

How the Internet of Things Is Transforming Medical Devices

The IoT is expanding the sensory capabilities for all products by providing visibility into the field and usage patterns, unleashing transformative opportunities for the entire ecosystem of caregivers, patients, payers, medical devices and pharmaceuticals companies. The lack of standards, a crowded product landscape and the relatively nascent stage of technology compel medical device companies to carefully craft their IoT strategies.

Executive Summary

Information technology reinvents itself every few years. The dawn of the Internet, the arrival of Web applications, ubiquitous mobility access and social networks have all altered the contours of technology's uplifting possibilities. Social scientists who study how society embraces newer forms of IT note the continued enthusiastic and accelerated acceptance; for example, it took social networks much less time to reach widespread acceptance compared with Web applications.¹

The effort to get most of the world's 7+ billion people on the Internet has nearly come to fruition. And with the emergence of the SMAC Stack (aka, social, mobile, analytics and cloud technologies), digital fields (or Code Halos²) that surround people, processes, organizations and devices offer deeper understanding about how individuals interact and transact online. This in turn has

driven the hyper-personalization of products, services and offers.

The emergence of the Internet of Things (IoT) - where physical devices are instrumented to capture and transmit data covering everything from environmental conditions to usage patterns and user behaviors - is arguably the next wave of information technology advancement. The "things" in IoT can refer to a wide variety of devices - implants, sensors, automobiles, buildings, etc. The expanded sensing and communicational capabilities of these "things" is a harbinger of new business possibilities. Industry leaders, academics and analysts are unanimous that IoT constitutes the third big wave of the Internet.³

Estimates indicate that some 12 billion devices are already connected to the Internet. This figure is expected to grow to 50 billion devices by



At a Glance: The Connected Devices Space






IVD devices	Physiological Monitors	Mobile Medical Apps	Wearables	Capital Intensive Devices
				
Blood Analyzers Immuno-assays Breast Biopsy Equipment HIV Detection Systems	Weighing scales Pulse Oximeter BP Meter ECG Ventilators Blood Glucose Meters Heart Rate Monitors	Medication Adherence Systems Dosage Calculation Systems	Activity Tracker Pedometer Sleep Apnea Detector	Implants Prostheses MRI/CT/ Ultrasound Scanners

Figure 1

2020 - multiple times that of the human population.⁴ Advancements in wireless technologies, the continuing fall in silicon costs and unprecedented miniaturization are all aiding this growth. A recent McKinsey study reveals that linking the physical and digital worlds could generate anywhere from \$4 trillion to \$11.1 trillion a year in economic value by 2025.⁵

The IoT's power lies in connecting dots in an innovative fashion. The transformative possibility is evolving across the broad spectrum: Connected homes, connected healthcare, connected factories and connected enterprises. In connected healthcare, connected medical devices are delivering a unified view across patients, devices, diagnoses and medications. The entire ecosystem - caregivers, patients, payers and providers - is experiencing a new level of engagement that results from remotely monitoring patients and remotely maintaining connected equipment, thereby providing visibility and insights about exercise regimens, diet and vitals.

Increasingly digitally-savvy customers, the focus on overall experience and new connected possibilities have propelled the medical device industry to seriously explore IoT's short- and long-term business possibilities. This paper examines how the IoT is transforming the medical device space, and how medical device companies can harness the IoT's potential.

Digitization & Medical Devices

Industries across segments are moving from selling products towards selling services: wind turbines, locomotives and jet engines are now sold as services. Concomitant to this is the rapid digitization of business processes and the attendant innovations that spur new business models based on outcome, reduced risk and metered usage.

Not surprisingly, the IoT is making strong inroads in the medical devices industry. Medical devices companies are transforming themselves from devices/consumables providers to disease/care management organizations. Digitization in acute care, chronic care or in adherence is greatly aided by IoT-powered medical devices such as subcutaneous drug delivery units, continuous glucose monitors and vitals monitoring equipment.

There are also more fundamental shifts forcing medical devices companies to reinvent themselves: the consolidation of group purchasing organizations (GPOs) and accountable care organizations (ACOs) under healthcare reform, the growing focus on prevention and wellness management, technology convergence, value-based healthcare, etc. The arrival of digital enterprises such as Google and Apple into the consumer health space is ushering in new possibilities. The confluence of all these currents has led medical device companies to innovate from within or via deeper ecosystem collaboration. For

example, pharmaceuticals companies are now forming partnerships with medical devices enterprises to help increase adherence.

Sensors and embedded software are now integral parts of most of the mechatronics medical devices. Medical technologies range from implantable devices, capital-intensive diagnostic and monitoring equipment, to mobile medical apps. Figure 1 (on preceding page) illustrates the diversity.

Three distinct drivers for medical devices industry digitization have emerged:

- **The need to increase operational efficiency:** I.e., preventive maintenance of devices, remote diagnostics and software upgrades, etc.
- **The ability to innovate digitally:** I.e., the need to digitally communicate vitals and device information.
- **The creation of industry ecosystems:** I.e., the ability to link devices and systems together -

implants, wearables, diagnostics, monitoring devices, health records, etc.

Medical devices present unique IoT challenges. These include the wide spectrum of therapeutic areas, the broad range of medical technologies, the diversity of network protocols, critical security and vulnerability considerations, regulatory compliance imperatives resulting from the handling of patient data and stakeholders with varied interests.

The 3C Model

Medical devices makers need a concerted IoT strategy to drive business success. The true value of IoT lies in its transformative potential and innovation. A passionate community is required to provide leadership and drive the initiatives across the organization. As there is a large set of solutions in the marketplace, it is essential to understand how and when a particular solution is relevant for a medical devices company. Creating assets helps in

Quick Take

Devising an Enhanced Monitoring Environment

A leading U.S.-based medical devices and consumer goods manufacturer needed a better way to monitor, provision and maintain thousands of its devices in the field. Due to lack of connectivity to the devices, any access to information stored internally on the device required that highly trained personnel visit each customer site and tend to each device. This manual process was error-prone and burdensome for the sales reps.

The company engaged us to help understand the IoT's transformative possibilities. We helped in the design of a connected device infrastructure. Functioning as system integrators, we also conceptualized and implemented an IoT architecture to remotely monitor the company's thousands of devices in the field.

Projected results:

- Savings of \$6 million annually as devices can be attended to remotely.
- ROI in less than one year as the saved sales time can result in additional revenues.
- Improved customer satisfaction resulting from smooth and timely software upgrades.

- Faster deployment of software updates as the need for physical presence is removed.
- Better device performance overall as the software within the device is constantly kept up-to-date.



Quick Take

Managed Care Services Provider Brings IoT Home

Kaiser Permanente, the global leader in managed care services, wanted to provide care to its patients in the place most convenient for them – at home. The health organization also sought to improve connectivity between hospitals, clinics and medical devices to enable secure, remote, real-time access to patient data.

Working with us, Kaiser Permanente created a remote patient-monitoring system prototype powered by Microsoft Azure IoT cloud computing services. The system connects to smartphones and devices such as blood pressure and glucose meters in patients' homes and integrates the vitals with analytics. The cost of care is reduced as vitals are recorded at home and visits to the clinic/lab are eliminated. Physicians get real-time access to data facilitating proactive healthcare.

Projected results:

- Enhanced patient care and safety.
- Reduced outpatient visits for routine checks and reporting of vital signs.
- Near-real-time remote monitoring of vital signs, and automated alerts.
- Better insights into patient data.
- Improved efficiency and workflow for nurses and other care providers.



standardization, consistency and cost efficiencies. Figure 2, on next page, illustrates the 3C model, which aims to address these drivers.

Community of Practice

Since the IoT could fit the needs of various divisions within a medical devices company, we suggest that business leaders set an overarching direction to ensure coordinated efforts. This begins by establishing a collaboration-oriented community of practice (CoP) for IoT (see Figure 3, next page). This will function as a clearing house for best industry solutions, provide strategic direction, set governance and ensure broader alignment with the enterprise goals. An important point to note is that IoT efforts should be considerably top-down driven.

The charter of a CoP could vary depending on the size of the enterprise and the strategy. Broadly, the mandates could include evangelization, training sessions, thought leadership, proof of concept applications, standards/best practices and governance. The CoP can use media such as exploratory programming events/hackathons

to unpack technology trends, enhance ideation and innovation, and spot talent.

The CoP can consist of business architects, divisional heads, enterprise architects and product owners. It can be embedded into the CIO organization to help provide organization-wide visibility and impact.

Cultivate Partner Ecosystem

Rather than reinventing the wheel, it is prudent to harness best-in-class solution frameworks and proven methodologies, and to work collaboratively with partners. In the IoT world, there is a diverse array of solutions and partners to consider (see Figure 4, page 6).

By cultivating a strong partner ecosystem, medical devices companies can benefit by mitigating concerns around regulatory requirements, accelerating time-to-market and reducing technology risks. Figure 5, on page 6, reveals considerations that will help guide the right choice of solution.

Modeling IoT Best Development Practices

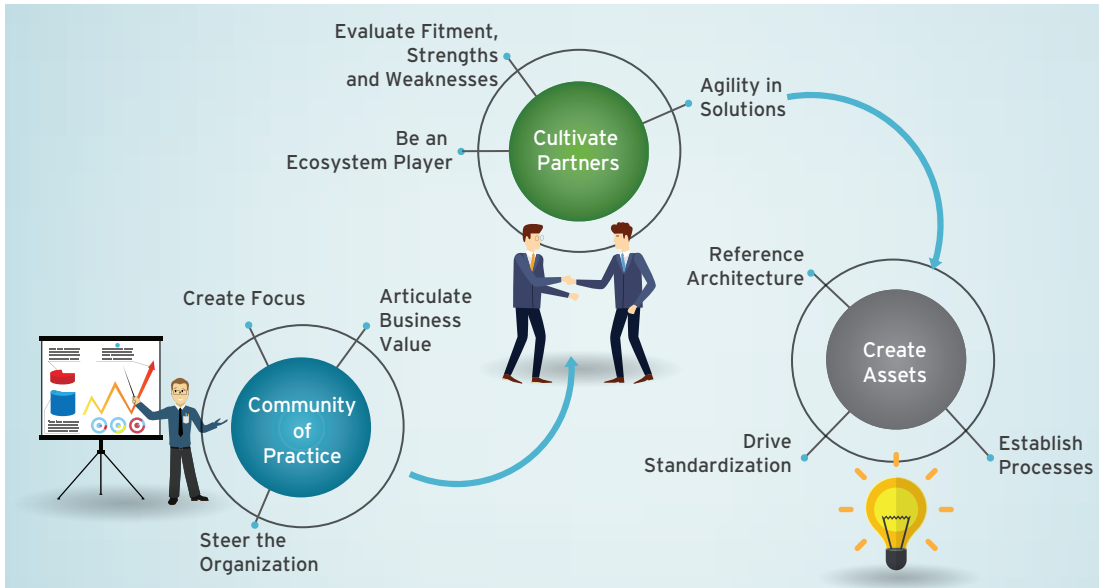


Figure 2

Create Assets: Building a Reference Architecture, Tools, & Templates

Medical devices companies must consciously build a reusable assets repository based on project executions, PoC, etc. The assets could be in the form of templates, guidelines, reference implementations, tools, reference architectures, etc. This asset base will help jumpstart new initiatives by providing the basic framework. Considering the complex challenges, we have created a reference architecture (see Figure 6, on page 7).

Our architecture consists of the following:

- **A medical device agent** is the layer that will reside on the medical device, providing information processing capability. The agent would register/provision the medical device and establish connectivity. It would capture the medical device data and provide security. It would also provide services like troubleshooting, software upgrades, etc. Moreover, it would execute the commands from middleware.
- **A medical device communicator** will also reside on the medical device and work closely

Setting up a CoP

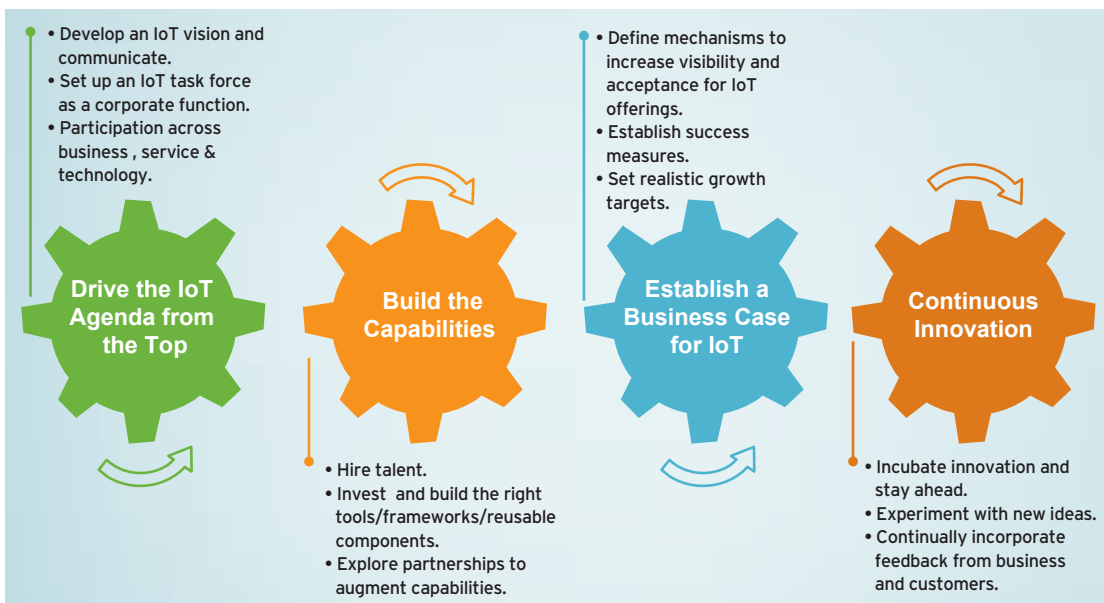
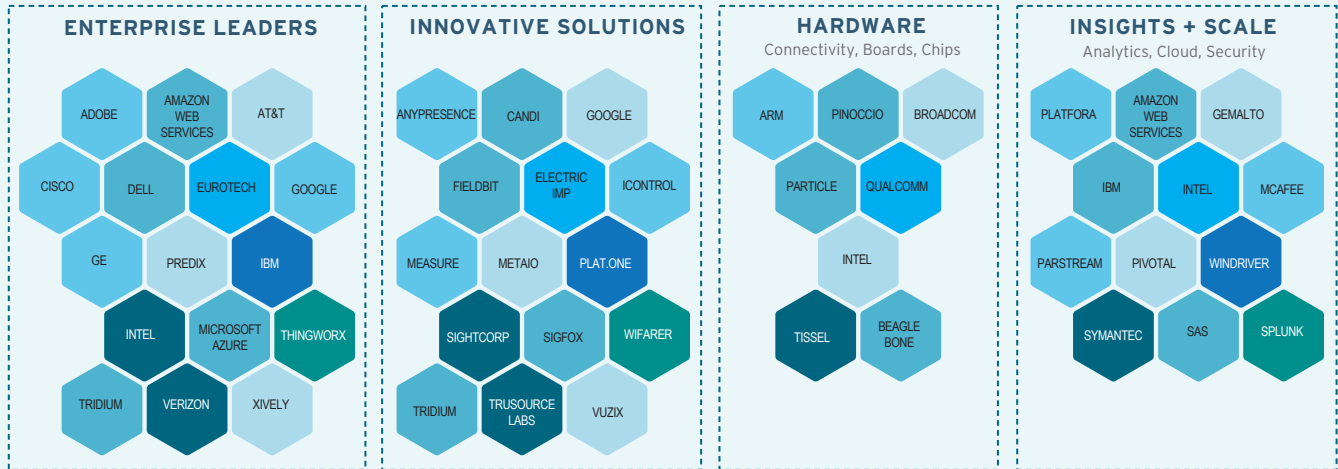


Figure 3

Partner Ecosystem



Note: Chart is indicative, does not cover all players and does not represent any endorsement.
Figure 4

with the medical device agent. It provides the connectivity from the device to other medical devices via middleware.

- **The middleware** consists of the following components: Gateway services, data processing services, device management services, algorithm services, storage services and application programming interface (API) services. The objective of this layer is to process data from medical devices and create consumable data sets for reporting and analytics purposes.

- **The consumption layer** is the means by which users consume information. Several types of applications can be built using the information gathered (i.e., cognitive analytics, a data scientist workbench, dashboards, and administration and user portals). For example, portals can be built for individual user communities such as healthcare providers, caregivers, patients and data scientists. A data science workbench can be created to provide access to data and facilitate the creation of new explorative programs for detecting patterns.

Illuminating a Way Forward

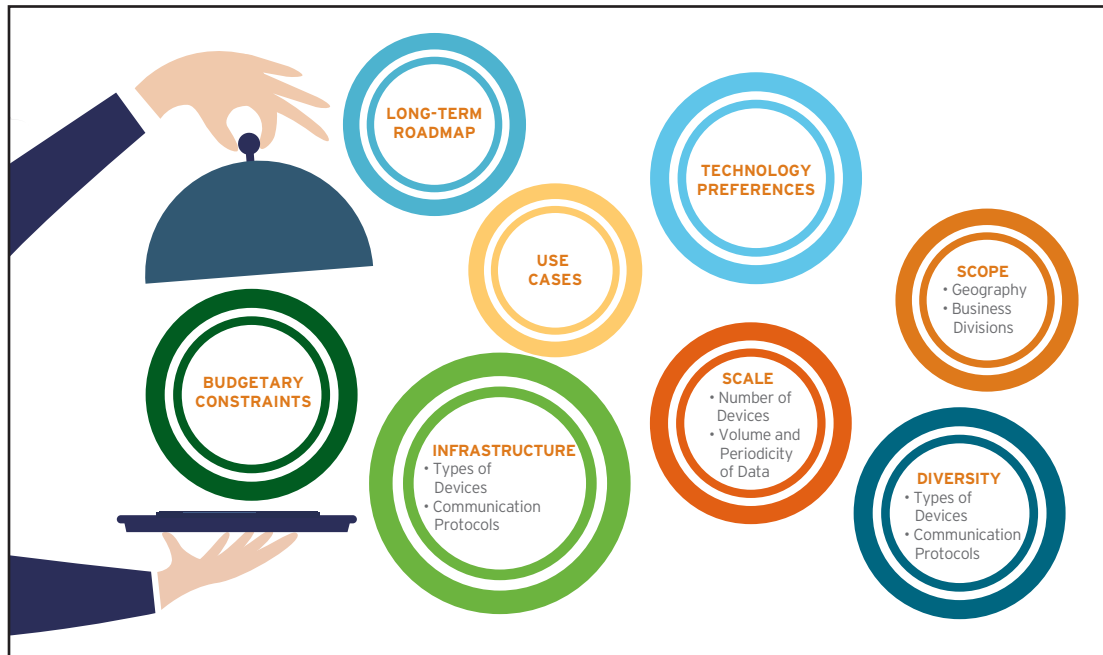


Figure 5

Reference Architecture

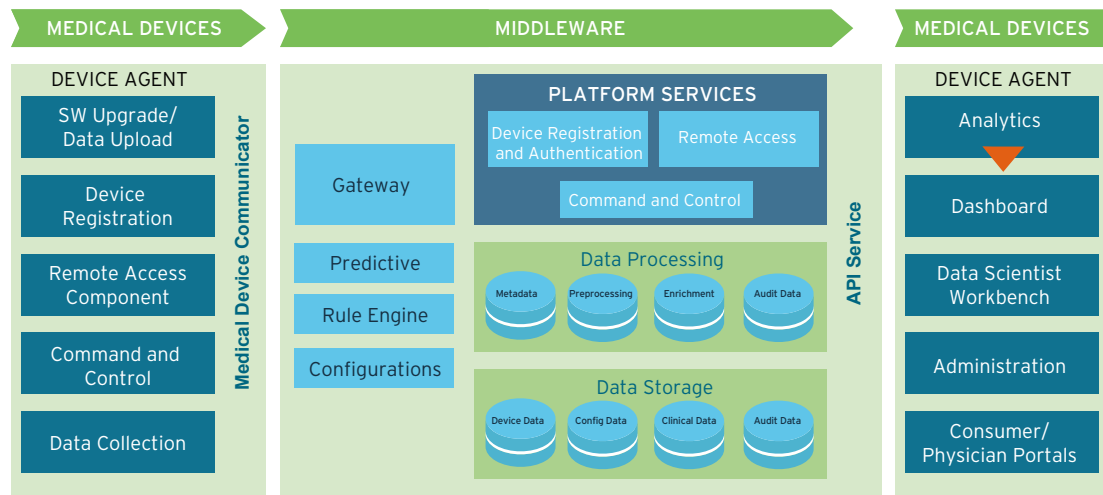


Figure 6

This architecture can be implemented in the cloud or on-premises. Due to elastic capabilities of cloud computing, it is emerging as the preferred choice. Privacy and security features are built into all layers of the architecture.

Given the cross-disciplinary nature of the IoT, the 3C model offers insights that can help steer the initiative, build the asset base and identify the most appropriate partners. Executed correctly, this model will pay rich dividends by focusing on creating transformative business outcomes with improved cost efficiencies.

Looking Forward

The complexity of medical device IoT is the result of the wide spectrum of medical devices that use different data communication protocols. We expect interoperability between devices will improve as standardization takes hold. Communication consumes a great deal of power in devices, and with the explosion of the number of IoT-enabled devices, we expect considerable advancements in energy harvesting technologies.

Social concerns of unlawful invasion to privacy must also be addressed. Moreover, there is genuine concern around how a device can be used to track movements of people. By enabling the medical devices with network connectivity capabilities, hospitals/patient home networks significantly increase the risk for data exfiltration. The U.S. Federal Drug Administration (FDA) has provided guidance for managing cybersecurity in medical devices.⁶ We expect security-related offerings in the IoT to have a vigorous interest in the years to come.

And as the technology evolves, we expect to see a strong convergence between machine learning⁷ and the IoT. The high velocity and enormous volumes of data generated by medical devices are a perfect fit with the capabilities of machine learning. Diagnostic equipment failure can be predicted by machine learning techniques. Decisions on production quality control in a vascular stent manufacturing unit can be made by applying machine learning techniques on IoT data.

We foresee that the digital divide between industrial IoT and consumer IoT will start to dissolve, giving rise to new business possibilities. For instance, the replenishment orders for nutrients used in a medical pump may find its way from consumer to logistics to production planning. In an abstracted and consumable form, medical device companies will be able to demonstrate how an ecosystem of devices work together as a way of providing transparency and facilitating more informed consumer decision-making.

Medical devices are likely to have built-in user preferences to control how personal data is communicated and shared. Consumers may opt to allow devices to communicate only the device's health status or allow exchange of full information, or various combinations thereof. We expect, in the next few years, user-controlled connected medical devices to become ubiquitous. The progression of the IoT is set to unleash new frontiers in customer-centricity with unprecedented levels of digitization in the medical devices industry. Is your organization ready?

Footnotes

- ¹ <http://digitalcommons.unl.edu/cgi/viewcontent.cgi?article=3114&context=libphilprac>.
- ² *Code Halos: How the Digital Lives of People, Things, and Organizations Are Changing the Rules of Business*, by Malcolm Frank, Paul Roehrig, Ben Pring, John Wiley & Sons, 2014. <http://www.wiley.com/WileyCDA/WileyTitle/productCd-1118862074.html>.
- ³ Simona Jankowski, "The IOT as the Third Wave of Internet" Goldman Sachs Global Investment Research, September, 2014. <http://www.goldmansachs.com/our-thinking/pages/iot-video.html>.
- ⁴ Dave Evans, "The Internet of Things," Cisco. http://www.cisco.com/c/dam/en_us/about/ac79/docs/innov/IoT_IBSG_0411FINAL.pdf.
- ⁵ "Unlocking the Potential of Internet of Things," McKinsey Global Institute Report, June 2015. <http://www.mckinsey.com/business-functions/business-technology/our-insights/the-internet-of-things-the-value-of-digitizing-the-physical-world>.
- ⁶ <http://www.fda.gov/MedicalDevices/DigitalHealth/ucm373213.htm>.
- ⁷ Machine learning gives computers the ability to learn without being explicitly programmed. By looking at the mounds of data from IoT sensors, machine learning algorithms can predict trends, detect anomalies, send alerts, etc.

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About Cognizant

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