

# Mobile Health (MH) Working Group – Projects Update

HL7 January 2022 WGM  
By Matthew Graham

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# Mobile Health Work Group Co-Chairs

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# Mobile Health WGM Sessions

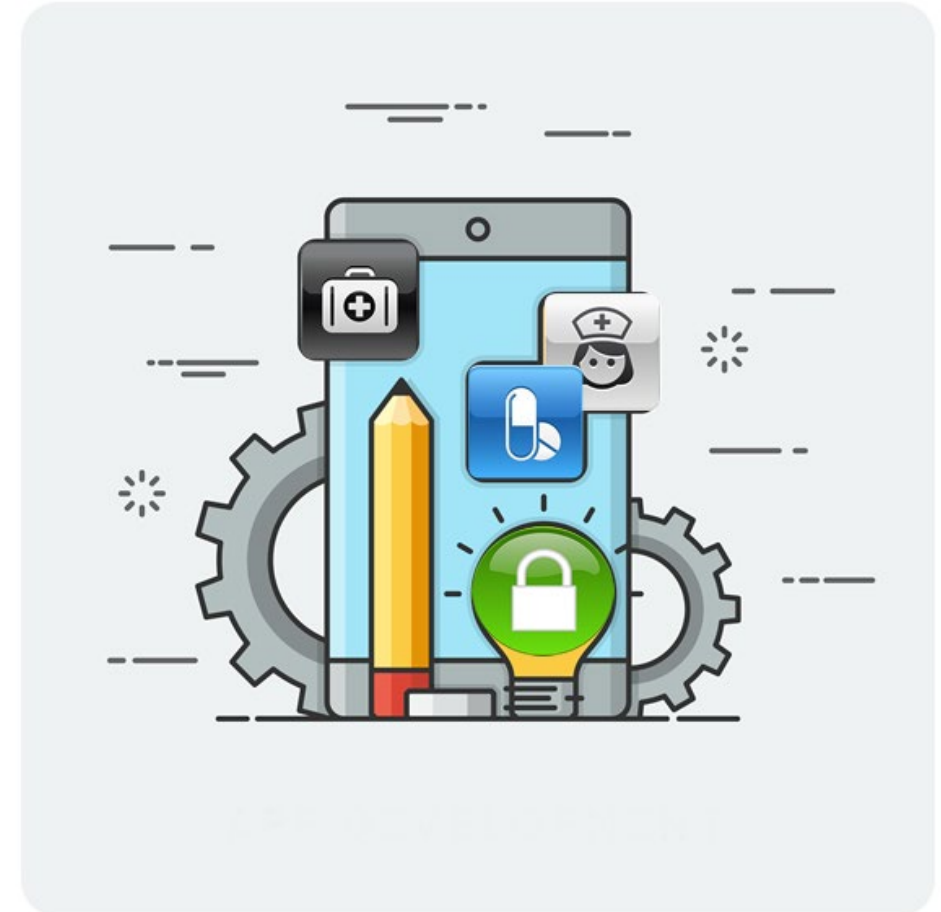
- Tuesday
  - Q1 - EHR hosting MH - Mobile Health Projects Update
- Wednesday
  - Q1 – State of Mobile Health (SoMH) Address
  - Q2 – cMHAFF: consumer Mobile Health Application Functional Framework Update
  - Q3 – Patient Engagement - Self Measured Blood Pressures – PGHD
  - Q4 – UMHAI: Unique Mobile Health App Identifier Update
- Thursday
  - Q1 – SHIFT: School Health Innovation Framework leveraging Technology Update
  - Q2 – Joint Devices and MH

# Mobile Health - Projects

- Consumer Mobile Healthcare Application Functional Framework (cMHAFF)
- Mobile Health App Data Exchange (MH-ADE)
- School Healthcare Information Framework utilizing Technology (SHIFT)
- Unique Mobile Health App Identifier (UMHAI)

# cMHAFF Scope and Goals

- Provide a framework for assessment of the **common foundations** of mobile health apps
  - Product Information (disclosures/transparency)
  - Security
  - Privacy/consent/authorization
  - Risk assessment/analysis
  - Data access privileges
  - Data exchange/sharing
  - Usability & Accessibility
- Assessment could include attestation, endorsement, testing, voluntary or regulatory-driven certification
- Out of scope: specific clinical content or functionality
- Includes functions, requirements, and IG



# CMHAFF Domains

## Functional Requirements

- Usability & Accessibility
- Download & Installation Considerations
- App Launch & Registration
- App Use & Operation
- Consent for Data Collection
- Account Synchronization
- Security for Data at Rest
- Security for Data in Transit
- Data Authenticity, Provenance, and Associated Metadata

- Data Exchange and Interoperability
- Product Upgrades
- Audit
- App and Data Removal
- Permitted Uses of Data Post Account Closure

## Non-Functional Requirements

- Product Risk Assessment & Mitigation
- Regulatory Considerations
- Product Information
- Conditions and Agreements

# Why cMHAFF? What's the Need?

- Target Audience: **mobile health app developers** needing guidance on building apps
- Beneficiaries: consumers, providers, caregivers
- Consumers need protection, transparency and assurance regarding mobile apps. Some examples:
  - What does the app **do**? What **evidence** supports it?
  - What **security** protections exist behind that “cloud?”
  - Who can the app **share** data with?
  - What does the app **know** about me (location, microphone, camera, contacts, etc.), and what can it **do** on my device?
  - Can I **access** my app data like I can under HIPAA?



# CEN/ISO Health & Wellness Apps

## Quality & reliability for health and wellness apps



Why this is needed:

- Many **uncoordinated national initiatives** for App Quality Frameworks
- **Thousands of Apps in the wild already** – unknown quality / safety
- Apps are developed on **App Platforms**, and are distributed through **App Stores** – distinctive opportunities for Quality Interventions
- **Software as a Medical Device** – Not the whole answer
- **Apps are developed by Very Small Entities** – need focused documents targeted at their needs.
- **Apps developers are Disruptive** – new community not part of the healthcare IT tradition

### Digital Health and Care

TRANSFORMATION OF HEALTH AND CARE IN THE DIGITAL SINGLE MARKET - Harnessing the potential of data to empower citizens and build a healthier society

**European health challenges**

- ⊗ Ageing population and chronic diseases putting pressure on health budgets
- ⊗ Unequal quality and access to healthcare services
- ⊗ Shortage of health professionals

**Potential of digital applications and data to improve health**

- ⊗ Efficient and integrated healthcare systems
- ⊗ Personalised health research, diagnosis and treatment
- ⊗ Prevention and citizen-centred health services

**What EU citizens expect..**

- 90% agree To access their own health data (requiring interoperable and quality health data)
- 80% agree To share their health data (if privacy and security are ensured)
- 80% agree To provide feedback on quality of treatments

**Support European Commission:**

- 1 Secure access and exchange of health data**  
**Ambition:** Citizens securely access their health data and health providers (doctors, pharmacies...) can exchange them across the EU.  
**Actions:**
  - eHealth Digital Service Infrastructure will deliver initial cross-border services (patient summaries and ePrescriptions) and cooperation between participating countries will be strengthened.
  - Proposals to extend scope of eHealth cross-border services to additional cases, e.g. full electronic health records.
  - Recommended exchange format for interoperability of existing electronic health records in Europe.
- 2 Health data pooled for research and personalised medicine**  
**Ambition:** Shared health resources (data, infrastructure, expertise...) allowing targeted and faster research, diagnosis and treatment.  
**Actions:**
  - Voluntary collaboration mechanisms for health research and clinical practice (starting with 'one million genomes by 2022' target).
  - Specifications for secure access and exchange of health data.
  - Pilot actions on rare diseases, infectious diseases and impact data.
- 3 Digital tools and data for citizen empowerment and person-centred healthcare**  
**Ambition:** Citizens can monitor their health, adapt their lifestyle and interact with their doctors and carers (receiving and providing feedback).  
**Actions:**
  - Facilitate supply of innovative digital-based solutions for health, also by SMEs, with common principles and certification.
  - Support demand uptake of innovative digital-based solutions for health, notably by healthcare authorities and providers, with exchange of practices and technical assistance.
  - Mobilise more efficiently public funding for innovative digital-based solutions for health, including EU funding.

#DigitalSingleMarket #DigitalHealth @eHealth\_EU @EU\_Health



# CEN/ISO – additional info/timeline

- TS: IEC 82304-2: Health Software — Part 2: Quality and reliability criteria for health and wellness apps
  - [IEC 82304-1](#): Health software – part 1: general requirements for product safety
  - [IEC 62304](#) – Medical device software – Software life cycle processes
- Timeline:
  - Draft Technical Specification (DTS) - Published August 2021

# Sample of European Guidelines Assessed

- [French mHealth Good Practice Guidelines \(2016\)](#)
- [German Mobile Health Assessment Criteria \(2016\)](#)
- [Andalusian App Recommendations](#)
- [U.K. PAS277 Quality Criteria \(2015\)](#)
- [Finland PHR Cert Criteria](#)
- [Other EU initiatives](#)



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  - [IEC 62304](#) – Medical device software – Software life cycle processes
- Timeline:
  - Published August 2021: <https://www.iso.org/standard/78182.html>

- European Innovation and Knowledge mHealth Hub
  - To operationalise an mHealth Innovation Hub for integration into the national health systems in Europe.
  - To serve as a focal point for expertise on mHealth in the WHO European Region.
  - To assist countries in implementing mHealth strategies.
  - To act as facilitator of innovation in mHealth.
  - To act as an accelerator for the EU Digital Single Market.
  - To produce Knowledge Tools for health systems and services on NCDs.
  - To provide a code of ethics for mHealth data

- Work Areas:
  - mHealth assessment frameworks, Evidence-based mHealth solutions on NCDs, Integration of mHealth into health systems, Support for large-scale implementation of mHealth programmes, Contribution to policy frameworks on mHealth topics, Ethics
- European project with involvement of HL7 Europe:
  - Catherine Chronaki, Giorgio Cangioli, Gora Datta, Frank Ploeg
- Project timeline: 01/2020 – 06/2022
- Publications so far
  - [Health Apps Assessment Framework](#)
  - Policy & Innovation papers on Italy, Austria, Portugal

# cMHAFF Policy Guidance & Collaborations

- Review of GDPR constraints
- Submission of CMHAFF related comments to the ONC Interoperability Standards Advisory
- Meeting with the University of Arkansas Medical Sciences
- Meeting with the All of Us research project ONC/NIH
- Gap analysis between cMHAFF and CEN/ISO

# cMHAFF Recent Updates

- CMHAFF STU1 (2018) to STU2 (2021) – Approved!
  - Affirmative=36 (27 required for approval)
  - Negative=9
  - Abstained =59
  - Quorum= 78.79%
- Ballot under reconciliation– goal to complete in Q1 2022
- Further alignment with EHR-FM format
- Push toward normative

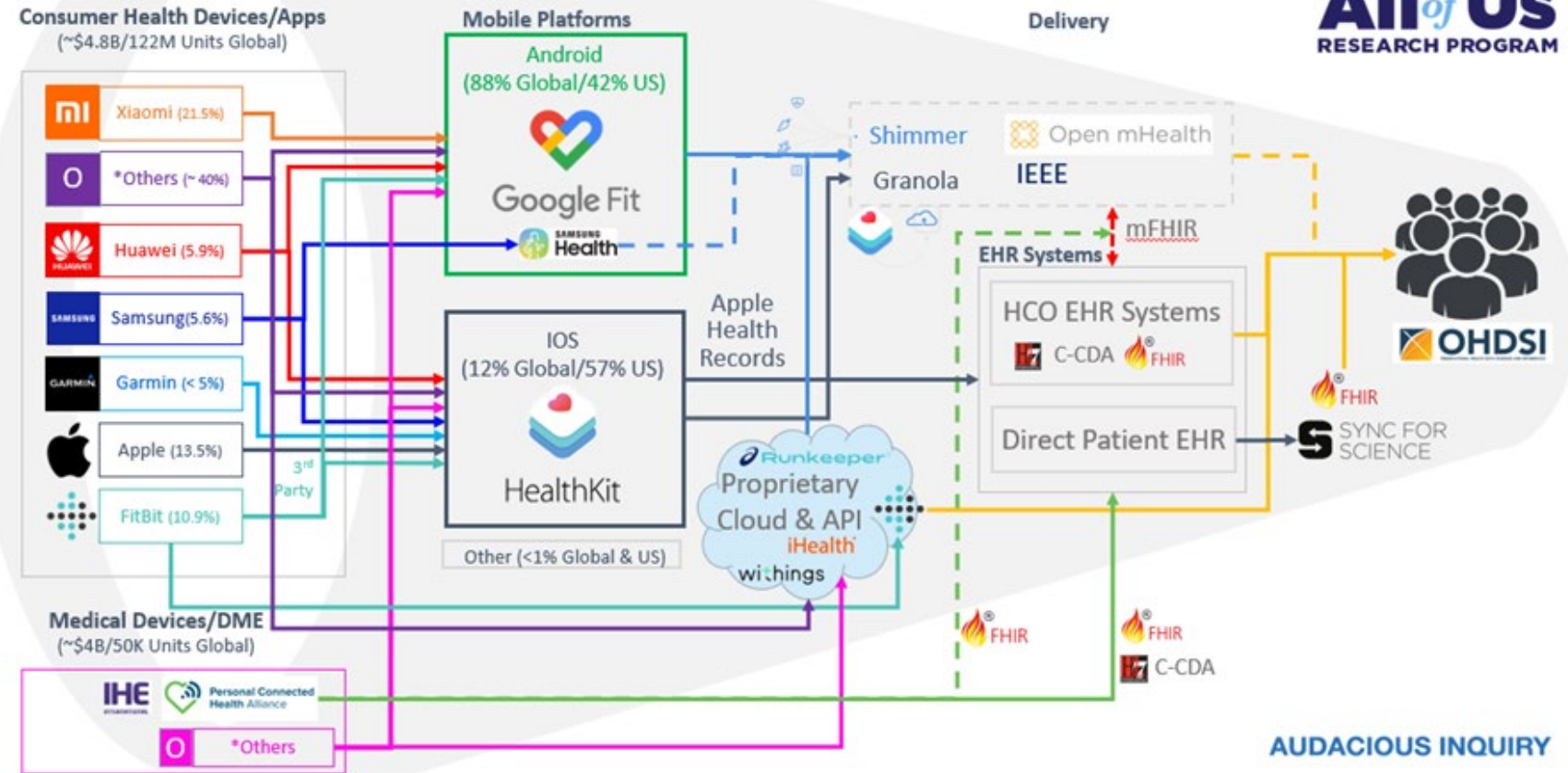
# Mobile Health App Data Exchange Project Scope

- The initial scope of this project is to analyze variation in FHIR data exchanged from mobile health apps and devices for personal health information. Because mobile health apps and devices can convey a wide variety of data including hundreds of different kinds of measurements, this project will first look at a limited scope of data, including vital signs, physical activity, sleep and blood sugar.



# Visualization

## Precision Medicine Data Funnel



# Mobile Health App Data Exchange Project

- Project Lead: Keith Boone
- Project was balloted in May 2020
- Ballot reconciliation completed September 2020
- Ballot content and FHIR Implementation Guide final review and publishing in May 2022

# Next Steps

- Ballot has past and notification has occurred
- Publication Readiness Checklist
- Publication Request has been completed [Keith W. Boone](#)
- FHIR Management Checklist for FHIR IGs
- Push latest build out and make sure all QA is complete
- Review HTA issues
- WG/ FMG and TSC approval needed

# SHIFT – Goal, Purpose and Vision

- Goal: Improve the health of students in order to improve the student's academic outcomes.
- Purpose; Improve the health of school students via enhancements to school health –based technology and services.
- Vision: Continually improving school health technology and health care services.

# SHIFT - SCOPE

- The scope of the SHIFT Project is to create a Framework that addresses the needs of various stakeholders who are involved in the health and well-being of students to facilitate learning and activities in the school environment. The White Paper envisions the set of healthcare standards that will support the Framework.

# School Healthcare Information Framework utilizing Technology (SHIFT)

- Project Leads: John Ritter and Gora Datta
- Developed Executive Summary February 2022
- Finish content and publish technical report June 2022

# Unique Mobile Health App Identifier (UMHAI)

- New Mobile Project [PSS-1867](#) ready for review September 2021
- Project Leads: Gora Datta / Matthew Graham
- Project Scope PSS-1867 reviewed by TSC and Mobile Health WG
- Project Confluence page:  
<https://confluence.hl7.org/display/MH/Unique+Mobile+Health+Application+Identifier+%28UMHAI%29+Project>

# USCDI UMHAI Proposal

- United States Core Data for Interoperability (USCDI)
- Draft USCDI V2
  - Level 2
  - Level 1
  - Comment
    - Medical Device or Equipment
      - Unique Mobile Health Application Identifier (UMHAI)

<https://www.healthit.gov/isa/uscdi-data/unique-mobile-health-application-identifier-umhai>



# Project Description

- This project will develop an Unique Mobile Health Application Identifier (UMHAI) which uniquely identifies a mobile health application instance as installed on a mobile device and used by a specific person. The UMHAI enables identification of application instance to provide precision therapy and facilitate recall, maintenance, transparency and traceability.
- The project will consider data elements which may be used to create, or incorporated in, a UMHAI. Potential data elements may include Application name, App Builder, version, build number, hosting device, and unique identifier(s) for the person.
- This effort will be aligned with existing work in HL7 standards (e.g., CDA, FHIR, V2) on UDI.

# Unique Mobile Health App Identifier (UMHAI)

- Use Cases:
  - Consumer use of Mobile Health Apps for Health and Fitness Tracking
  - Prescription of Mobile Health Apps for Care Management
  - Digital Therapeutics
  - Patient Safety and Data Privacy
  - Data Interoperability Compliance

# Benefits

- Allowing more accurate reporting, reviewing and analyzing of adverse event reports so that problem mobile health apps can be identified and corrected more quickly.
- Enhancing analysis of mobile health apps on the market by providing a standard and clear way to document mobile health apps use in clinical information systems  
A more robust post-market surveillance system can also be leveraged to support pre-market approval or clearance of new mobile health apps and new uses of currently marketed mobile health apps .
- Providing a standardized identifier that will allow App Developers and Stores and healthcare facilities to more effectively manage medical mobile health apps recalls.
- Leading to the development of a medical mobile health apps identification system that is recognized around the world.

# Project Meetings / Questions

- Mobile Health Fridays – Weekly Meeting
  - Every Friday at 11 am EST
- cMHAFf Project – Weekly Meeting
  - Every Thursday at 2 pm EST
- SHIFT Project – Weekly Meeting
  - Every Monday at 11 pm EST
- Unique Mobile Health Application Identifier
  - Every other Wednesday at 10 am EST and 11 pm EST