

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

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Mobile Health  
September 2016  
Working Group Meeting



# Why cMHAFF? What's the Need?

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- Consumers need protection, transparency and assurance regarding mobile apps. Some examples:
  - Who else 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 clinical **evidence** underlies this wellness app?
  - What **security** protections exist behind that “cloud?”
  - Can I **comprehend**, or even find, privacy policy and terms of use?
  - What happens to my **data** if I delete an app?
- Developers need guidance on building MH apps
- Benefits: consumer and provider confidence in the apps, and assistance to developers

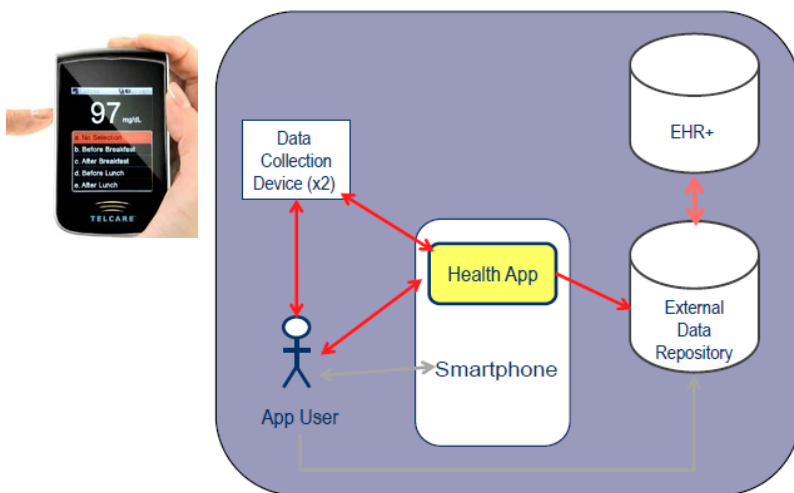
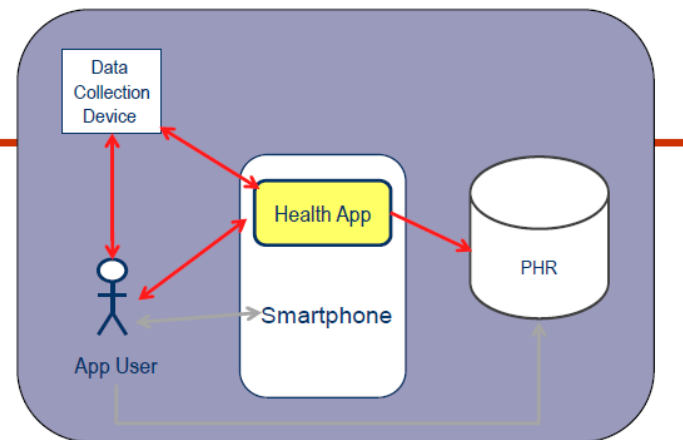
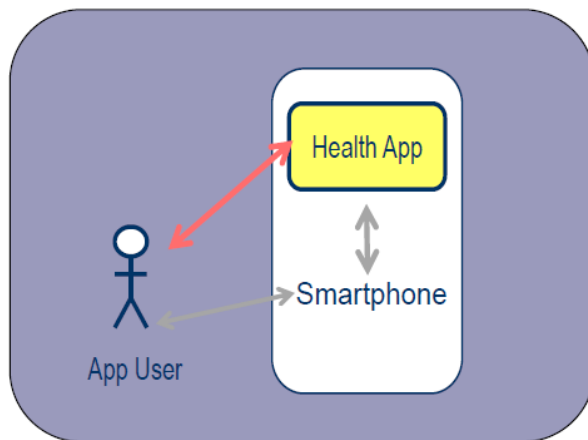


# cMHAFF Scope and Goals

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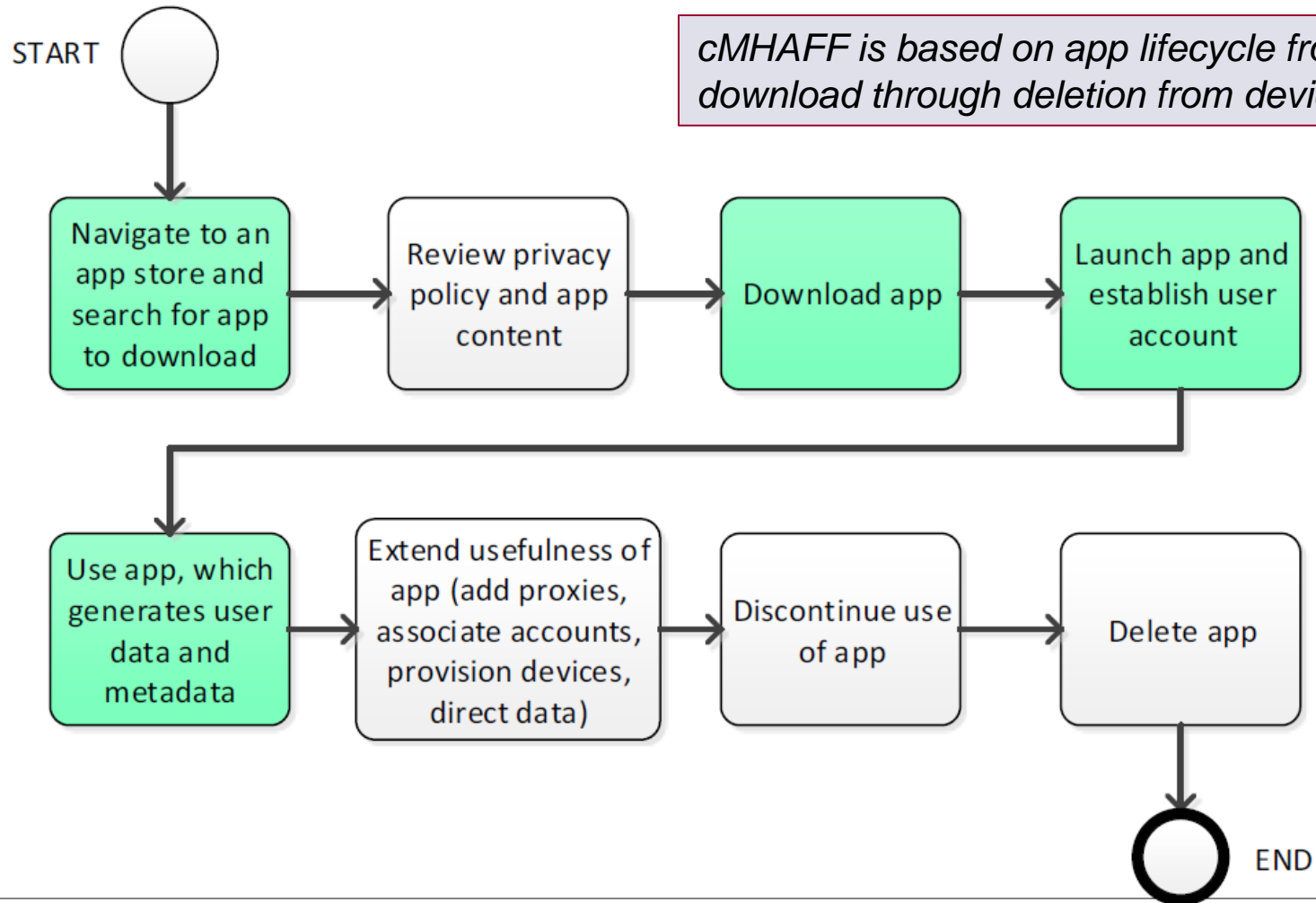
- Provide a standard against which the security and privacy of a smartphone (or tablet) app can be assessed
- Promote the generation of health data which is reliable, actionable, and accessible by consumers
- Promote transparency for consumers to understand what their apps do with their data
- Framework does **not** address the specific health content/functionality of an app

# cMHAFF Exemplar Use Cases



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

# Mobile App Lifecycle



# cMHAFF Topics

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- Product Development and Support
  - Risk assessment, usability, customer support
- Download and Install App
  - App store experience, establish account, launch app
- 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, in-app payments
- App Service Termination
  - App & data removal, post closure use of data

# Ballot: Current Status

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- 104 ballots received (many referring to the same spreadsheets), 30 negatives, 32 affirmative, 42 abstentions
- ~100 comments (35 negatives) received and dispositioned
- Ballot reconciliation approved by project team
- Next step: rewrite cMHAFf to move toward STU ballot (target 1H 2017)

# Ballot Comment Themes (1)

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- Scope of regulation vs certification vs testing vs guidance
- US Realm vs International Realm
- Need for more specific, testable, criteria, including reference to other standards
- “Guidance” vs “standards” (conformance statements)
- Debate about appropriateness of guidance in non-technical areas, e.g., terms of agreement
- Loosening or tightening some conformance statements
- Challenges establishing universal (vs conditional) conformance, considering huge diversity of “health” apps purposes, intended users, and connections to EHRs



# Ballot Comment Themes (2)

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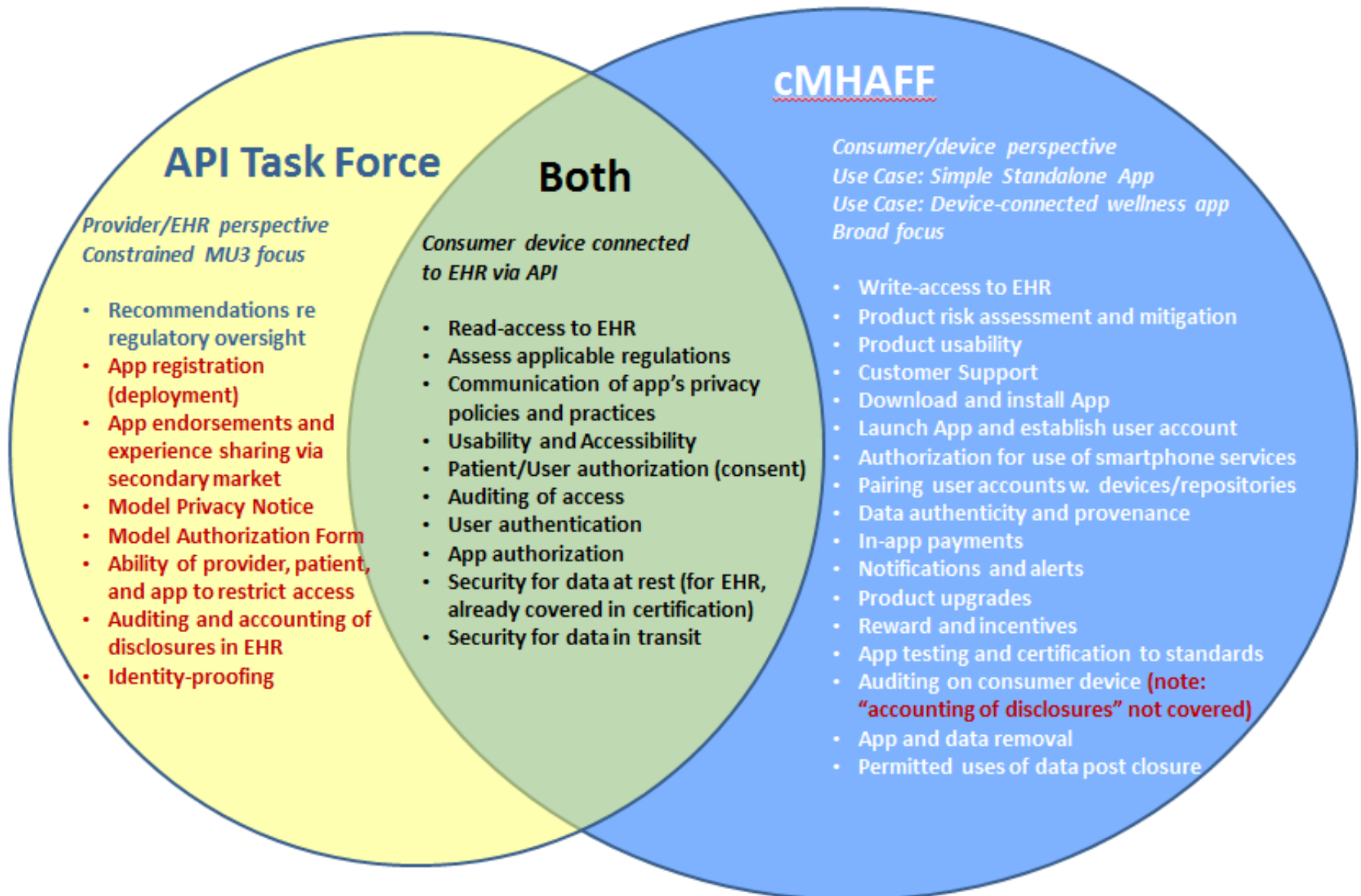
- Balancing usability vs stringency (e.g., notifications, alerts)
- Assessing developer burden, considering the landscape of small app developers
- Referencing other guidance, e.g., OCR, FTC, HIPAA, FDA, COPPA, NIST
- Applicability (or not) of other HL7 standards, e.g., FHIR, EHRS-FM, CDA, v2, in MH space
- Need for more examples

# Addressing US-realm Gaps

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- Opportune time for HL7/cMHAFf to consider
  - FTC/OCR Guidance
  - HIT Joint Committees API Task Force
  - ONC Report: Gaps in Oversight of Non-Covered Entities (MH apps, social media, PHRs)
  - ONC PHR Model Privacy Notice: applicable to MH?
  - MH platform-specific guidelines (e.g., new for iOS)

# cMHAFF and API Task Force Scope



# cMHAFF Motivation - Invitation

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- This is an exciting new opportunity in an exploding space: get in on the ground floor!
- Comment-only cMHAFF ballot permits 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

# Project and Contact Info

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- 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 to STU!