Consumer Mobile Health Application Functional Framework (cMHAFF) Overview and Update

Mobile Health

January 2017

San Antonio WGM

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cMHAFF Scope and Goals

- Provide a standard as a framework for assessment of a mobile app's foundational aspects:
  - Security
  - Privacy/consent
  - Risk assessment
  - Usability assessment
  - Data access privileges for consumers and others
  - Data export (sharing)
  - Transparency of conditions (disclosures)
- Assessment might include attestation, testing, endorsement, and voluntary or regulatory certification
- Out of scope: clinical/health content or functionality

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Why cMHAFF? What's the Need?

- Target Audience: **mobile health app developers** needing guidance on building apps
- Beneficiaries: consumers, providers
- Consumers need protection, transparency and assurance regarding mobile apps. Some examples:
  - What **security** protections exist behind that "cloud?"
  - Can I **comprehend**, or even find, privacy policy and terms of use?
  - Who can the app **disclose** data to?
  - What does the app **know** about me (location, microphone, contacts, photos, etc.), and what can it **do** on my device?
  - Can I **access** my app data like I can under HIPAA?
  - What happens to my **data** if I delete an app?

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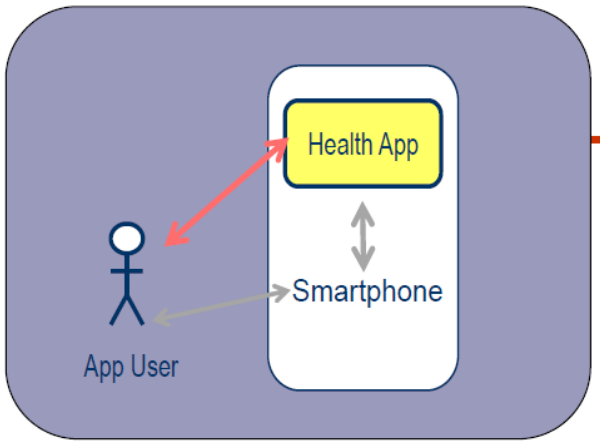
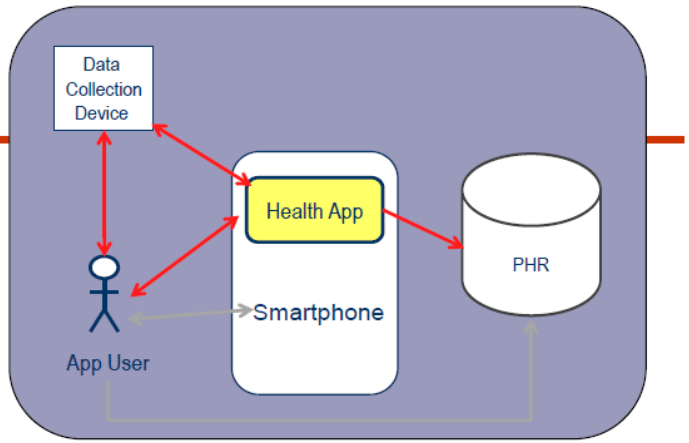
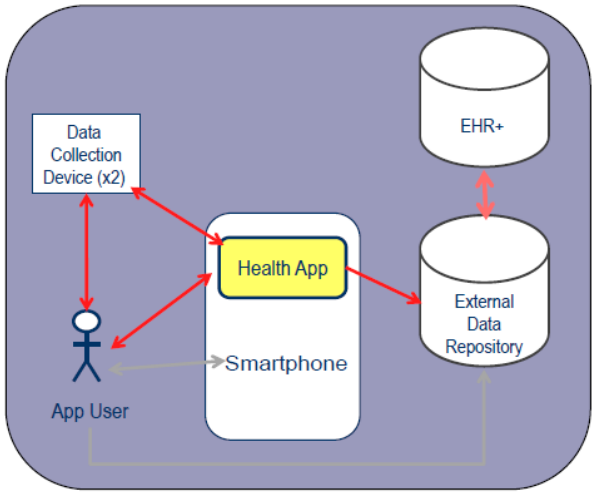
cMHAFF Exemplar Use Cases







	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

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cMHAFF Topics

- Product Development and Support
  - Risk assessment, usability, customer support
- Download and Install App
  - App store experience, establish account, launch app
- Conditions and Agreements (new)
  - Disclosures, terms, charges, in-app payments, incentives
- Use App
  - Authentication, authorization for app services, authorization for data, pairing user accounts, security for data at rest and in transit, data authenticity and provenance, product upgrades, audit
- App Service Termination
  - App & data removal, post closure use of data

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Ballot: Current Status

- ~100 comments (35 negatives) dispositioned and being incorporated into new cMHAFF
- Moving toward ballot in May 2017 cycle
- Keeping Informed by inviting guests from industry efforts (e.g., ONC/Accenture Patient-Generated Health Data; ONC Model Privacy Notice; SMART on FHIR; FTC Consumer Protection and Disclosure…)

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Current Project Plan

- Usability, Notifications, Wordsmithing (done)
- January-February 15: Security and Privacy (encryption, auditing, authorization, consent, etc.) to be refined by collaborating with Security and CBCC workgroups
- Feb 15-March 6: Regulatory and best practice references
- March 6-31: New material from industry developments, formatting, editing, NIB for May ballot

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cMHAFF Motivation - Invitation

- This is an exciting new opportunity in an exploding space: get in on the ground floor!
- We have leeway to make broad changes to meet emerging needs
- Help us take a right-sized approach, addressing important gaps without stifling innovation or being too prescriptive
- Help HL7 collaborate well with the public and private sectors

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Project and Contact Info

- Meets on Mondays at 5pm Eastern
  - Webex https://westat.webex.com/westat/j.php?MTID=mbd682bcdce33caf6ad89daaad8841d6f
  - Phone 770-657-9270, passcode 465623
- Project Leads: Nathan Botts / David Tao
- **Join us** to move cMHAFF forward!

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Backup Slides

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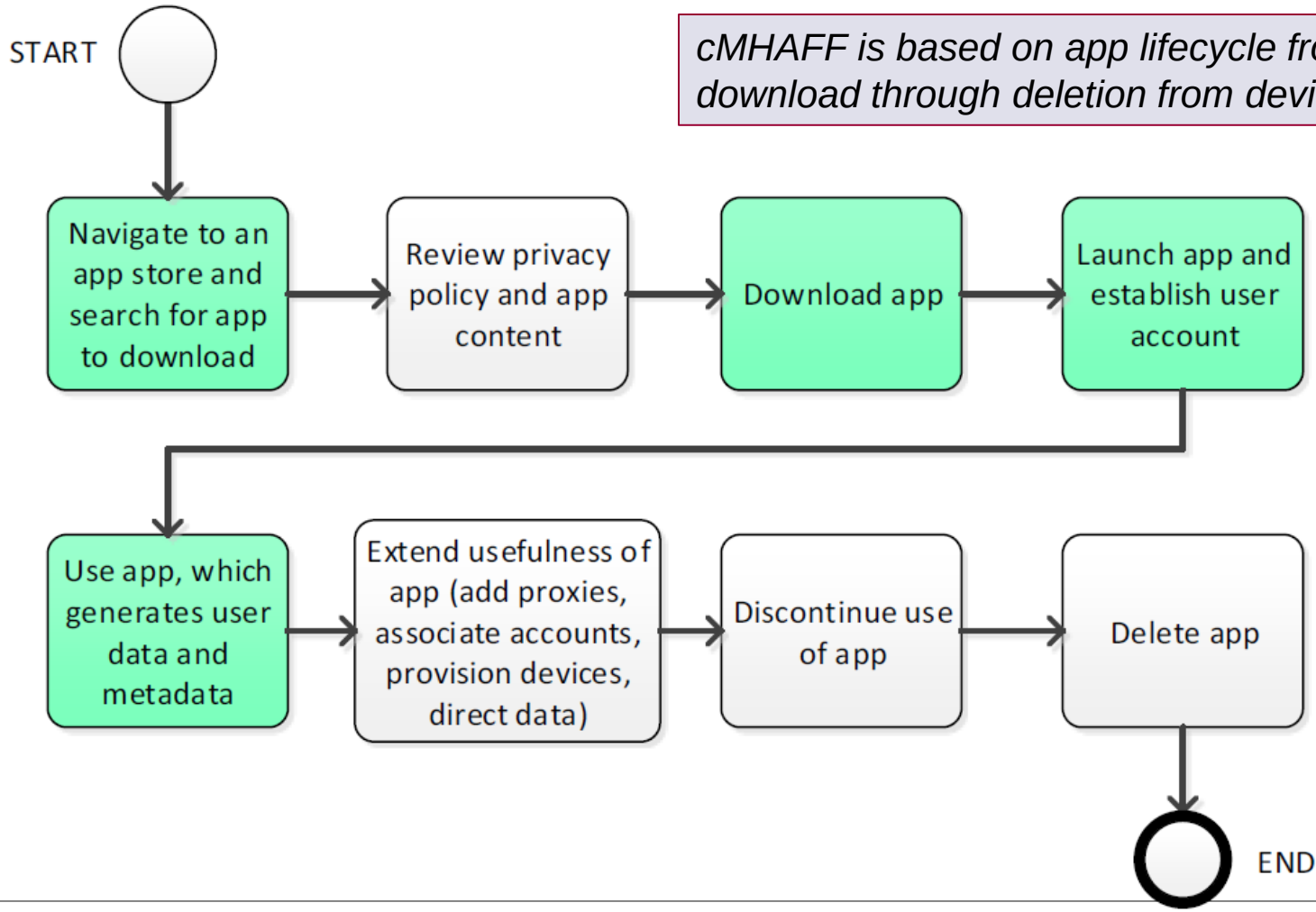
Mobile App Lifecycle



cMHAFF is based on app lifecycle from download through deletion from device

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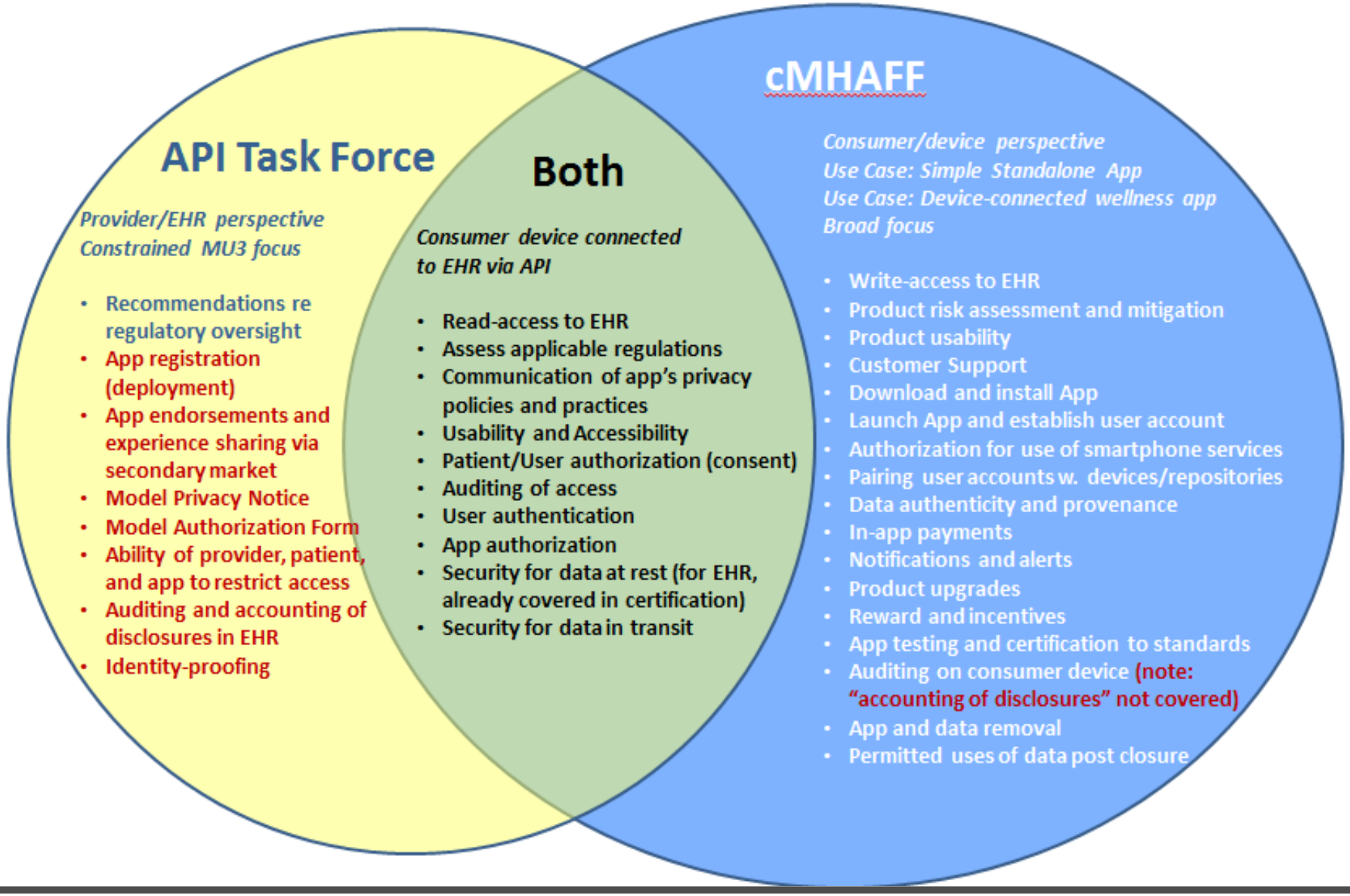
cMHAFF and API Task Force Scope



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