SPECIFIC AIMS

Mobile phones and devices, with their constant presence, data connectivity, and multiple embedded sensors, are producing tremendous amounts of data that are of increasing value and relevance to NIH's basic, translational, and clinical research mission. Mobile health (mHealth) data can provide fine-grained moment-by-moment views into physiologic, environmental, and behavioral features of health and disease states, and are thus particularly valuable for understanding complex multifactorial diseases but only if the mHealth data can be combined with electronic health record (EHR), genomic, and other data for fuller insight. Yet the rapid proliferation of APIs and platforms — many with proprietary closed standards — is resulting in a fragmented patchwork of systems that is impeding research discovery and innovation (1). *Open* data and metadata standards that reflect community needs and enable easy and accurate data sharing are thus a fundamental requirement for gaining the most value out of mHealth for discovery and health improvement.

The **Open mHealth** standard, co-created by PI Sim in 2011 and housed in its own non-profit organization, is the only existing open standard for mHealth data. It fills the standards gap for sensor and personally-generated health data by complementing lower-level device standards (e.g., IEEE 11703) and EHR data standards (e.g., HL7 Fast Healthcare Interoperability Resources (FHIR)). Open mHealth's open API, open source tools, and over 100 standard data schemas are being used in research consortia such as BD2K and PCORnet, and by leading organizations like Kaiser and Merck. The user community of ~6000 people from academia and industry are working on diverse use cases from biomedical discovery to clinical and self-care.

Now is a pivotal moment for the mHealth ecosystem. The wearables market is projected to triple in size by 2021 (2), while NIH projects on "mobile health" increased from 7 in 2014 to 238 so far in 2016. There is as yet no dominant data standard, leaving a golden window of opportunity to establish Open mHealth as *the* open data standard to foster data interoperability for research, consumer health, and clinical care across the entire mHealth ecosystem. **The goal of this project is to drive Open mHealth adoption past the tipping point to become the dominant mHealth data standard and increase the value of mHealth for research and care.** A virtuous cycle of adoption and value requires both data producers (e.g., device makers, developers) and data consumers (e.g., app developers, health systems) to embrace the standard. In prior work, we have identified barriers to adoption for these two crucial user communities: 1) for mHealth data producers, official (e.g., IEEE) standards are preferred to minimize regulatory risk and assure market acceptance, 2) for mHealth data consumers, HL7 FHIR-compliant standards are preferred to reduce their already complex tasks of health data integration. This project will drive synergistic adoption by data producers and consumers by increasing the richness and scope of Open mHealth, by securing Open mHealth's official status with both IEEE and HL7, and ensuring a sustainable community-based standards development process. Our Specific Aims are:

Aim 1: Increase Open mHealth's scientific value by expanding engagement with researchers
- Expand domain coverage via multidisciplinary **Cli**nical **Me**asur**es** schema design sessions (CLIMES)
- Extend Open mHealth schemas and tools to support the mProv provenance metadata approach
- Engage researchers to use and contribute to Open mHealth via testbeds, training, and events

Aim 2: Secure IEEE certification through extensive engagement with the developer community
- Following the IEEE Standards Development Lifecycle, draft, ballot, achieve approval of, and continuously evaluate and maintain an official IEEE Open mHealth standard

Aim 3: Develop an official HL7 FHIR mHealth Implementation Guide and test it via an open testbed
- Engage the HL7 FHIR community via a new mHealth track in the HL7 Partners in Interoperability program to define and gain approval for a new, collaboratively developed mFHIR Implementation Guide and associated FHIR extensions
- Test and evaluate the mFHIR Implementation Guide via an open testbed and other activities

Aim 4: Promote and ensure discoverability and adoption by all user communities
- Make the standard available via NIH and other relevant data and metadata standards repositories
- Conduct ongoing outreach, engagement, and promotion with new and evolving communities

Aim 5: Ensure sustainability of the standard through the Open mHealth non-profit organization
- Develop community governance through User Communities, a User Council, and a Corporate Council
- Expand corporate sponsorships and other income sources to ensure financial sustainability
- Implement program monitoring and evaluation

Achievement of our Specific Aims will catalyze a feedback loop of increasing Open mHealth adoption by mHealth data producers and consumers, which through network effects will maximize the value of mHealth data across the entire health ecosystem to speed discovery and enable more continuous, integrated and personalized care.

References

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2. Wearables Market to Be Worth $25 Billion by 2019 2015 [updated 1 September 2015; cited 2016 November 3]. Available from: http://www.ccsinsight.com/press/company-news/2332-wearables-market-to-be-worth-25-billion-by-2019-reveals-ccs-insight.