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Co-development of Healthcare IoT Software: Software as a Medical Tool (SaMT)

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June | 2018

Co-development of Healthcare IoT Software: Software as a Medical Tool (SaMT)

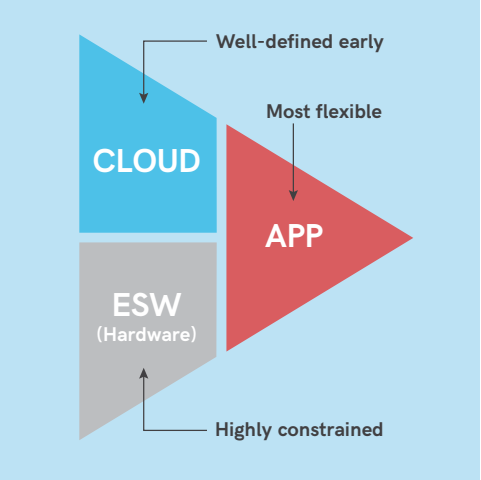
What unique characteristics in current Healthcare and Medical fields have altered the world of software developers?

To sum it up, while security and compliance remain of prime importance, today's software teams must often be adept at developing complete, connected IoT (Internet of Things) ecosystems. These connected solutions require engineering expertise in embedded systems, cloud and typically mobile or app development-skillsets that are usually dispersed across multiple development teams. The most streamlined method for developing rock solid IoT applications involves regular, well-cadenced interaction and collaboration between these teams.

Embedded system architects and app-level UX/UI developers must work hand in hand to provide an experience that is both seamless AND flawless for the end user or customer. This "co-development" requires that multiple teams make dynamic changes to software and hardware iteratively in order to arrive at the desired end product. Effective co-development processes that support cross-discipline collaboration require better integration among all of the tools used for hardware and software development, requirements, modeling, configuration management, and more. The processes rely on vigilant management of team collaboration.

IoT systems for the medical products category provide the opportunity to produce remarkably intricate software designs; however, managing separate software teams while integrating input and designs from UX/UI groups is a big challenge. A co-development approach makes it possible to minimize confusion, redundancy and bugs that could result from overlapping embedded, application and cloud efforts. Each separate piece of software must be written with clean, well-defined external interfaces that allow for easier integration with the other components. To some degree, this is good programming practice regardless of the type of software application you're writing, but it's absolutely essential to the team's success in an IoT solution.

Avoid additional dangers that lurk in the parallel development approach by prioritizing the robustness of embedded and cloud systems early in your process. This defines clear interfaces where the app can be integrated to both ends. Essentially, you want the embedded and cloud systems to tell the app software, "Here's what I can do, and what I can't do."



The Co-Development Triangle

The components of full stack IoT SW development are both separate from and connected to each other. The relative flexibility of each component drives the pace and collaborative nature of the development process throughout the effort.

Software as a Medical Device (SaMD) is defined by the International Medical Device Regulators Forum (IMDRF) as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device. Greenlight Guru expands on the FDA and IMDRF's reports by noting that the distinction is that software may interface with physical devices, but it is not an SaMD if its intended purpose is to power a hardware medical device. SaMDs are required to run on standard computing platforms. They may be deployed in combination with additional medical devices or tools.

This newly redefined IoT application encompassing medical devices, systems, users and the backend, can be referred to as ***Software as a Medical Tool*** (SaMT). IoT software project leads must prioritize work on the key components of SaMT, which are the application, the user interface, the embedded software, and the architecture of the system that allows it to push critical data through its components.

The intended uses of SaMT falls into three related categories:

1. software that streamlines workflow for medical practitioners, practices and facilitates workflows for improved efficiencies that saves money and process time, resulting in...
2. improved patient experiences, either as a system user, or as a recipient of the information drawn from the system while...
3. regulatory requirements, security concerns, patient safety, and the potentially life-altering functionality of healthcare software underpin every aspect of the process.

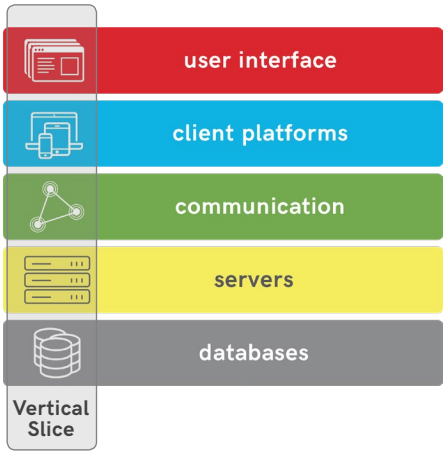
This review of SaMT methodology will explain what codevelopers of IoT systems must do to meet the unique demands of the healthcare environment.

The Software Stack for SaMT Medical Solutions; Successful Integration

In our paper Traversing the Software Stack, we reviewed the software stack elements used in developing enterprise applications that deliver a high-performing, secure solution.

And while the basic stack components are the same for SaMT system development, there are clearly shifting priorities for medical industry products provided to patients, caregivers, and medical staff users. (Note: the FDA endorsed agile methodology in 2013, and it has since been used to develop compliant medical software.)

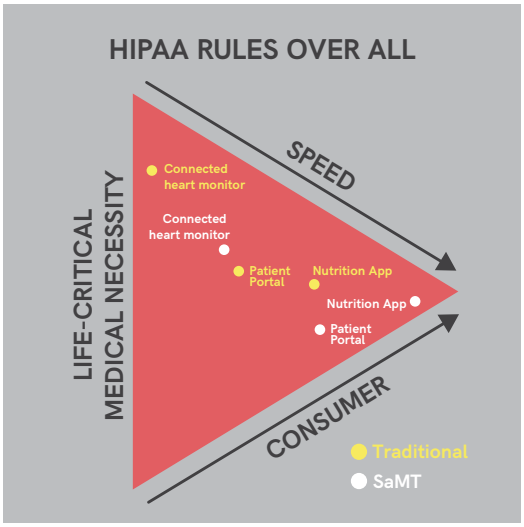
Security is a primary concern across the SaMT stack, at every stage of system development. Most software teams would agree that security is the focal point of the Server and Database layers in the software stack. A team that can vertically slice through all layers can adapt their security coding practices to build secure User Interfaces on secure Client Platforms with secured Communication endpoints.



The SaMT SW Stack

Development teams enabled to vertically slice through all the layers in quick iterations can adapt their security coding practices to build secure UI's on secured Client Platforms with secured Communication endpoints more quickly and efficiently. Those teams structured to develop only one layer of the stack at time cannot deliver fully operational pieces of the application as quickly.

The quickly-changing, agile development world we live in is encroaching upon the medical industry as a whole. Patients, caregivers, and even clinicians are all pressuring the industry to bring solutions to market quickly. However, they must strike a balance in order to maintain and preserve safety of patients and any users of a SaMT. *The amount of flexibility and speed incorporated into the agile process will be directly proportional to the impact of the SaMT on patient results and the criticality of the tool to life-critical care.*



Traditional SaMD versus SaMT

Speed to market and consumer appeal are often at odds with life-critical medical necessity. While many medical SW applications remain beholden to this, products such as nutrition or fitness apps, or even some patient portals and health monitors can be developed with a greater focus on speed, agility and consumer appeal.

User Interface

Historically, the focus of software solutions for medical systems has been on the Server and Database stack layers. For two decades, HIPAA has driven the primacy of patient data privacy, which naturally falls into these bottom layers of the stack. However, in today's consumer-focused smartphone world, the value any system provides is largely driven by the user interface and experience. Within the User Interface layer, SaMTs have the biggest opportunity to make a difference.

For example, a surgeon performs a successful total knee replacement and immediately after the one month follow-up visit with her patient, she dictates all relevant notes for the record into her digital recorder using a speech-to-text software application designed for this purpose. At the patients' three month follow-up visit, those notes are displayed on the examination room monitor for convenient reference. A simple, clean interface provides a pleasing and efficient interaction for all stakeholders: the surgeon, her office staff, the patient, the payer, and the hospital records.

All of the new rules still apply to SaMT user interfaces. The interface must be crystal clear and focus on ease and clarity of use. The developers' and UX/UI designers' mission is to create an experience that is easy and intuitive, with no ambiguous features. The risk of human error must be significantly reduced – always with the goal of eliminating it altogether. When user errors do occur, the interface should provide a well-defined method of recovery.

The user experience on a smartphone app is successful when the developers and UX team keep the end-user in mind along the way. In SaMT, this link is crucial. Usability must be smooth and flawless, mapping various users in their realistic settings, not in idealistic environments. Developers must understand the circumstances a user will face when using the software. For example, patient users may be under emotional or physical pain, nurses may be using the system while multi-tasking, and doctors are interested in efficiency to keep up with their busy schedules. It's important that any "noise" is cut out, and the user interface emphasizes only that information which is critical to the target end-user.

The importance of the user experience

PwC reports on Customer experience in the New Health Economy: The data cure. According to this report, healthcare leaders are making the user experience a top priority:

- 49% of provider executive say customer experience is a top strategic priority over the next five years.
- 81% of payer executives say their company is investing in technology to improve the member experience.
- 91% of pharma executives believe that patient self-management will increase over the next 10 years.

Client Platform

Health IoT developers should select a platform that works best for the intended use instead of depending on technology that they're comfortable working with. Some solutions may call for a traditional Windows, Android or iOS app, while others may require an embedded Linux environment that's tightly coupled with a medical device. This is an area where IoT developers will need to adapt to the industry environment, and not the other way around.

When collaborating with a client to choose a platform, there may be market considerations and also hospital-specific or practice-specific considerations impacting the choice. Many practices and facilities access scheduling software and patient information on mobile tablet devices. In these environments, security must be a primary concern. Security will dictate the coding standards.

Medical applications, such as asset tracking tools, will often interface with various external hardware systems; hence the platform must have the ability to be integrated with ease. For embedded software to communicate effectively with the platform, developers must determine the interactions and limitations between the software and hardware, taking into account that SaMT embedded software is typically written to work on a device other than a computer, such as a pill bottle, heart monitor, glucose monitor, or pacemaker.

Communication

For SaMT development, it is better to establish clear interfaces between components that can be tested and proven independently with regards to security and performance. In the Communication layer, security between hardware and software components is a key requirement. Security must be strictly maintained for all protected health information (PHI) as it flows throughout the system.

The critical imperatives of potentially life-saving accuracy and patient privacy:

SaMT systems cannot transmit data inaccurately or unreliably. Examples of potentially life-saving data communications:

- Patient's information on lab samples
- Asset counts for surgical equipment
- Medication dispensing systems or drug infusion pump
- Vital sign monitors

The FDA published an article on Cybersecurity that states while wireless technology and software in medical devices increase the risk of potential cybersecurity threats, these communications features enable and improve healthcare and increase the ability of health care providers to treat patients. This is at the root of the FDA's efforts to prevent cybersecurity threats.

Servers

The backend, also known as the server side, contains the logic and data that operates the application. Users do not interact directly with any of the backend components, but they depend on an accurate performance that results in actionable information. Software application backend malfunctions can result in huge losses of time and money. SaMT has the added burden of affecting public health and the potential loss of life.

According to Gartner 7 Top Security Predictions, by 2020, at least one major safety incident will be caused by an IoT security failure, leading to significant injury.

> *"A temporary loss of power from a failed power grid is inconvenient, a loss of control by an automated medical device administering a drug could be dangerous. It is easy to imagine a scenario that an IT failure could have a physical safety outcome. The increasing complexities of connections means things and infrastructure with different levels of security are now interacting. It will be difficult to predict the risk that will arise."*

The means to a successful back-end or server-side SaMT development is an iterative learning environment. A co-development process for hardware and software collaboration is the best way to get a medical system to market.

The FDA has a document that explains General Principles of Software Validation for medical devices.

The effective back-end testing process for SaMDs is:

- Code reviews: Source code is evaluated against a baseline to verify it performs as intended and meets the design specification.
- Static analysis: Identifies potential and actuals code defects without executing the software. It will discover any run-time errors in the source code.
- Dynamic testing: check the execution flow of inputs, and outputs. Although this is the most difficult testing method, dynamic tests expose defects through use cases.

State-of-the-art pacemakers may contain up to 80,000 lines of code, while infusion pumps may have more than 170,000 lines of code. These devices must provide the utmost in safety and reliability.

Medical software is no different from systems in other industries when it comes to the need for server scalability. An SaMT solution's focus is on security and accessibility; developers are required to work with hosting solutions and IT infrastructures to put failover provisions in place. The medical tech industry is very familiar with this concept already.

As SaMT solutions push medical systems towards more open interaction with consumers, traditional med tech server backends are being taken out from behind corporate firewalls and placed on the open internet, creating a new level of exposure. Thankfully, trusted and true IoT testing techniques can be easily incorporated in SaMT.

Databases

The need for data accuracy and availability through robust reporting capabilities weighs heavily with healthcare software systems. Real-time access to patient data can save lives.

EHRs allow medical practices to use data analytics along with big data to understand health conditions and manage local populations. Embedded software provides an extra layer of complexity to the process. Medical devices require dedicated data management to handle requirements, such as constant data collection and distribution.

Two important data issues are:

- regulatory requirements for confidentiality (HIPAA), such as an audit trail.
- interoperability so that systems integrate and work together without restriction to provide useful information or patient solutions.

These data issues are often at odds with one another, one requiring the restriction of data sharing while the other requesting data openness. An SaMT solution must strike a fine balance between these requirements.

Earlier we mentioned that part of the SaMT value is driven by the user interface experience, but clearly the data opportunities in SaMT solutions provide much of the core system value.

Software/Hardware Collaboration

Entire teams work together to bring medical IoT products to market, and applications featuring SaMT's are no different. Success is due to collaboration amongst teams with the knowledge to work across all levels of the SaMT stack in a coordinated effort. To design and develop a fully integrated, connected medical device, individuals or teams with the following areas of expertise are key:

Industrial Design
Industrial Designers create concepts and final design for a device that is easy to use, efficient and aesthetically pleasing to the end user.

Mechanical Engineering
Mechanical Engineers integrate all components into the design, ensure that they perform as intended and that the device can be manufactured without difficulty.

Systems Architecture
These engineers design the framework for how the connected device will communicate. They code and test the embedded software and diagram the flow between device, application software and the cloud.

Software Application Engineers
Application Engineers write the code so applications work with the embedded software and required devices.

Electrical Engineering
Electrical Engineers select relevant components to sense and monitor and process data in the device as well as modules that push data from device to cloud.

UX/UI Design
User Experience and User Interface Designers create the look and feel of the application to provide a smooth, intuitive and enjoyable experience for the end user.

Conclusion

Data availability is the game changer. What we now know as "big data" allows the medical field to perform at an impressive level of detail while data at the end of the consumer's fingertips enhances the experience and increases the level of care. Health care providers and practitioners, along with their patients, want this enhanced experience. A device or application that is cumbersome or awkward to use, or an interface that is unpleasant, slow or confusing is counterproductive to care and healing. Consumers will avoid using them and in the end, these products will not succeed in the marketplace. Whether a doctor, an MRI technician or a patient, the interfaces provided to end users will drive much of the success and impact of these new medical products. Every aspect of medicine and medical care are impacted.

If we look at the software stack in reverse beginning with the backend, the database design sets the groundwork for any SaMT. The servers and communication layers dictate how the database information will be processed, stored, and shared. Following, the client platform has been redefined to encompass devices other than a computer, many of which we certainly have yet to see. And finally, this is all moot if the SaMT is not presented with a perfect interface that allows users to achieve the tool's intended benefits.

There have been few significant life-changing advances in the history of medicine. Many would put penicillin, organ transplant, anaesthesia, insulin, DNA, vaccines, and x-ray imaging on this relatively short list. It is truly amazing to realize that we are once again living through another time of such radical transformation. History will surely reflect on how internet technology has improved patient care. Specifically, IoT and SaMT technologies are saving lives and bettering the quality of life for patients under care and treatment. It's up to everyone who develops medical technologies to ensure that the advancements made with these new capabilities perform flawlessly.