



Business Case for mHealth Open-Source Architectural and Standardized Platform

Situation Analysis:

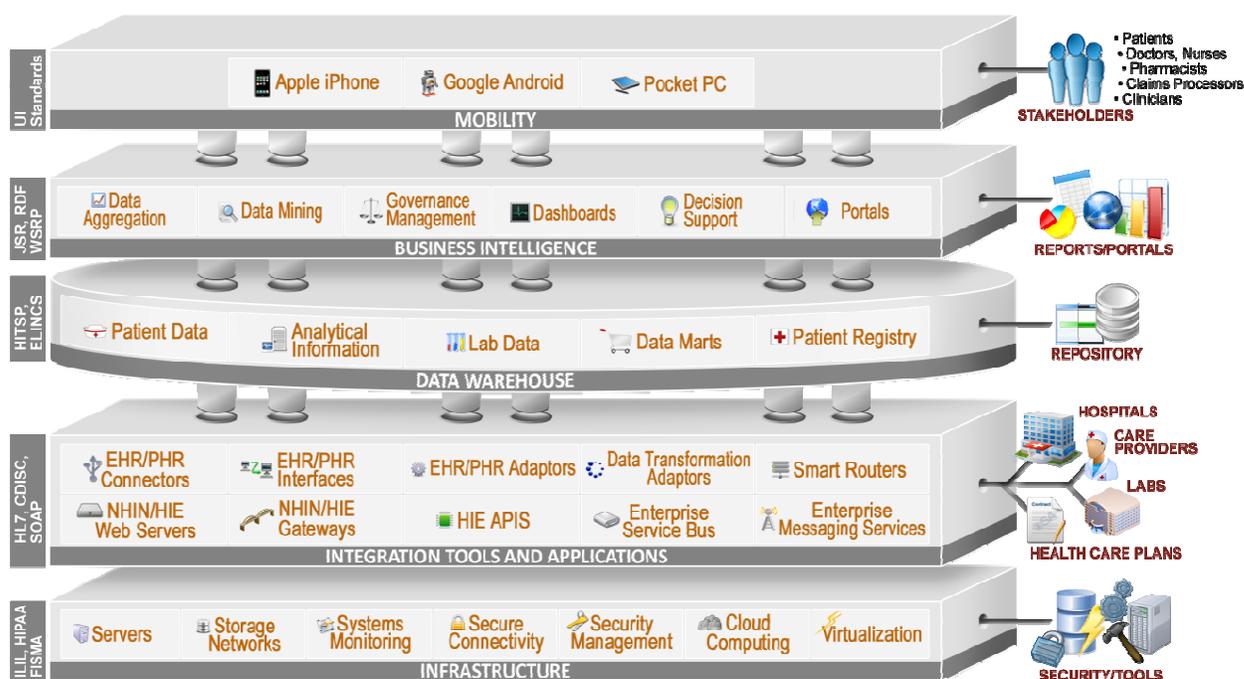
The health industry is facing a 7-10% increase in annual cost, largely due to the industry's inability to manage high costs, due in part to: chronic disease patients within the "*community in need*", fragmented processes, incomplete best practices, technology incompatibilities, organization redundancies, lack of collaboration, incomplete and low availability of on-demand information, and changing regulations/standards. A "*community in need*" is defined as one comprised of minority, underserved, and poor populations across all states with populations finding themselves in health disparity due to disease, shortage of healthcare stakeholders, age, location, culture, religion, education level, military status, and other backgrounds that contribute to disparity. The healthcare stakeholders are defined as four major groups: Provider Health Systems (hospitals, academic medical and research institute and other care organizations); Payors (government and private insurance organizations); Physicians (affiliated with providers and independent doctors and their support staff); and Patients (individuals and their family/support system). Over 75% of healthcare costs is among chronic disease patients, who represent over 35% of the population, and over 60% of them are in the "*community in need*". Chronic diseases are responsible for about 40% of deaths today.

By 2025, the U.S. healthcare cost is expected to be over 20% of the nation's GDP and nearly 50% of the population will be diagnosed with at least one chronic disease, with the "*community in need*" expected to have 65% of that share. Those with chronic diseases account for 81% of hospital admissions, 91% of all prescriptions filled, and 76% of all physician visits.

Current Commitment to Solve the Problem:

To deal with the healthcare crisis, the government and public/private sectors have come together to create a model for an efficient, value-based learning healthcare system through the innovative deployment of interoperable, open-source, and standard architectural informatics (Health Information Exchange- HIE) to address the situation. This informatics infrastructure will support the industry strategy by building the Information Management Platform. Between Federal organizations such as the HHS/ONC, NIH, VA/DoD, state-level HHS, private sectors, foundations, and the investor community, over a trillion dollars is committed to solving the crisis and over \$100 billion will be spent in HIT to deliver this model. The model Health Information Technology (HIT) is developed by building the five layers of the informatics platform detailed below. It is expected that, once properly implemented, the model can cut healthcare costs up to 30% by 2025.

Figure 1: The Five-Layered Informatics Platform



- Layer 1 - Infrastructure:** Hosting and Federated secure and regulatory/privacy compliance information services. Assure privacy by building Personal Health Records (PHRs)/Personal Data Vaults that will give patients control over their information, requiring patient approval prior for dissemination to stakeholders, in an on-demand data exchange process with storage, exchange, analysis and visualization.
- Layer 2 - Integration Tools and Applications:** Build interoperable information exchange - HIE (acquisition, integration and management).
- Layer 3 - Data Warehouses:** Data, information, and knowledge application repositories (data marts) from patient to population level information that is available on demand and on time for patient care, research, and public health studies.
- Layer 4 - Data Mining, Analytics, and Portal and Dashboard:** The use of Analytics and visualization to develop meaningful and minimum data sets for monitoring, tracking, management, and decision support across the industry stakeholders to support better care by providing tailored and targeted treatments, outcomes, and evidence-based performance.
- Layer 5 - Mobile Application Devices:** Personal mobile devices that push and pull information on demand, as needed, and on time to improve patient self-management and compliance, physician monitoring, provider management, and payor participation.

The Proposal:

The Federal government (ONC/NIH, VA/DoD) and private sector/ foundations should make the investment to establish an open-source, standards-based architectural platform to build ubiquitous, mobile device-independent applications that also interoperate with the HIE-interoperable informatics platform. Mobile applications are the front-end in delivering the best patient and population care and are driven by proven models in other industries, such as marketing, banking, music and manufacturing. This commitment to an open-source and standard based architecture will be the determinant in the success of the overall model and provide substantial Return on Investment (ROI), with savings in the billions.

The benefits of the proposed investment:

- **Clinical Research:** Enhances quality, efficiency, efficacy, and safety through improvement of workflow and on time information that will provide tailored targeted therapies; social/cultural and lifestyle/behavior characterization, regulations and standards compliance, and faster clinical research process. Improved protocol approval, adverse event reporting, drug tracking, patient monitoring and patient compliance with increased sponsor and Contract Research Organization (CRO) management and governance.
- **Healthcare System:** Increases productivity, effectiveness, safety, and integrity due to better access, intervention and continuity of care for managing acute attacks, in-patient episodes, emergencies, ambulatory/community referrals and practices (health disparities and chronic disease). Improves performance, evidence, management, incident/attack prevention, and early detection. Increased digital training, collaboration and coordination between providers, physicians and patients.
- **Personalized Medicine Delivery:** Better clinical, translational, and comparative effective research; case and disease management; pharmacovigilance and genomics; and Electronic Data Capture (EDC), Electronic Health Record (EHR), and Personal Health Record (PHR) integration due to higher collaboration between patient, physician, providers and payors.
- **Patient (Population) and Physician Levels:** higher safety and quality of care due to better critical path management and reduction in bottlenecks for the development of tailored, targeted, therapeutic treatment plan; improves point of care delivery (care access, coordination, continuity and management); management of chronic diseases and health disparity; and increase in Public Health services for prevention, surveillance, control, and epidemiology. Better and higher use of social network, higher compliance and better patient outcome.
- **Payor (Insurance):** Faster, accurate, efficient, cost-effective, and quality coding; supply chain management; case management; meaningful data, analytics use, and population studies.
- **Software (Application) Development:** Avoiding the silos of the mHealth ecosystem, will substantially save in application development, maintenance, integration and upgrade costs.

Minimizing data incompatibility will also provide substantial saving of cost and time in building interfaces to multiple systems.

- Overall, an open source and standard architecture based mobile platform will contribute to:
 - Better safety and efficacy in therapies, drugs, and devices
 - Better safety and efficiency in care process
 - Better care outcomes and value
 - Better care access, control, and management

The investment made in building the open source, standards-based architecture will deliver ROI in excess of 500% with savings in billions.

Next Steps:

- Establish organization framework, charter, governance and participants
- Running focus groups and collaboration mechanisms with participants to define standards, architecture, best practice and education mechanisms
- Server side data management, analysis and visualization infrastructure
- Pilot Mobile applications, user interface design/engagement/usability/user experience
- Development of use cases, pilot studies, and learning iteration based Authoring tools for design/configuration of new clinical interventions
- Documentation, hosting facility, operational mechanism, certification and sustainability framework
- Governmental and standards organization approval and integration