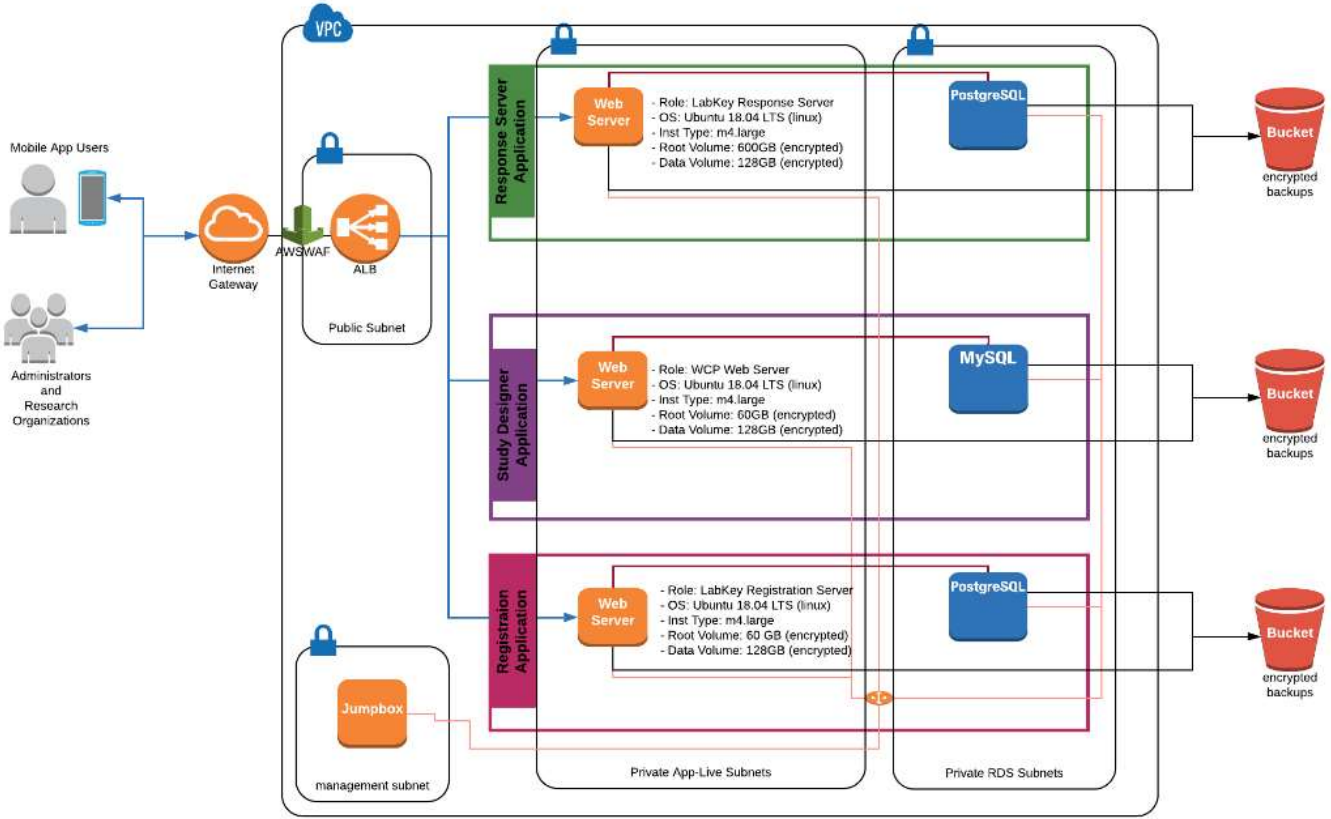
Which sort of resembles this…



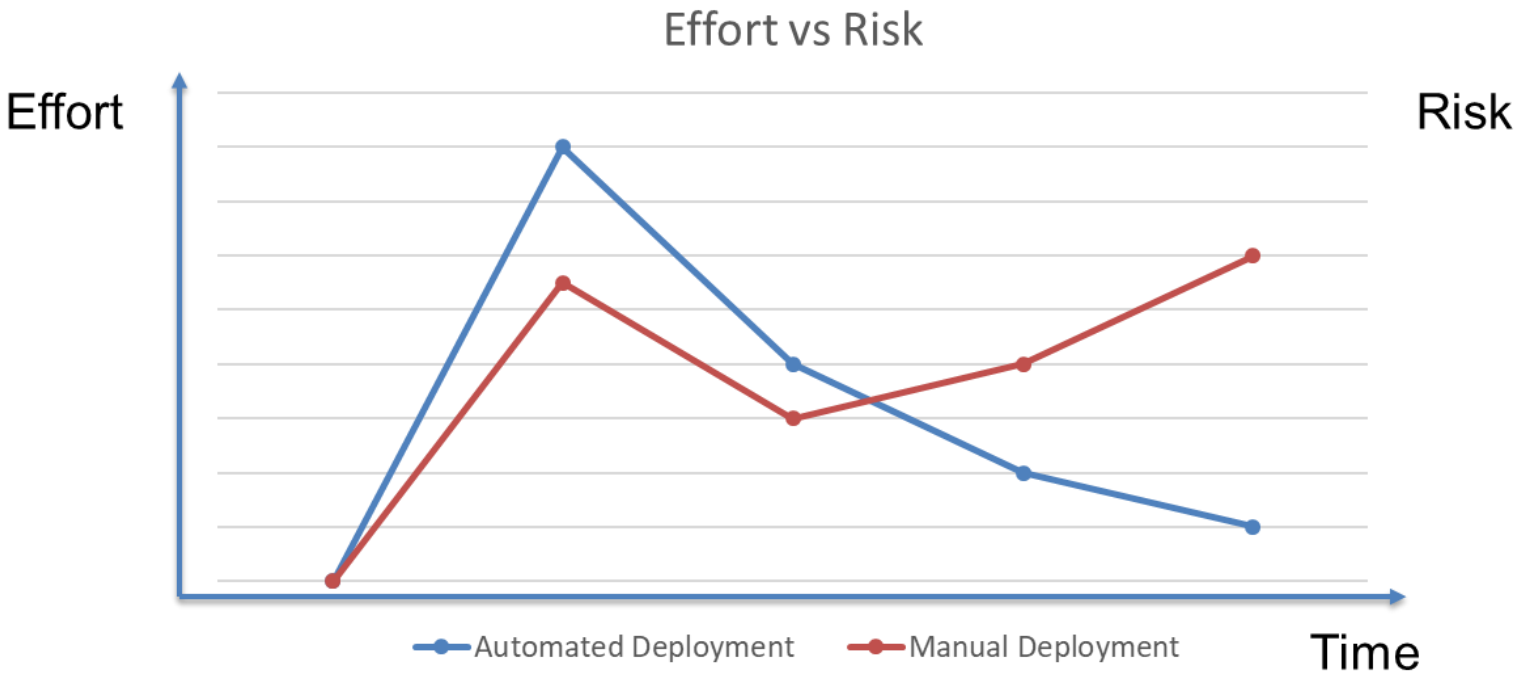

WCP
Participant
Response Server
LabKey API
Patient Records
R/SAS
Data Analyst at Provider
Registration Server



MyStudies System Data Flow


VPC
Mobile App Users
Administrators and Research Organizations
Internet Gateway
AWS WAF
ALB
Public Subnet
Response Server Application
Web Server
- Role: LabKey Response Server
- OS: Ubuntu 18.04 LTS (linux)
- Inst Type: m4.large
- Root Volume: 600GB (encrypted)
- Data Volume: 128GB (encrypted)
PostgreSQL
Bucket
encrypted backups
Study Designer Application
Web Server
- Role: WCP Web Server
- OS: Ubuntu 18.04 LTS (linux)
- Inst Type: m4.large
- Root Volume: 60GB (encrypted)
- Data Volume: 128GB (encrypted)
MySQL
Bucket
encrypted backups
Registraion Application
Web Server
- Role: LabKey Registration Server
- OS: Ubuntu 18.04 LTS (linux)
- Inst Type: m4.large
- Root Volume: 60 GB (encrypted)
- Data Volume: 128GB (encrypted)
PostgreSQL
Bucket
encrypted backups
Jumpbox
management subnet
Private App-Live Subnets
Private RDS Subnets

Why Automate?



Keys to addressing compliance requirements

- Design
- Automation
- Defense

Keys to addressing compliance requirements

1. Design
   - Tiered application design - segmentation and isolation
   - Encryption everywhere
   - NACLS, Firewalls (security groups)

Keys to addressing compliance requirements

2. Automation

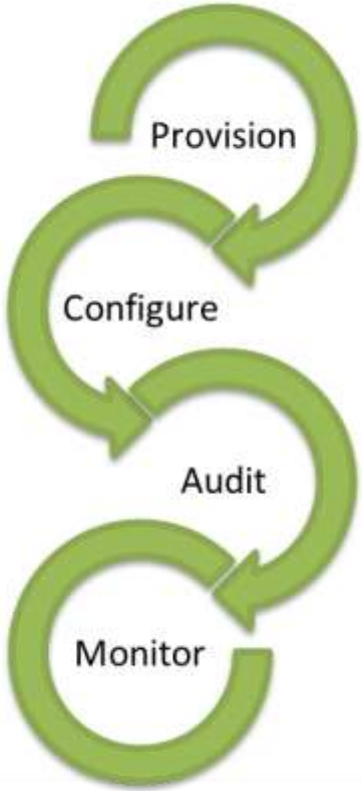
a) Use automation to deploy and enforce the security design

b) Use configuration management to enforce the configuration and prevent drift

c) Use automation for testing of security controls

d) Blue-Green deployment model - no more patch in place - deploy new instead

LabKey Automation Tooling



Terraform

Chef

Inspec, AWS Inspector, Wazuh

Splunk, Wazuh, CloudWatch etc.

Keys to addressing compliance requirements

3. Defense

a) Web Application Firewall

b) Intrusion Detection & Prevention

c) Log Aggregation

d) Log Monitoring

e) Vulnerability Scans

Do's & Don'ts

Do's

- Do design and plan for changes
- Do consider using a Cloud Provider
- Do use automation to provision, configure and validate your infrastructure
- Do use encryption everywhere

Don'ts

- Don't deploy the platform manually
- Don't forget about backups, data retention and data recovery plans
- Don't forget about important processes and procedures
  - Change Management
  - Security Incident Management
  - Compliance policies, procedures and documentation

Compliance Quote of the day….

“It is not only for what we do that we are held responsible, but also for what we do not do.”

-Moliere


BREAK

Q&A and Resources

Click for:

- https://www.fda.gov/NewsEvents/Newsroom/FDAInBrief/ucm625228.htm
- https://www.fda.gov/Drugs/ScienceResearch/ucm624785.htm
- https://github.com/PopMedNet-Team/FDA-My-Studies-Mobile-Application-System
- https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-electronic-informed-consent-clinical-investigations-questions-and-answers
- https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-electronic-records-and-electronic-signatures-clinical-investigations-under-21-cfr-part-11
- http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM193282.pdf
- https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence

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Open Q&A begins shortly – type in your questions now.

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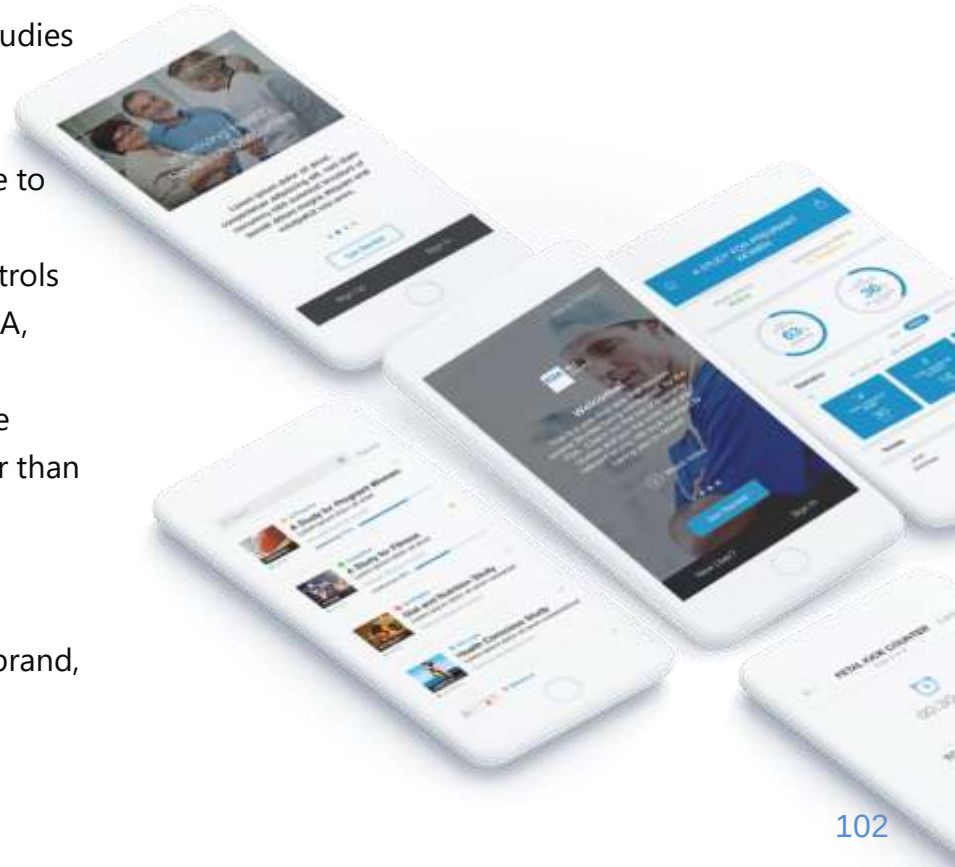
MyStudies Team

MYSTUDIES CLOSING THOUGHTS AND RESOURCES

Key System Attributes

- **Scalable**: Capability to simultaneously support multiple studies for a research organization
- **Modular**: Various modular components of the platform can be integrated with external/3rd party system of choice to create a tailored solution for your organization.
- **Secure**: Partitions all data and provides robust access controls
- **Compliant**: Can be deployed to comply with HIPAA, FISMA, and 21 CFR Part 11
- **Customizable**: All study content as seen in the app can be authored and updated via the WCP web application rather than through new software development per study or app
- **Tested**: FDA and PCORI sponsored clinical research demonstration projects
- **Open-source** and ready for research organizations to re-brand, publish, and use!



Call to Action

- Review code in the GitHub repository and ask questions
- Clone, build, and test the code in your development environment
- Work with today's presenters to deploy and configure the system for your studies:
  - Harvard Pilgrim Health Care Institute (Zachary_wyner@harvardpilgrim.org)
  - Boston Technology Corporation (Shyamd@boston-technology.com)
  - LabKey Software (adam@labkey.com)
- Or deploy the system yourself to your own hosting environment


FDA
U.S. FOOD & DRUG
ADMINISTRATION