Consumer Mobile Health Application Functional Framework *Overview & Update*

Mobile Health Workgroup

October 2015

Why start this project?

- **Need for criteria to enable development of consumer health apps which promote a uniform approach to security, privacy and data use**
- **Current HL7 functional models cannot be used as-is to allow for certification of secure consumer-facing mobile health applications**
- **Shift in consumer health offerings from being**
  - Global in scope and Web by channel to
  - Narrow in scope and Mobile by channel
- **Provide a path for the certification of apps**
  - Consumer confidence
  - Provider confidence

Out of Scope

- This project will NOT define standards for the content of mobile applications.
- This project will NOT address apps written for basic phones.

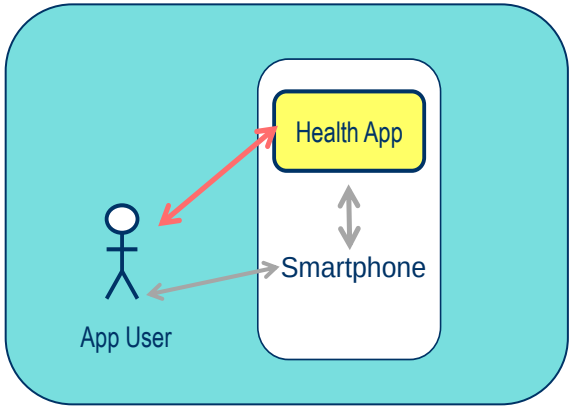
Approach

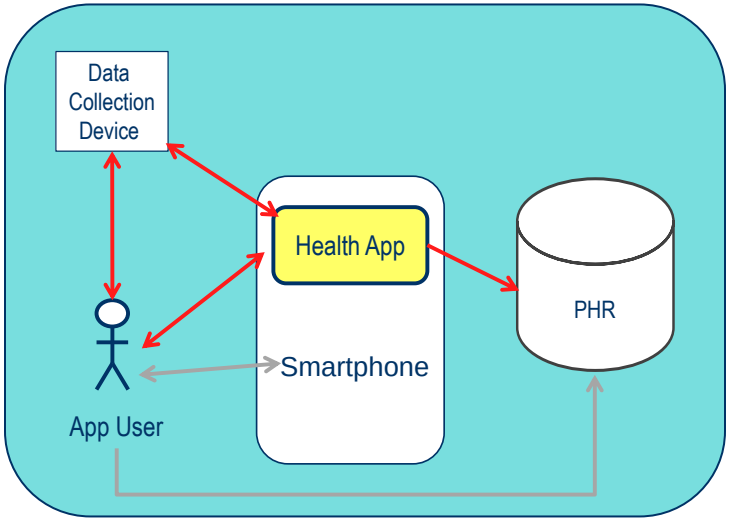
- **Speed to market is valued more than a 100% complete model**
  - Target: have draft ready for comment-only ballot for by year-end 2015. Use comments to address significant gaps to prepare for DSTU ballot for May 2016.
- **Model is lightweight**
  - Emphasis on “shall” and “should” criteria over “may” criteria
- **Conformance sections based on app lifecycle from the point of view of the primary user of the app**
- **Criteria consider 3 model use cases of consumer apps in creating conformance criteria and reference information**

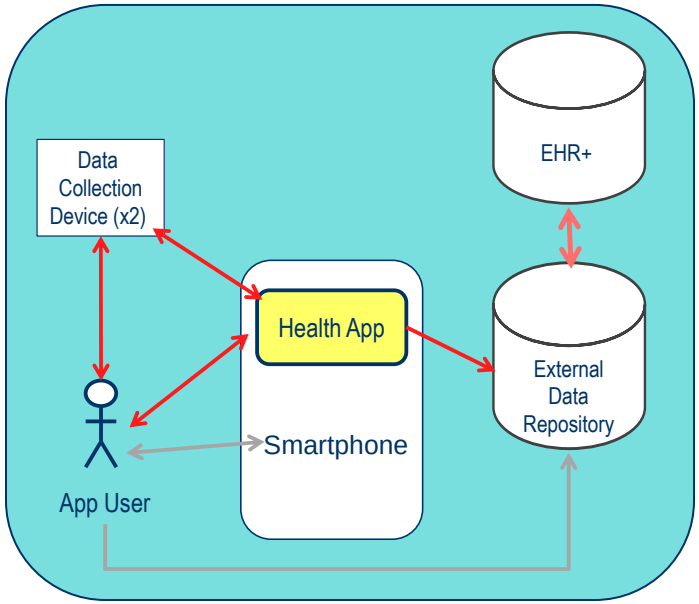
Publishing Format

- **Structure designed to facilitate standards-conformant product development**
  - Conformance criteria applicable to all apps
  - Conformance criteria conditionally applicable to some apps
  - Easy to convert conformance criteria to product requirements
  - Within standard be able to reference workflow diagrams, exemplary use cases/user stories, enabling standards and FHIR® resources applicable to fulfilling conformance criteria

Model Use Cases

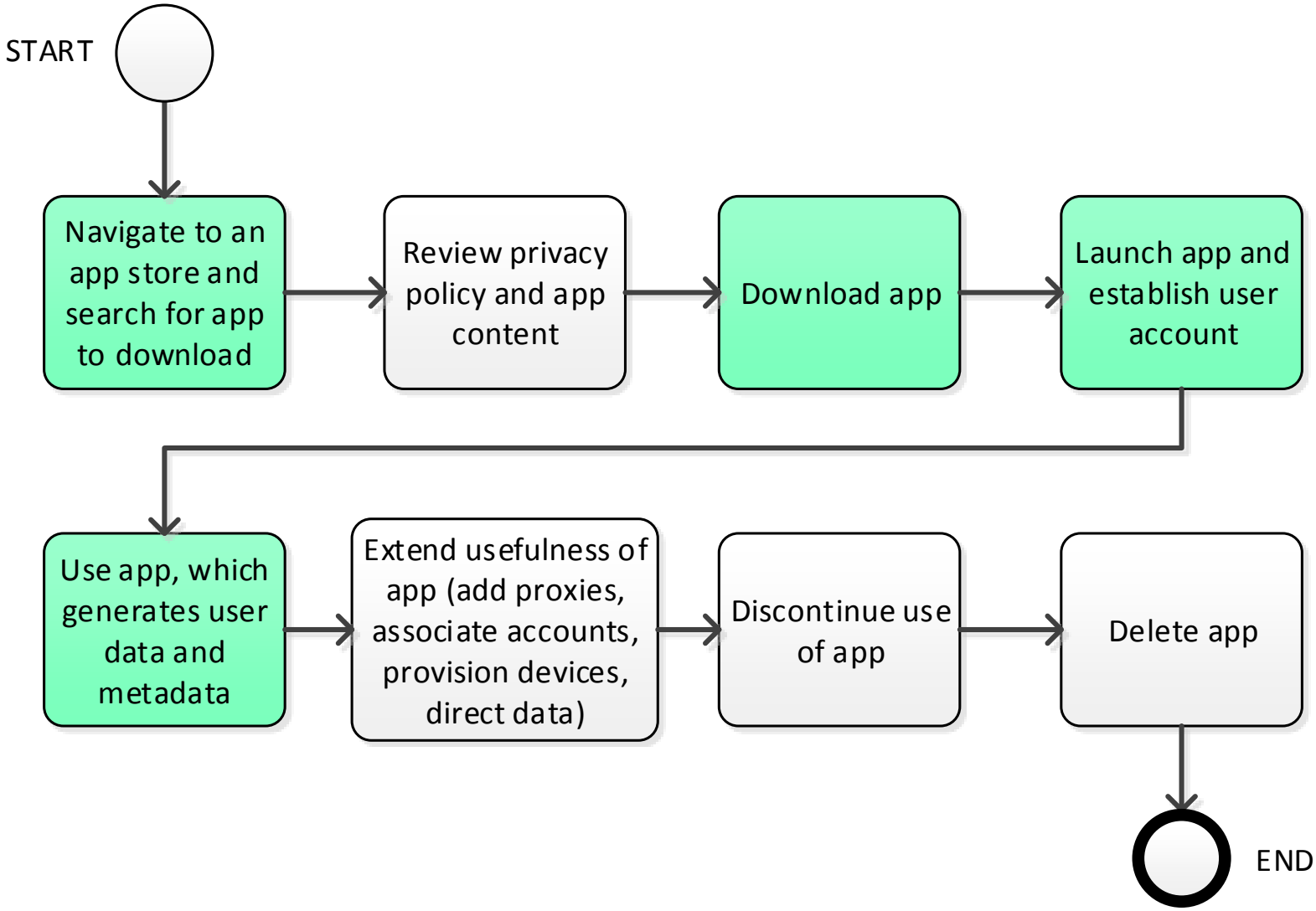






	Simple	Device Integrated	EHR Integrated
FDA App Categorization	wellness	wellness	medical
Device Data Collection	none	unregulated device	FDA regulated device
PHI Data Storage	smartphone	smartphone/PHR	cloud/EHR
Data transmission by App	none	device-app-PHR	device-app-cloud-EHR
Importance of Data Integrity	low	mid	high
HIPAA covered?	no	no, but yes, if white-labeled	yes

Mobile app lifecycle



Outline of Conformance Sections

Product Development and Support

- Regulatory Considerations
- Product Risk Assessment and Mitigation
- Product Usability
- Customer Support

Download and Install App

- App Store Experience
- Launch App and Establish User Account

Use App

- User Authentication and Authorization to Access App Services
- User Authorizations for Data Collection and Use
- Pairing User Accounts with Devices and Data Repositories
- Security for Data at Rest
- Security for Data in Transit
- Data Authenticity, Provenance and Associated Metadata
- In-app Payments
- Notifications and Alerts
- Product Upgrades
- Rewards and Incentives
- Audit

App Service Termination

- App and Data Removal

Conformance Section Organization

Section Title

Universal Criteria

Conditional Criteria

Resources

Implementation Guidance

1.1 Regulatory Considerations

1	Shall	Following Realm-specific regulatory rules, determine if the app needs regulatory approval before the app is used by the general public. For example, in the US realm this would include determining if the app is a regulated "medical device" according to the U.S. Food and Drug Administration (FDA), and if so, obtaining necessary pre-market approval.
2	Shall [IF]	[App requires regulatory approval] Regulatory approval is obtained before app is made available to the general public.

Regulations, standards, and implementation tools

U.S. Food and Drug Administration: Mobile Medical Applications, http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ConnectedHealth/MobileMedicalApplications/ucm255978.htm

Implementation guidance by use case

Use Case A: In the US Realm, a walking app which encourages general wellness is not considered a medical device by the FDA.

Use Case B: In the US Realm, a weight management app is not considered a medical device by the FDA as long as it makes no claims to improve/cure a disease. How the app is described is important, and FDA guidance defining wellness vs. apps which aim to improve specific disease conditions should be referenced and reviewed before making a definitive decision as to its FDA classification.

Use Case C: There are two distinctions regarding compliance issues for this app. For the data collection devices in this use case, a glucometer would be FDA regulated, while a general activity monitor, would not. Apps which collect and display disease information would not typically be regulated until the information is compiled or transformed and clinical decisions are made on the data. In this case, the app is capable of receiving alerts, but the logic behind the alerts are based on individualized settings through a rules engine which is integrated into an EHR. In this case, the locus of regulation is not clear, and as such counsel should be engaged in forming a definitive case as to what regulatory approvals might be needed.

Project and contact information

Meetings:

Standing meetings are on Mondays at 2 PM Pacific (5 PM Eastern)

- WebEx: https://kponline.webex.com/kponline/j.php?MTID=mde22960aeb299e4a13407f4aa8a0dc2f
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Wiki:

http://wiki.hl7.org/index.php?title=MHWG_Consumer_Mobile_Health_Application_Functional_Framework

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