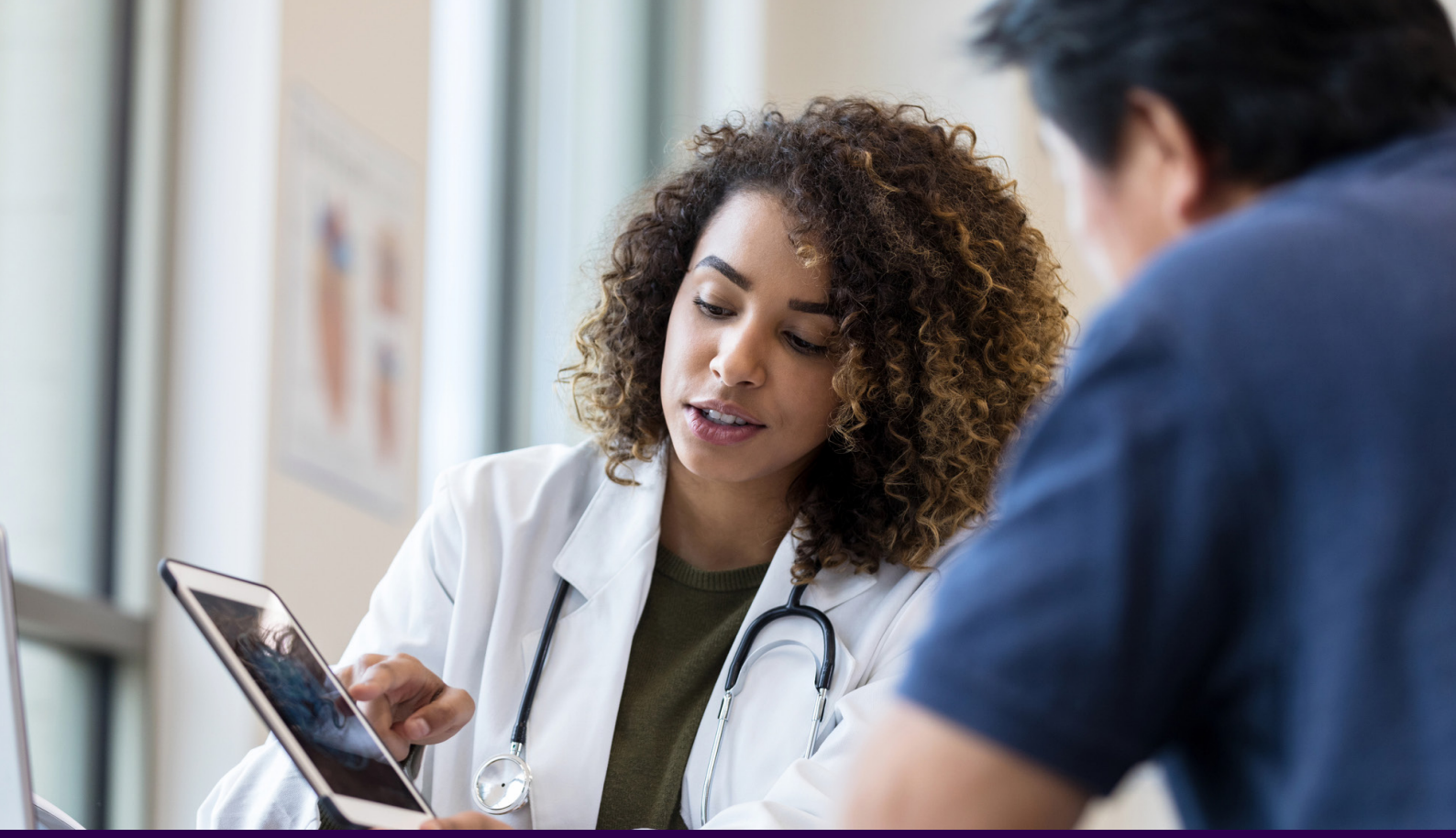
MASTERING THE MEDTECH GAME

How to overcome the 4 connected health hurdles



By 2030, the global connected medical devices market size is projected to grow at a compound annual growth rate of more than 22%, reaching a total market valuation of $181.9 billion[1].

But, as many life sciences organizations well know, spending does not guarantee success. In fact, an estimated one in four connected medical devices are not approved by the FDA. For those that are accepted, regulatory review times can range from 7 to 10 months, depending on the classification and complexity of the device.

In an industry where the first mover is likely to become the long-term market leader, delays and denials can be devastating. This implies that success for MedTech organizations hinges not just on the willingness to act, but on the ability to design programs to overcome the challenges that often stand in the way of success.

22%
CAGR of global medical device connectivity market by 2030[2]

$850B
Expected value of the medical device market by 2030[3]

$181.9B
Expected value of the global connected medical device market by 2030[4]

[1] Acumen Research and Consulting
[2] Acumen Research and Consulting
[3] Precedence Research
[4] Acumen Research and Consulting

4 CHALLENGES IN CONNECTED MEDTECH AND HOW TO OVERCOME THEM

1 Increased risk as it relates to regulatory compliance, cybersecurity and data privacy

As with any health device or service, connected MedTech products, including Software as a Medical Device (SaMD) and digital therapeutics (DTx), are subject to strict and often complex regulations about data security and privacy, many of which vary from country to country.

While compliance can be challenging in any case, the level of difficulty can seem far higher for many MedTech organizations that are venturing into the world of connected health for the first time.

For example, does the organization understand the regulatory requirements for handling patient data? Is the company subject to additional regulations if that data is transported across country borders? What impact, if any, will the organization bear if they integrate the device within a connected ecosystem? When it comes to SaMD, is the selected technology partner a legal manufacturer of software that will manage the oversight of all data-related regulations and engage with health authorities on behalf of the development team? These questions and others present a series of firsts that MedTech organizations will need to navigate as they operate in the world of connected health.

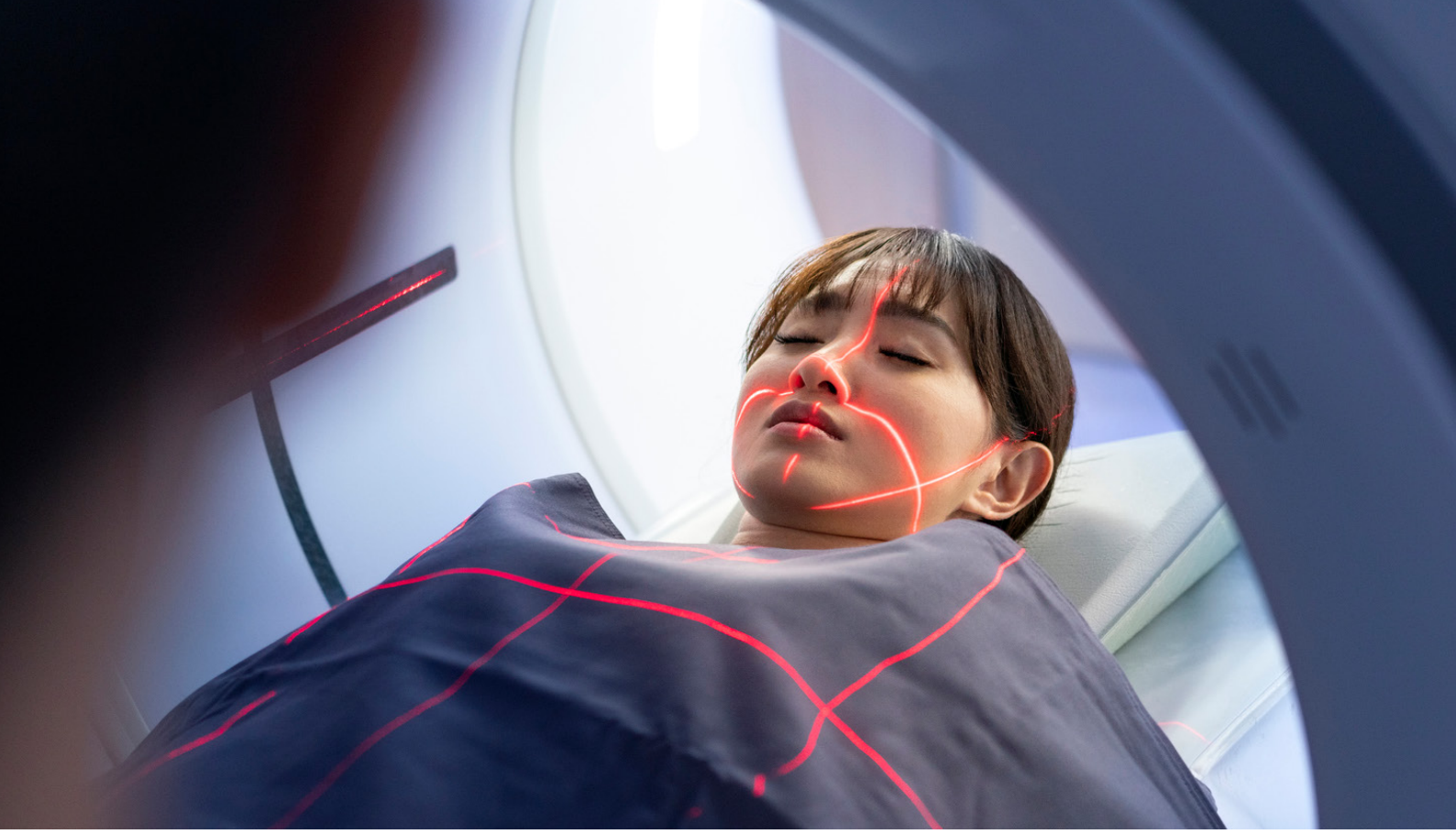
Unfortunately, the regulatory landscape is likely to become more complex as the risk of cyberattacks grows. According to data released by the FBI, more than half of all connected medical devices and other internet of things (IoT) devices in hospitals (53%) had known critical vulnerabilities[5]. It is perhaps no wonder that healthcare organizations experienced a 60% year-over-year increase in cyberattacks between 2021 and 2022[6]. These attacks have the potential to erode trust in connected devices and the health care system in general, thus highlighting the need for robust security measures by MedTech organizations, such as equipping devices with the ability to be updated Over the Air (OTA) to address potential vulnerabilities without returning the device to the manufacturer to be updated.

Ultimately, uncertainty about how to safely and securely manage data from connected devices and comply with regulations poses a major hurdle to developing, launching and operating new products. To do so successfully, companies need to have a clear understanding of regulatory, issues and how each guidance affects internal operations, infrastructure investments, and procedures.

To that end, companies should conduct an extensive, comprehensive audit of existing processes and structures to determine what changes need to be made to ensure the program is compliant and secure.

53% of all connected medical devices and IoT devices in hospitals have known critical vulnerabilities[5]

[5] FBI
[6] Check Point



Takeaways: Managing regulatory, security and privacy risk

- Map the global regulatory environment as it relates to relevant guidances, cybersecurity risk and data requirements.
- Conduct an audit of all existing processes and structures, as well as product and product ecosystems, to highlight compliance issues and develop specific mitigation strategies, such as OTA update capabilities for all connected devices.
- Develop a clear strategy for data governance that is compliant with current guidances and can be evolved over time to meet new regulatory needs and support scalable growth.
- Map cybersecurity guidances against product development plans to ensure product security.
- Pressure test legacy products to identify vulnerabilities before they happen, allowing for the removal of barriers to product expansion across borders and uses.
- Evaluate technology and transformation partners carefully and consider working with companies who are designated as a legal manufacturer of SaMD to reduce risk.

When we talk about mitigating risk, it's really about removing the barriers for growth."

2 Legacy infrastructure and technology architecture

Connected devices operate as part of the broader connected health ecosystem – the evolving, responsive digital environment that unites all products and services within the patient experience.

As such, modern MedTech devices must be designed to support connection with a wide range of stakeholders and partners, such as provider networks, hospital systems and public health systems, and communicate with other devices, systems, and services.

In most cases, legacy infrastructure is incapable of enabling this level of connection. To deliver on the promise of connected health, MedTech companies must design and build data sharing and integration capabilities and attributes into the product at the outset. This requires a singular architecture that serves as the foundation for the product, as well as the common DNA and connective tissue that will enable the device to connect with the broader ecosystem.

To that end, companies need to create a clear roadmap that includes all required tech investments needed to launch and operate connected devices and unite activity across the broader network. The architecture should be designed to be flexible and scalable, work with an evolving product roadmap and grow to meet the changing needs of the landscape.

Takeaways for enabling a connected ecosystem:

- Conduct an audit to understand the current architecture and determine future infrastructure needs and investments.
- Develop a clear vision of the end user experience, as well as other stakeholder experiences (e.g., the HCP experience, the internal stakeholder experience, partner experience, etc.) to ensure the architecture can support the full vision of the product.
- Ensure cloud, product, service, and stakeholders are connected by a scalable ecosystem that optimizes data and product value.

3 Failure to embrace experience-based design

MedTech companies are primarily in the business of creating devices. But in an experience-first world, users often place as much value on an intuitive interface as they do a quality product.

To that end, MedTech organizations must understand what patients, HCPs and marketers want to get out of interactions with their device and design an experience that delivers on their expectations.

For example, companies shouldn't just think of their device simply as a plasma extraction tool. Rather, they should consider if it is a practice management solution. Does it feed data into the ecosystem? Are donors connected through a particular location or community? All of these areas must be considered at the onset of the program to ensure the device plays the leading role in an effective and intuitive experience.

Key takeaways on delivering a connected experience:

- Design the device and its accompanying services to operate as part of an ecosystem from the beginning.
- Assign commercial value to extended services and incorporate them in the development plan.
- Ensure the core of the device is a connectivity tool that is enabled with the necessary software and firmware that enables it to interface within the ecosystem.
- Enable rapid prototyping, using data and insights from existing programs, combined with AI, to quickly iterate and speed development times.
- Embrace outcomes design, leveraging best practices from clinical, data, and behavioral sciences to optimize outcomes, while lowering costs and shortening timelines.

4 Innovation silos

Like any ecosystem component, connected health devices must be capable of evolution. To that end, organizations should develop an innovation strategy that enables both continuous and purposeful innovation.

We sometimes refer to this concept as intentional innovation – which means developing the foundational processes, systems and technologies that underpin and unite all innovation activity and ensuring those efforts are carried out in a way that aligns with the organization's specific business goals.

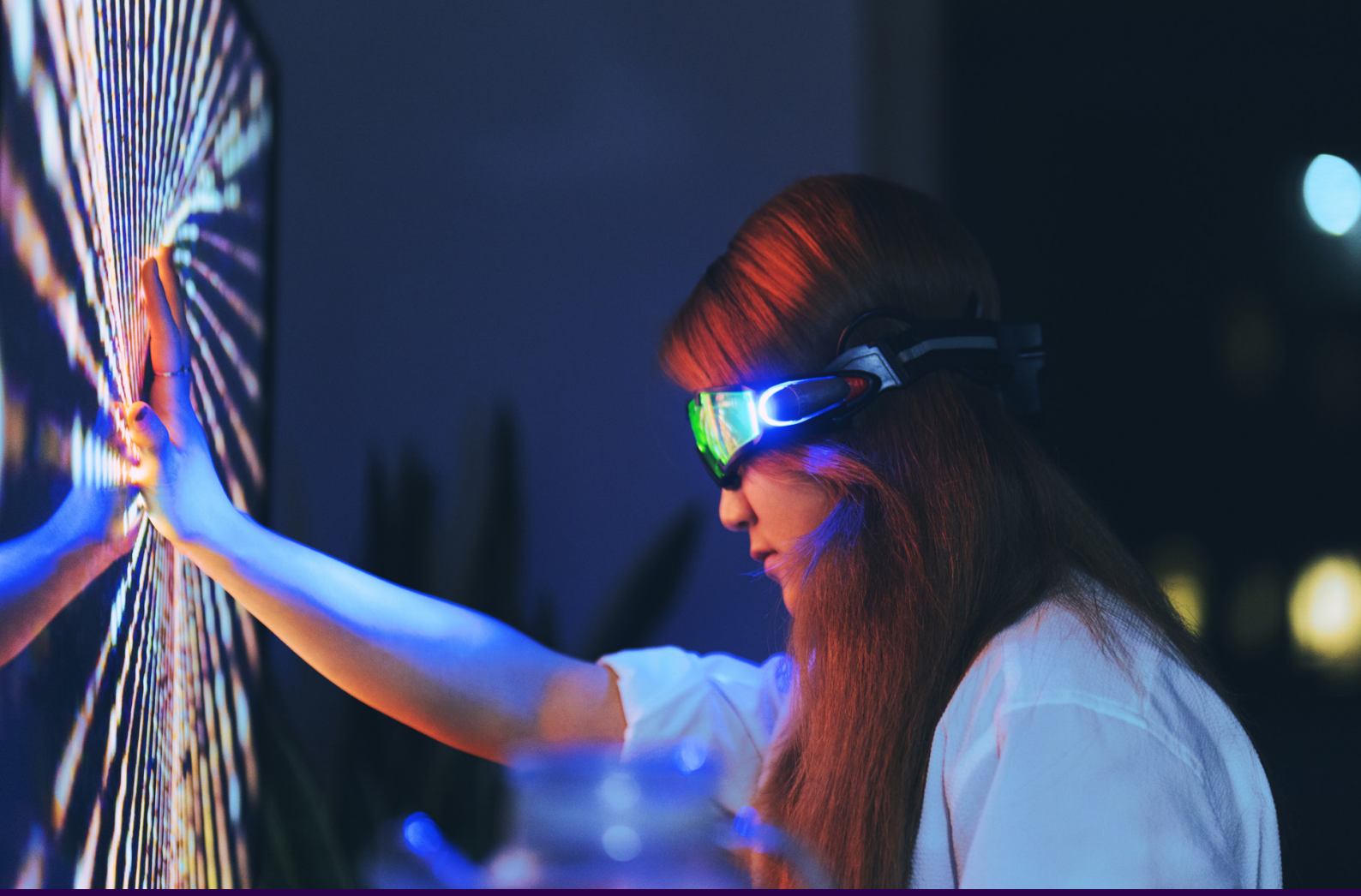
For example, if a MedTech company wants to reduce waste in product design by 40%, what does the company need to do to reach that goal? What existing processes and structures are already in place to provide the foundation for this activity – and what technology investments and partnerships are still needed? If a company wants to personalize patient interactions to improve engagement and influence behavior, how can the organization intelligently leverage generative AI to customize and scale communication? Technology has great potential for solving problems and improving existing processes – from more effectively collecting digital biomarker data to enabling a real-time patient/physician experience – but life sciences organizations must be thoughtful and strategic in selecting the right tools to meet their needs.

By embracing this concept idea of intentional innovation, the company can continuously advance the product in a way that drives value. Further, operationalizing the innovation cycle enables companies to optimize resources and shrink development timelines. Ultimately, this helps the business avoid silos and develop IP that is unusable or requires significant rework to adapt.

> *Intentional innovation is the idea that innovation is done with a purpose. There's a plan, there's a purpose, there's a structure."*

Takeaways for embracing intentional innovation

- Develop innovation models that are purpose fit to organizational needs and horizon strategies for product development.
- Form partnerships and alliances that bring the right innovations to R&D efforts in conjunction with an established roadmap.
- Invest in new technologies are purpose built for integration into development programs.



LEADING THE WAY TO A CONNECTED FUTURE

The unfortunate reality is that many MedTech companies have historically underinvested in digital R&D, leaving them trailing in the exploration of connectivity solutions for both legacy and next-gen devices.

At the same time, this overall lack of investment underscores the possibility of widespread change if the industry collectively implements new technologies at scale. Companies that act quickly have an added advantage since being first-to-market often leads to a long-standing leadership position.

By proactively addressing the largest and most significant challenges within the connected health landscape, MedTech organizations can develop and launch connected health devices more quickly and efficiently. This is the key to creating value – for each company, every patient, and the healthcare industry at large.

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