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How Digitization Is Changing Medtech, Life Sciences, and Healthcare

The future of healthcare through the lens of technology

The Rapid Advance of Technology in Medtech, Life Sciences, and Healthcare Businesses

Just as necessity is the mother of invention, the recent rush of digital advancement across the Healthcare and Medical Technology sector these past few years can be traced back to the COVID-19 pandemic. When traditional in-office visits were no longer advisable, or even possible, telehealth solutions leveraging internet-based devices provided a way for doctors to still be able to track their patients' health. The use of telehealth solutions more than doubled as a result.

The growing prevalence of chronic diseases and the growing number of patients managing their own healthcare have both further accelerated digital advancement. Portable wearable devices are enabling physicians to remotely monitor a patient's blood pressure, heart rate, blood sugar levels, oxygen saturation, and other parameters related to their specific medical condition. New diagnostic applications that leverage the power of artificial intelligence (AI) and machine learning (ML) are creating new opportunities and advancement in the Medical Technology space, attracting a new generation of entrepreneurs. Collectively, these events have propelled digital health utilization to new heights, creating both challenges and opportunities throughout the industry with the expectation of lasting impact.

The rapid and ongoing digitization in Medtech, Life Sciences, and Healthcare will drive significant advancements across virtually all aspects of healthcare, creating the potential for the industry to deliver better health outcomes more often, for more people, more efficiently. But realizing such benefits will require equally widespread transformation, particularly to enable and improve operational agility and to embrace the critical and pivotal role data now holds. In this paper, we will provide insights that will shed light on the future of increasingly digitized healthcare in areas such as medical software development, digital health platforms, healthcare information exchanges (HIEs), internet of medical things (IoMT) and smart healthcare systems, telehealth, and health data intelligence and diagnostics (HDID).

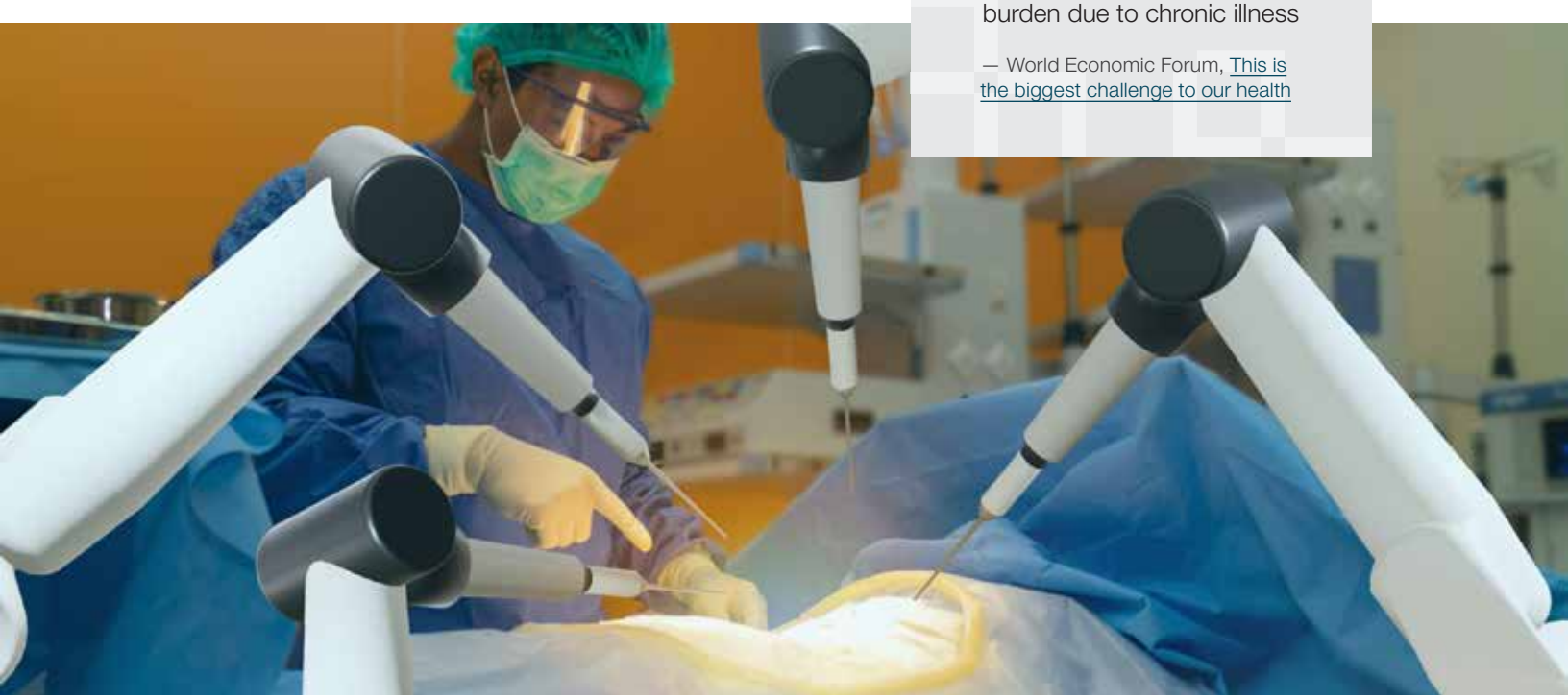
More than

50%

and growing

Portion of the global disease burden due to chronic illness

— World Economic Forum, This is the biggest challenge to our health



Digitization Will Raise New Challenges in Medical Device Software Development

Increasingly Pervasive Regulations

As a highly regulated industry, medical device production requires clearance and approval by a governmental regulator before devices can be sold commercially. To attain this approval, medical products need to be developed and tested in accordance with the harmonized standards that govern medical device software, namely ISO 13485, ISO 14971, IEC 62304, and IEC 62366.

Only companies that have quality management systems (QMS) in compliance with ISO 13485 are eligible to develop these products. Increased regulations and process compliance are now required for in vitro diagnostic products and are now at a level similar to the regulations affecting Medtech and Medical Device companies over the past two decades. Software product development and engineering service offerings must therefore come intertwined with deep regulatory expertise.

The Proliferation of SaMD Applications

Over the last few years, the Medical Devices industry has seen exponential growth in the category of Software as a Medical Device (SaMD) mobile and cloud systems. SaMD applications are becoming more commonplace within medical device systems, either as systems of care applications or medical device accessory applications (e.g., diabetes insulin dosing). Engineering firms that have only limited skills with embedded systems or lack the resources needed for developing software for newer mobile and/or cloud-based systems will need to find a way to bridge that capabilities gap.

Medical Device Software Development spans embedded software systems for:

- Patient monitors
- Surgical robots
- Cochlear implants
- External and implantable cardiac defibrillators
- Insulin pumps / glucose monitors
- Spinal cord simulators
- Pain management systems

SaMD products are also regulated under ISO and IEC standards and include:

- Patient engagement applications on mobile devices that are associated with diagnosis or therapy
- Patient and healthcare clinician applications deployed on healthcare networks and clouds used for making patient treatment decisions

From an industry perspective, we consider Medical Device Software to be embedded software encapsulated within a medical device (including an in vitro diagnostic instrument), or any software that is standalone used for diagnosis and treatment of an individual patient, as SaMD software.

The Rising Cost of Customer Support

One of the major challenges medical device companies face is around the issue of customer and product support. Unlike with traditional embedded applications, where the manufacturer had a high level of control of the product environment, with mobile phones, when applications are released, global regulators expect the manufacturers to have a robust, sustainable product support plan in place to deal with the weekly or monthly changes and updates for commercial mobile operating systems and the potential impact of these on the SaMD application. This creates a resource and financial burden for manufacturers since they are not experts in this area. Medical device companies will require access to mobile OS (iOS/Android) expertise combined with experience with relevant regulations.

The Importance of User Experience and Interaction in Medical Devices

Human factors engineering has been a major challenge for medical device manufacturers for years. The ISO 62366 standard has multiple elements to make sure applications are safe and effective, so these important attributes generally receive ample attention. However, most medical device groups fail to adequately leverage experience design as a system-design driver — to use human interaction as a baseline for the "efficiency and effectiveness" described in FDA guidance materials.

As manufacturers embrace mobile devices, patients (i.e., consumers) are much more critical of these interfaces. The lack of priority on interface and visual design quality is impacting the medical device manufacturers' image on the market (and could even be affecting stock price). Changes in the digital landscape have led to a greater emphasis on the individual digital experience for patients and trial subjects.

Higher quality standards for interaction efficiency have been set by leading digital solutions providers — think of offerings in the Apple App Store and Google Play marketplaces — as well as the ISO standards. More than ever, therefore, a lack of interface efficiency can significantly decrease a medical device app engagement score — to the point where most users will toss it into the same "unenjoyable necessity" category to which so many poorly performing government services apps are condemned.

Digitization Will Accelerate the Platforming of Digital Health Solutions

Healthcare platforms typically exist within each of the technology blocks. For example, within instrument systems, the client may develop an embedded platform that can be deployed across multiple instruments. Many of our clients are focused on developing multiple applications that derive from the same mobile platform. The same situation exists with clients who want to develop a cloud platform. This process is called "platforming."

Enhancing Patient Engagement with Clinical Trials Platforms

Building modern strategies to effectuate patient engagement in clinical trials is essential to maintaining interest and compliance during the study. Most existing tools use trial/therapy inconsistencies as the red flag indicating a support needed. But a better approach is to take preemptive measures that guide the patient through the correct workflow by integrating with their daily digital routine. This provides opportunities to engage them (via messages and notifications) or prompt them to take actions (e.g., activity, medication) when they are most receptive and able to comply.

The ideal platform provides patients with a contactless method of reviewing and signing required documentation — including consent, evaluation questionnaires, and other regulatory documentation. That ideal platform may well use companion applications (e.g., gamification) to help subjects stay more engaged in the routine throughout the entire span of the study. And on the analysis side, the ideal platform can aggregate study data (open to third-party integrations) and provide submission instruments for CROs to report findings back to sponsors.

Using Data Visualization for Better Patient Management

Advances in data science, data analysis, and visualization tools, and healthcare clinicians' growing awareness of the power and usefulness of data visualization are combining to have a significant impact on patient care — individually and at a population level.

The key use cases for data visualization are:

- **Care coordination** helps medical professionals interpret research and leverage that information — for instance, by accessing the data of patients with similar conditions to understand common timelines for recovery.
- **Patient education** uses data visualizations to illustrate a patient's health status compared to others in the same demographic. This can provide, for example, a clear indication of the areas they need to improve (exercise, BMI, cholesterol, etc.).
- **Public health** refers to data visualizations used by the media to convey health-related trends on a large scale. For example, a national map can depict the state-by-state number of COVID-19 cases by using distinct colors to represent different values.

The COVID-19 virus helped to further mainstream big data and data visualization tools at the public health level, where clinicians and individuals alike could see the power of data.

Digitization Will Increase Complexity for Healthcare Information Exchanges (HIEs)

A Lack of Interoperability Thwarting Progress in U.S. Healthcare

Interoperability and the ability to easily exchange individual patient data between systems is a significant issue in the U.S. healthcare system. (It's less of a problem in other regions of the world where countries have adopted single, nationwide health record systems.) U.S. patients are very motivated to share their healthcare records with their healthcare clinicians for the purpose of the betterment of their individual care, and healthcare providers are equally motivated to share their patient data — but only within their own healthcare system. Why? Providers are concerned that sharing data outside of their system could harm their ability to retain patients in their own healthcare network.

The bottom line is, with an ever-increasing number of patients suffering from comorbidities that require their personal physicians and specialists (neurologist, cardiologist, endocrinologist, etc.) to work together to successfully diagnose and treat them, it's important that up-to-date, timely, and complete medical data is available to them in a consumable form.

The Problems Still Arising from Data Exchange Solutions

In theory, Health Level 7 International (HL7), Fast Health Interoperability Resources (FHIR), and FHIR-based APIs were constructed to solve this problem and make medical data accessible, computable, and usable to improve outcomes. Unfortunately, this is a significant challenge in the U.S. market, where there is not a unified patient ID and there are many concerns about PHI, security, and potential misuse of data. The other factor is that electronic medical records (EMRs) and other healthcare IT projects are extremely expensive to execute and to update. So, once a healthcare provider implements HL7, they usually do not upgrade on a timely basis. As such, a lot of our customers in the Medical Device and Life Sciences segments need to create and support numerous versions of these interfaces. Since billing is critical to the survival of U.S. Healthcare, billing data is where the integrated investment occurs.

Medical device (or in vitro) manufacturers are often required to enable data sharing per their RFP responses and contracts with healthcare systems. They also know, however, that their data is valuable and sticky and that sharing data openly with other manufacturers could impact their ability to maintain brand loyalty.

1 in 3 adults

suffers from two or more chronic illnesses

— World Economic Forum, This is the biggest challenge to our health

For most of our customers, these interfaces are required but a nuisance to manage. Some third-party interface engines have emerged on the market, but to date, they have not been adopted by enough healthcare providers to reduce this burden on our customers.

The Promise of Self-Service Portals for Patients

Patient self-service portals can be useful in providing basic services for patients and their providers. Moreover, patient self-service portals are highly valued in healthcare systems because of the ease of basic engagement (scheduling, questions, test results, prescription renewals, etc.). But such portals can also be a major frustration for patients that require multiple portals to manage their healthcare, each with separate passwords, links, and logins.

The lack of data integration across manufacturers of health monitoring devices (like wearables) and healthcare providers presents a challenge for this industry. Providers and patients want a single portal that integrates all their healthcare needs into a single view, with a high fidelity UIX and intuitive data visualization across an integrated timeline.

Many healthcare providers seek to expand the use of their patient portals to include integrated data from medical device manufacturers and pharmacies via RFPs and contracts that specify a minimum set of data integration. They also want to add telehealth, mental health, and dietary consultations.

As they compete for patients, healthcare providers are starting to focus more energy on creating these highly functional, well designed, and highly usable portals. One key challenge is that EMR companies are slow to change. Since the cost for any provider to switch EMR vendors is high, healthcare providers have less influence over EMR vendors to establish strong patient portals. This has led some healthcare providers to break ranks and begin funding their own internal efforts in this area.

Digitization Will Increase Development of IoMT and Smart Healthcare Systems

The Scope of IoMT

The internet of medical things (IoMT) is a fast-growing market sector that involves using Wi-Fi, Bluetooth, and other wireless technologies to connect healthcare systems and monitoring devices (i.e., wearable devices) to a cloud, creating a large ecosystem of connected products. Similar to standard IoT implementations, IoMT is when a medical device establishes a connection to the internet either directly or through a gateway (like a mobile phone) for the purpose of the management of the medical device asset or medical device application.

IoMT includes the development of IoMT platforms with wirelessly connected devices, systems, software applications, and other technology used to manage the millions of data connections and device sessions. These systems provide the capabilities for remote service, software deployment, and automating device data collection used by customers and manufacturers. Common uses for these IoMT platforms include remote firmware/software updates, obtaining device diagnostics and operating trends, monitoring performance levels, and preparing service personnel for efficient service actions.

A key distinction between IoMT and IoT is the process compliance required by IoMT systems.

The Role of IoMT in Simple and Affordable Healthcare Solutions

The latest generation of IoMT systems for support of medical devices or SaMD applications has significantly reduced the cost of ownership of these devices for both manufacturers and consumers alike. Once an internet connection is established (either directly or via gateway for clinical system collaboration), an IoMT service or system can be implemented using the same hardware and communication ports.

Cloud providers and other third-party vendors are now providing services that can be packaged along with custom implementations to create effective solutions with minimal upfront costs. As a partner with many of these cloud providers, we often consult with customers on this process to help them make the best decision on custom implementation versus use of third-party solutions.

From

$30.79B

to

$187.60B

Projected growth of the global IoMT market from 2021 to 2028

— Fortune Business Insights, Internet of Medical Things (IoMT) Market Size, Share & COVID-19 Impact Analysis

Digitization Will Increase the Availability and Use of Telehealth

A Working Definition of Telehealth

Telehealth, sometimes referred to as telemedicine, can be thought of as the enablement of healthcare via any remote capability. It could be a remote mental health engagement between patients and psychologists, a cardiac patient having a remote follow-up with their cardiologist, or clinical trial participants using their smartphone via a video link to communicate to the clinical study coordinator. Developing new generations of telehealth products with increased/improved capabilities will require expertise with emerging communications technologies.

The Need for Consistency

Healthcare companies are increasingly adopting systems that enable them to care for patients remotely. Smart devices, wearables, or off-the-shelf (OTS) medical devices — all of which will become more widely available — enable remote monitoring. These OTS devices gather data from a sensor worn by the patient and transmitted via BLE connection to a mobile phone application or proprietary data hub. Regardless of how the data is gathered, these remote monitors will require a patient engagement app through which patients can enter and track data, maintain a "data diary," and connect securely to the cloud for data storage, integration and reporting.

Telehealth via monitoring devices will enable many different use cases. Given the private nature of the data, it will be important that companies developing telehealth apps have the expertise to provide a consistent set of features associated with patient identification, patient sessions, patient data storage/retrieval, and secure data communications between the various elements of the systems (sensors, mobile phones, and cloud applications).

154%

increase in telehealth visits

between March 2019 and March 2020

— CDC, Trends in the Use of Telehealth During the Emergence of the COVID-19 Pandemic

Digitization Will Enhance the Effectiveness of Health Data Intelligence and Diagnostics

Maximizing the Value Extracted from Available Data

Health data intelligence specializes in healthcare analytics and evidence-based business decision support for hospitals and health systems. It includes doing data trending, disease diagnostic applications, clinical trial data, and data warehousing. Health intelligence often incorporates tools and methods from AI to capture data in the process of performing care management, utilization management, assessments, and appeals.

The Use of Remote Health Monitoring Frees Up Clinical Resources

The shift toward telehealth practices — initially instituted as a stopgap measure in response to COVID-19 — yielded measurable healthcare improvements. Unlike a traditional doctor visit where a small number of discrete measurements are taken in a clinical setting (along with a few modifying factors like age, weight, and gender), telehealth practices allow for the collection of large quantities of high-quality data via wearable devices. Smartwatches are used to continuously monitor a patient's blood pressure and pulse rate from home, where they are free from the stress of being in a clinical setting.

Besides the benefit of more data (which means more information), remote monitoring reserves the use of clinical resources, so they can be prioritized and made available to the patients who need them most. This allows for an increase in the scope of what can be addressed, and the number of people who are treated as early as possible.

The continual advancement and application of AI and ML to analyze and extract useful and actionable information from all this collected data has initiated a spiral of progress. The more these "smart" algorithms are developed and refined, the more devices will be used. More devices mean more high-quality data being generated to facilitate the further development of ML and AI algorithms.

253

million

Projected worldwide smartwatch shipments in 2025

— Statista, Smartwatch shipments forecast worldwide from 2016 to 2025

Data collected in this way also removes the bias traditionally present in medical data. Often, people receiving tests (and generating data) in a clinical environment present symptoms of some condition. This means that the medical data may be biased toward symptomatic people rather than asymptomatic (i.e., healthy) people. Diagnostic programs will be able to identify these differences and provide a much better understanding of a population's health as a whole.

The Enhancement of Disease Diagnostic Applications

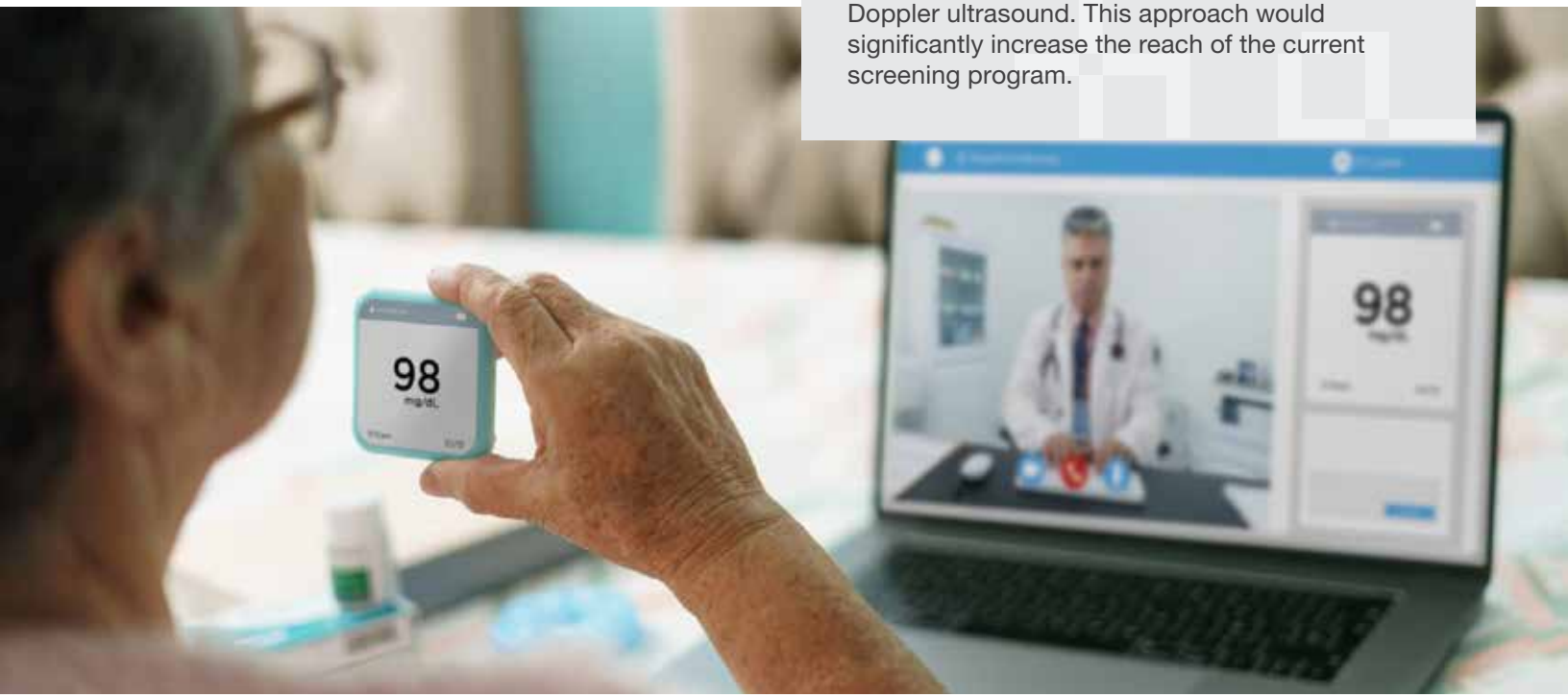
Specialized clinicians and nurse practitioners focused on managing a patient's disease condition use dedicated disease diagnostic applications. In the case of heart failure, for example, a patient might have an implantable cardiac device that provides daily feedback to the patient, caregiver, and clinician through a variety of sensors or device inputs, along with a patient diary that captures the patient's daily information. The data gathered might trigger any of a set of alerts to notify the nurse practitioner or clinician when the patient is approaching a preset level, thereby facilitating a patient physical visit, patient telehealth visit, or other appropriate interaction.

Producing actionable information from a variety of data sources requires integration of numerous applications or subsystems. These can span embedded software, medical devices, secure communications, mobile applications, and cloud systems. As a result, disease diagnostic application developers will require expertise in data integration, interoperability, security, and the ability to find and utilize the islands of data that currently exists in healthcare systems.

Rethinking Screening Programs

The NHS offers a screening program for abdominal aortic aneurysms. Currently all men aged 65 are invited to undergo a Doppler ultrasound. (No screening is offered to women due to lower prevalence, and consequently cost effectiveness.) During the screening, if the aorta measures less than 3cm, no further treatment is carried out. If the aorta is larger than 3cm, further monitoring or treatment is arranged.

Rather than undergo this traditional screening (which many men won't do), individual assessments of arterial health could be done remotely using peripheral measurements of pressure and flowrate obtained by a wearable device. In this way, any person (male or female) who is found to be at high risk of having an aneurysm could be invited to undergo the Doppler ultrasound. This approach would significantly increase the reach of the current screening program.



The Increasing Quality and Consistency of Clinical Trial Data

Among the types of data gathered during clinical trials, data around patient engagement has been impacted with particular strength by digitization in forms such as wearables and social media. These technologies have made it both easier and more enticing for patients to participate in the tracking of their own vitals. Moreover, the expanding use of wearables and the ease of their use combine to make it more common for patients to engage with clinical trials from their homes.

The competition for attention in the digital world is intense, but the higher and more consistent patient engagement is, the more valuable the data will be. Leveraging digitization in the pursuit of clinical trial data will require cross-pollinated expertise in areas such as UIX design, digital health and clinical trial management platforms, and the use of AI and ML to unlock the value in the data gathered.

The Challenges Arising from Data Lakes

The digital transformation of the Healthcare industry is generating ever-increasing swathes of data that will ultimately improve diagnosis, treatments, and outcomes. Currently the three main sources of this data come from genomic studies, patient data collected by clinical facilities, and mobile/wearable devices.

And while data overload is a huge topic in Healthcare, the problem is industry agnostic. Data management challenges are currently facing all industries and it all centers around data accessibility — how to make data centrally accessible so it can be quickly accessed from a single source and analyzed to produce valuable actionable information.

The Importance of Quick Access to Key Business Data

The ability for enterprises to establish 360-degree views of key business data entities — such as customer, product, account, and transaction — has already become critical to running the business and is among the biggest technology trends shaping (or disrupting) multiple industries.

Enterprises often struggle because they have only fragmented views of their key business data entities due to siloed business units and product lines, mergers and acquisitions, etc. The ability to achieve a mature, functional, scalable enterprise data platform (wrangling, lakes, serving, etc.) will be a basic requirement for success.

163

zettabytes

Estimated amount of data in the digital universe in 2025

— IDC, The Digitization of the World from Edge to Core

The View of Enterprise Data Platforms As Internal Products

Healthcare companies have an opportunity to realize the new requirements for an enterprise data platform and embrace it along with their other product initiatives. The data platform needs to be seen and managed as if it were an internal product, which means taking a disciplined approach to product management, architecture, SDLC, DevOps, quality, etc. It's not something that "data science folks" do in the back room apart from engineering and product-team processes. Enterprises that embrace this elevation of enterprise data platforms as products will excel — and enterprises that don't will fall behind.

The Opportunities Presented by PaaS Solutions

The requirement for enterprise data platforms (centralized or mesh) has spurred a wide spectrum of open-source and commercial technologies that help enterprises accelerate and implement enterprise data platforms. These technologies include real-time/batch ingestion/storage, data pipelines, polyglot storage, catalogs, data mastering, and data warehousing functionalities. Mainstream cloud providers offer these technologies in PaaS form, so the enterprise doesn't need to self-manage or host them, but the enterprise must still do the work of integrating and customizing on top of these technologies.

Healthcare companies that proactively establish enterprise data platform capabilities will be able to leverage 360-degree views of the data they need to run their business and build new insights and monetization on top of that data. And they can do all that while addressing the data governance concerns — such as those around data rights, licensing, privacy, anonymization, and sovereignty — critical for the Healthcare and Life Sciences industries.

The Final Word on Data

Healthcare companies, like other enterprises, need to embrace enterprise data platform capabilities as a first-class strategy requirement alongside other strategy initiatives such as cloud, microservices, DevOps, etc. Enterprises also need to form the associated product management and data governance capabilities that are needed to support enterprise data platform initiatives. Finally, enterprises will need to take advantage of available/matured cloud/PaaS technologies and use them as a platform on which to build.

Conclusion

Digitization is bringing about tectonic shifts in healthcare delivery. Organizations race to create software and digital experiences that will help them deliver better and faster healthcare at lower costs, ensure that they remain relevant and differentiated, and unlock new business value and revenue streams.

Tremendous opportunities and challenges abound in both the short and long term. As a result, Medtech, Life Sciences, and Healthcare businesses realize they need a software engineering product development partner.

Finding that ideal software engineering partner can be daunting — but it can also lead to enormous benefits. Beyond black-and-white metrics like ROI, partnering with a software engineering product development company, like GlobalLogic, can provide you with a unique outside perspective that leads to surprising new innovations — and new and expanded revenue streams.

To learn more, or to speak with one of our experts, please reach out to info@globallogic.com.

About GlobalLogic

With more than 20 years of experience in regulated software product development and engineering, GlobalLogic helps leading Medical Technology, Medical Devices, Pharma, and Life Sciences organizations create world-class digital experiences, accelerate product development, and capture new revenue streams.

Our 2,300+ industry-dedicated engineers use their deep knowledge of ISO/IEC standards to build fruitful partnerships with developers of regulated medical products. We have extensive clinical-trials experience and have developed highly valued consumer apps (across multiple industries).

We've also developed numerous data interfaces—some proprietary, some using HL7 standards — to meet complex data analysis, security, and integrity challenges. In all, GlobalLogic has helped more than 90 clients create more than 300 new products in the Healthcare and Life Sciences sector.

20+ years industry experience

2,300+ industry-dedicated engineers

300+ new products

90+ clients

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