



# The MedTech technologies fuelling SaMD product development

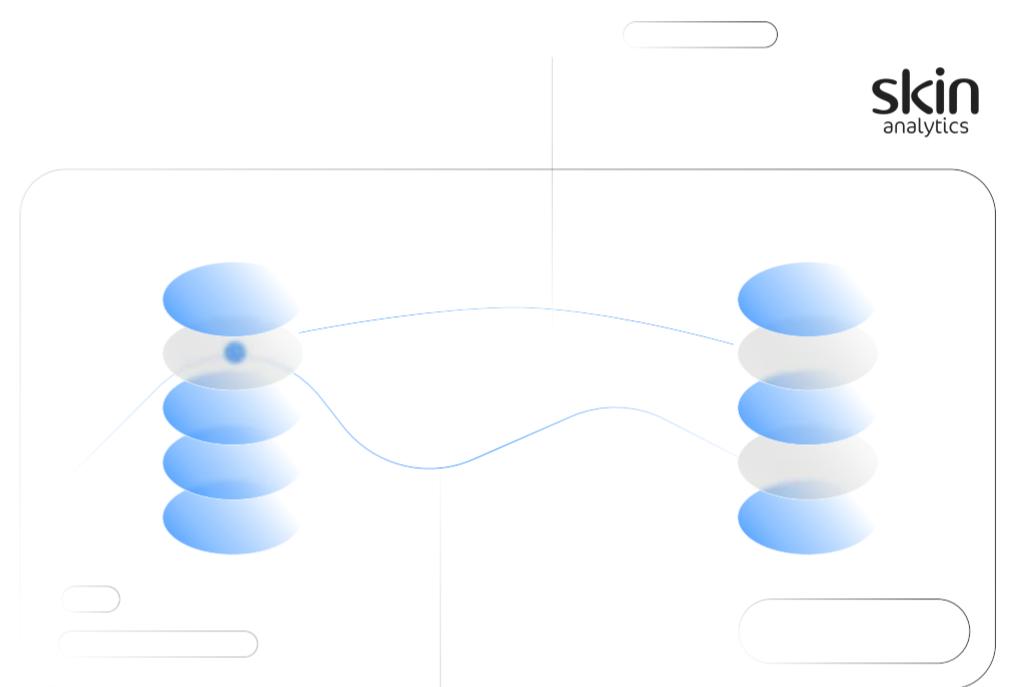
# Intro

We live in a solutions-driven world. This shift continues to accelerate and reach new domains. For healthcare, we're at the beginning of a bold transformation that will make care more accessible, affordable, personalized and effective.

That's why we at Star are so excited about software-as-a-medical device (SaMD). Even in these relatively early days, SaMD and DTx breakthroughs have already significantly improved the lives of millions.

**Star's HealthTech Practice helps companies at every stage of their product journey. From ideation and definition through design, development, launch and post-market surveillance to create groundbreaking SaMD, DTx, medical devices and other digital healthcare products.** Our regulatory consultants, healthcare-specific engineers, strategists and data scientists work to accelerate the innovation process and co-create solutions that result in meaningful value for all users.

So, we created this report to share with you some of the most exciting technologies fueling the SaMD revolution, key insights on MedTech and digital healthcare product development and insights on our dramatically shifting global health system. Our goal is to inspire you to see how these different emerging technologies can work together to create game-changing MedTech and digital healthcare. Your next big idea is right around the corner. Ignite it with Star.



# Contents

**Intro**

02

**Our changing global  
healthcare system**

04

**The current state of  
MedTech and in-home care**

05

**Key applications for serving  
aging populations**

06

**Regulated MedTech vs.  
consumer digital healthcare  
product development**

07

**Estimating the cost  
of SaMD product  
development**

08

**Essential considerations for  
developing user-centric, secure  
and market-ready SaMD**

09

**Choosing the right MedTech  
and digital healthcare product  
development partner**

12



# Our changing global healthcare system

The past few years have shown how impactful and necessary in-home care technologies are on a global scale. Between 2016 and 2028, the US home care market is projected to **grow from \$100B to \$545B contributing to the \$12.6T Longevity Economy**. A major part of this is the proliferation of technologies like remote patient monitoring, implants, apps, sensors and virtual assistants and other tools. With them, it's possible to deliver more care outside of traditional healthcare settings.

This is a win on several fronts. Increasing in-home care frees up the resources of hospitals to focus on those with the most urgent needs. It also improves safety. Between 5–10% of all patients contract at least one hospital-acquired infection during their stay in an acute care hospital resulting in direct medical costs of \$28.4B per year.

Simultaneously, the global healthcare system is buckling under several interlinked challenges. We have yet to put the pandemic behind us, but larger systemic issues need to be addressed. First, the **global population is rapidly aging**. In the US alone, more than **10,000 people turn 65 each day**. As these people grow older, their care needs will naturally increase. Compounding this problem, the WHO projects that by 2030, there will be a shortage of 18 million healthcare workers. There simply won't be enough people to take care of our aging population.

We are in a moment ripe for innovation. Technology will be key to overcoming these challenges, but it must be created in such a way that it embraces value-based care, payment reform, and the shift toward consumerization and personalization. It's not an easy feat, but we're already seeing examples of emerging healthcare technologies that are making an immense impact.

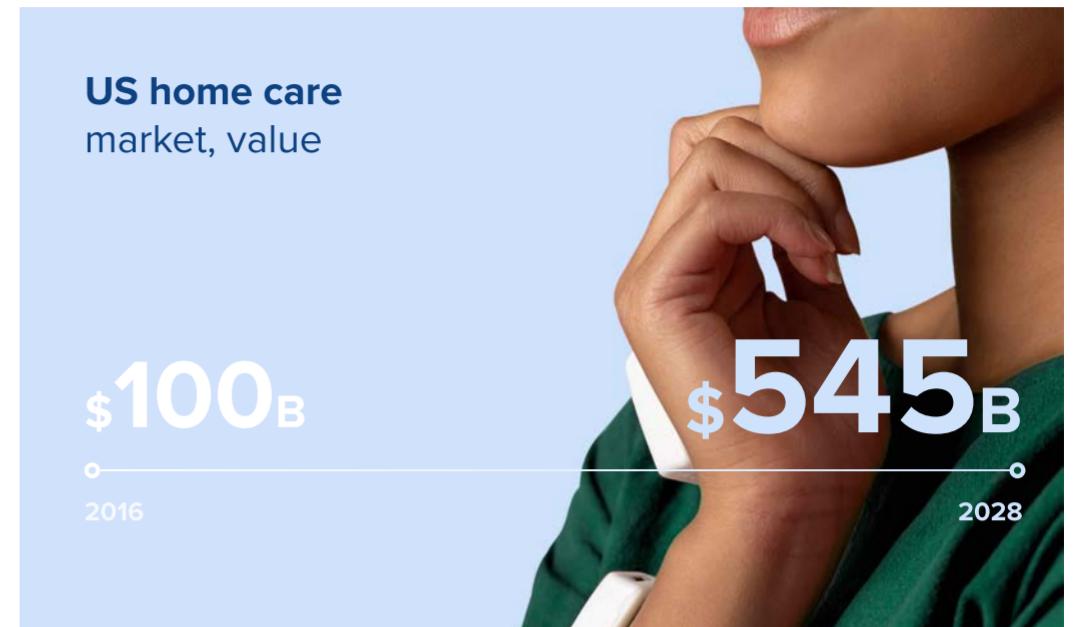
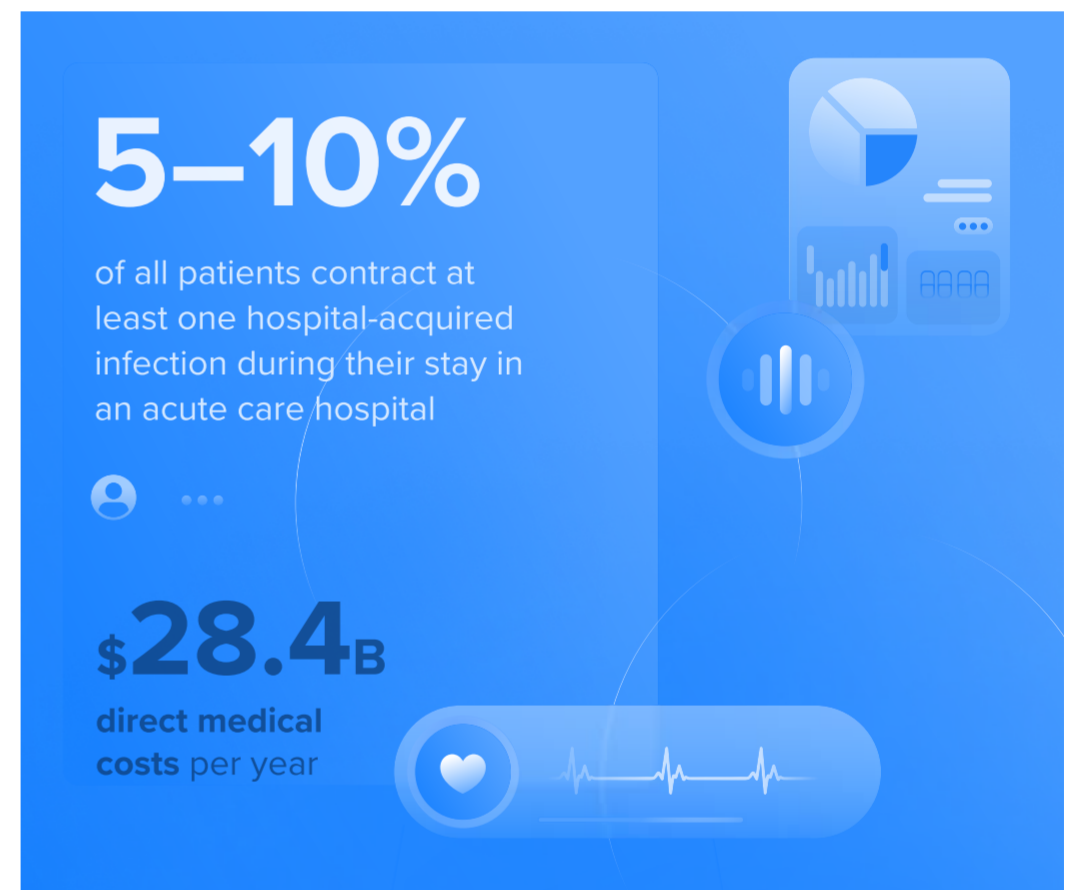


image source: [Tenzr](#)



# The current state of MedTech and in-home care

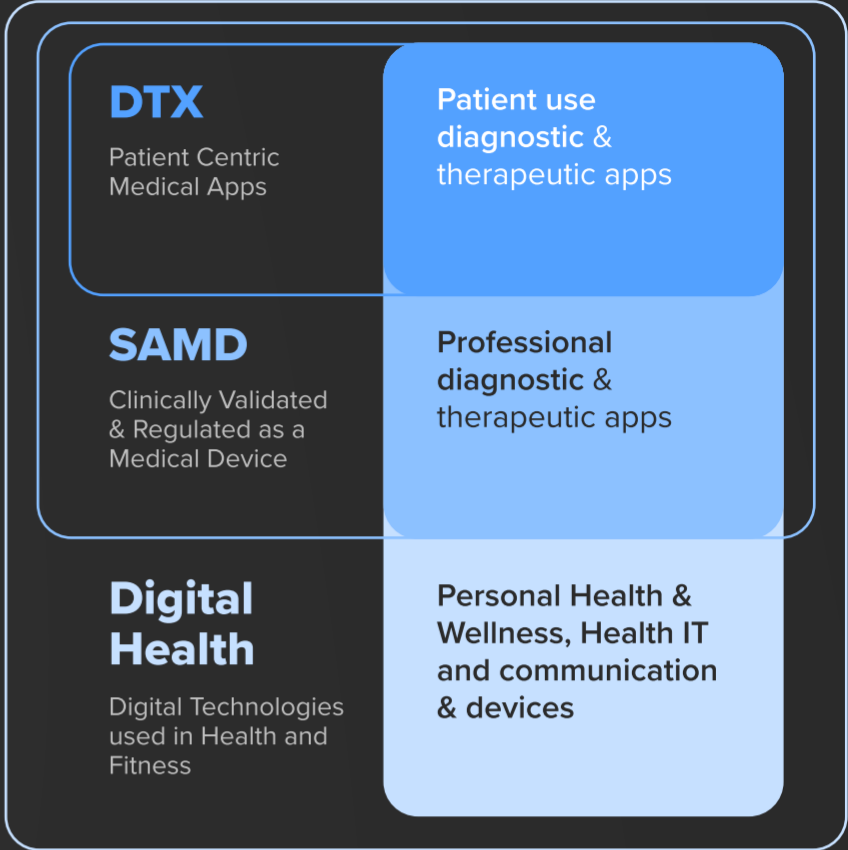
Home-based care is already here. We have seen a massive uptick in the rise of SaMD, DTx and remote patient monitoring (RPM) tools during the past few years. Concurrently, a proliferation of companion applications that boost adherence, engagement and education have flourished in the marketplace. Finally, new hardware and software medical devices enable the diagnosis, treatment, management and prevention of a growing variety of health conditions.

Broadly speaking, RPM technology facilitates condition management, monitoring, planning, analytics and more. Some of the most promising examples are technologies that for now do require a provider to utilize them, but are quickly evolving to where more and more can be self-managed.



For example, our HealthTech Practice has been working with a UK SaMD product development company to evolve its digital skin cancer diagnostic platform. **We designed, built and delivered a flexible AWS-based, AI-driven Class III medical device that seamlessly integrates into their technology ecosystem.** With the combined hardware/software solution, nearly any healthcare practitioner—and not just a specialist—can perform skin cancer screening with a handheld device and instantly receive a diagnosis. In the past, the process could take weeks. Now a person can receive treatment earlier, significantly improving outcomes while reducing costs.

This is what's so exciting about SaMD. You can apply it almost everywhere to enhance the patient and provider experience and drive real impact.

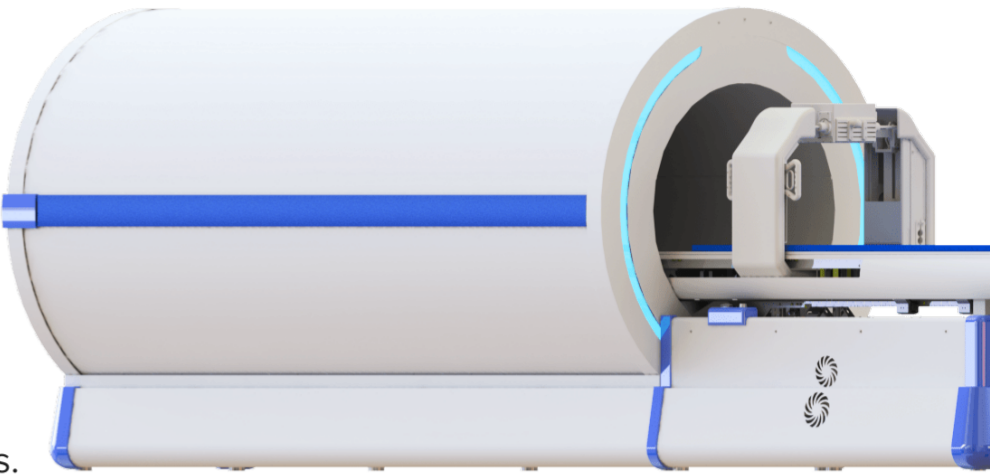


# Key applications for serving aging populations

## 01 Screening and diagnosis:

Instead of bulky, hospital-based equipment, small devices that can be used by patients or those without specialized training

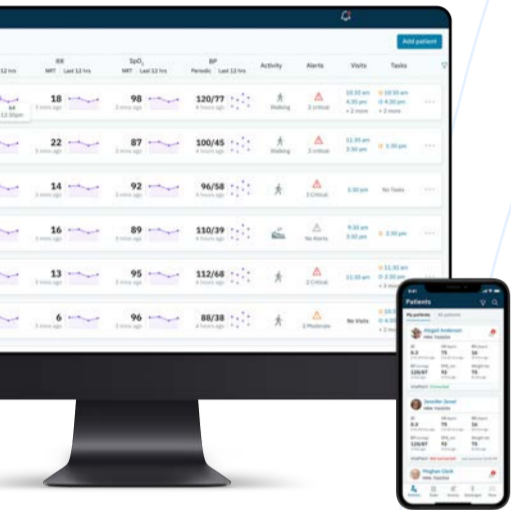
**Genetesis'** non-invasive biomagnetic imaging system is used to measure and display the electromagnetic signals produced by a patient's heart within minutes of scanning. Utilizing the power of machine learning, radiologists can identify anomalies that are often missed by other tools such as electrocardiograms.



## 02 Digital therapeutics

**Biofourmis**

Utilizes machine learning, integrated technology and an FDA-cleared analytics engine to develop clinically validated DTx, enabling better outcomes for patients, smarter engagement and tracking tools for clinicians and cost-effective solutions for payers.



## 03 Mental/neurological health: tracking cognitive decline, promote mental wellness

**Linus Health**

## 04 Chronic condition management

Poor medication adherence costs the US healthcare system an estimated **\$100 Billion** annually indirect costs, as 20-30% of medication prescriptions are never filled, and 50% of medications for chronic disease are not taken as prescribed.

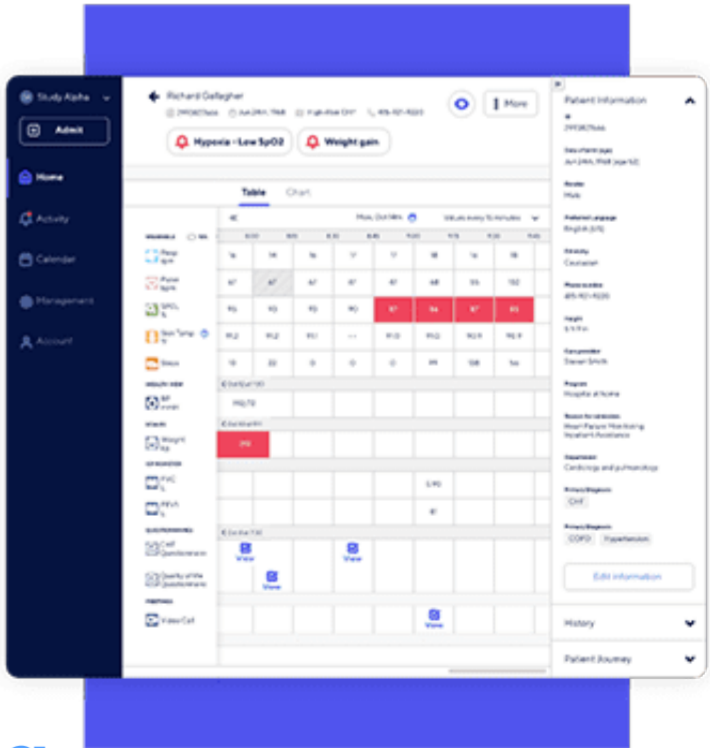


**TandemDiabetes**

## 05 Remote monitoring systems

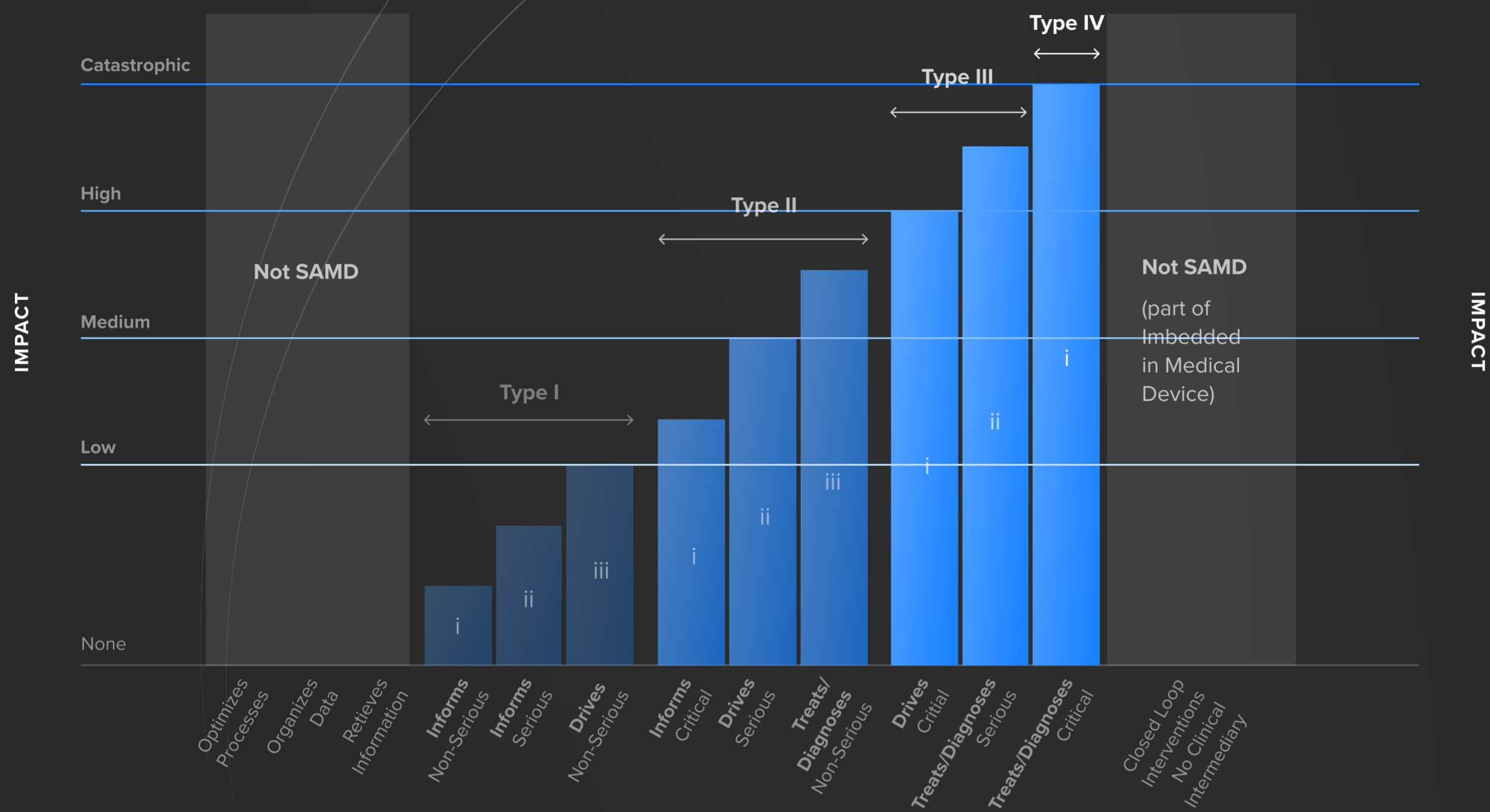
(vital sign and health assessment)

**Current Health**



# Regulated MedTech vs. consumer digital healthcare product development

Types of SaMD



One of the first things we help our clients understand is whether pursuing regulated MedTech development is the best course of action for them. The benefits of regulated SaMD far outweigh the consumer route, but cost, available resources and complexity must be considered.

While every company's product development journey and operational reality are different, their horizons should be set on regulatory approval, if not now, then in the future. This is especially true as the lines between consumer and regulated medical devices start to blur.

We are increasingly seeing medical-grade devices become more consumerized and user-friendly. Looking at some of the aforementioned projects such as Caption Health or our teledermatology, it's easy to imagine patients using future versions of these projects to self-manage care.

However, the same cannot be said for consumer products. While simultaneously growing more sophisticated, they will run into functional limitations imposed by the FDA, EU and other authorities that form the basis of medical device classification.

Sooner than later, people will have the option between similar products: a consumer version with limited functionality and a regulated one that collects high-quality data, is FDA-approved, reimbursable, integrates into a broader health technology ecosystem while also likely being able to diagnose and even treat. The choice will be clear.

# Estimating the cost of SaMD product development

The answer to this question is unique to every project and company. It's critical to understand the complexity of product requirements, device technology, company goals and expertise, whether predicate devices exist and a host of other factors.

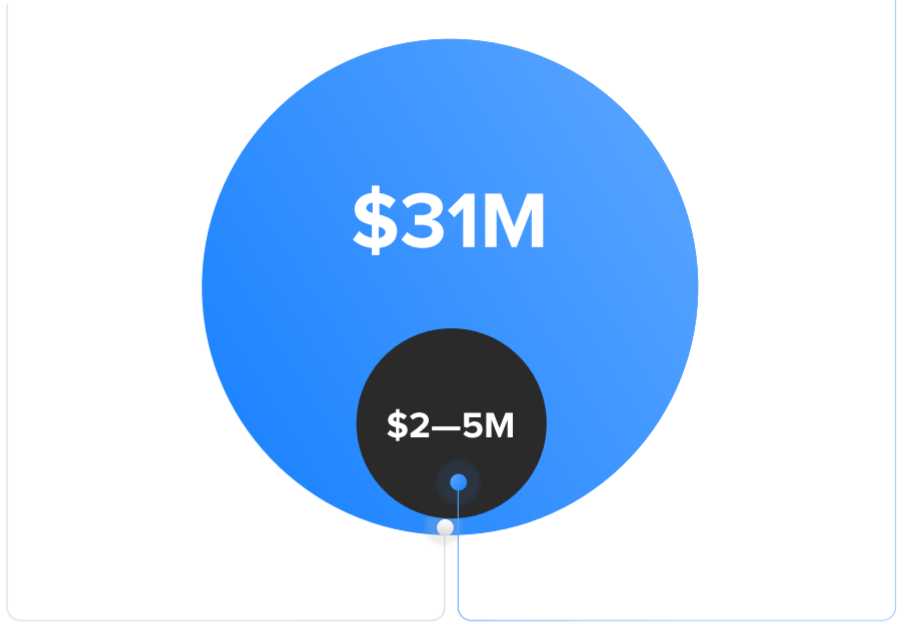
The current average price for bringing a medical device to market is around **\$31M**. However, this statistic factors in all medical devices and not just SaMD. Narrowing the focus to software development, for a medium complexity Class II medical device with proven technology, end-to-end development costs are between **\$2—5M from our project experience**.

This includes regulatory consulting, ideation, design, engineering, testing, documentation and other requirements for successfully launching a MedTech project along with associated regulatory fees. Nonetheless, with this large of a range, we recommend companies interested in SaMD development to connect with our HealthTech Practice to **help them get a better understanding of the costs, considerations and opportunities and answer key questions, such as:**

The bottom line is that estimating costs can be challenging even for incumbents. That's why it's imperative to partner with a SaMD engineering firm that can help you optimize your budget, reduce your time to market and co-design a product that will win with the end user and provide flexibility over a 10+ year lifespan.

Current average price for bringing device to market

Software development, for a medium complexity Class II medical device



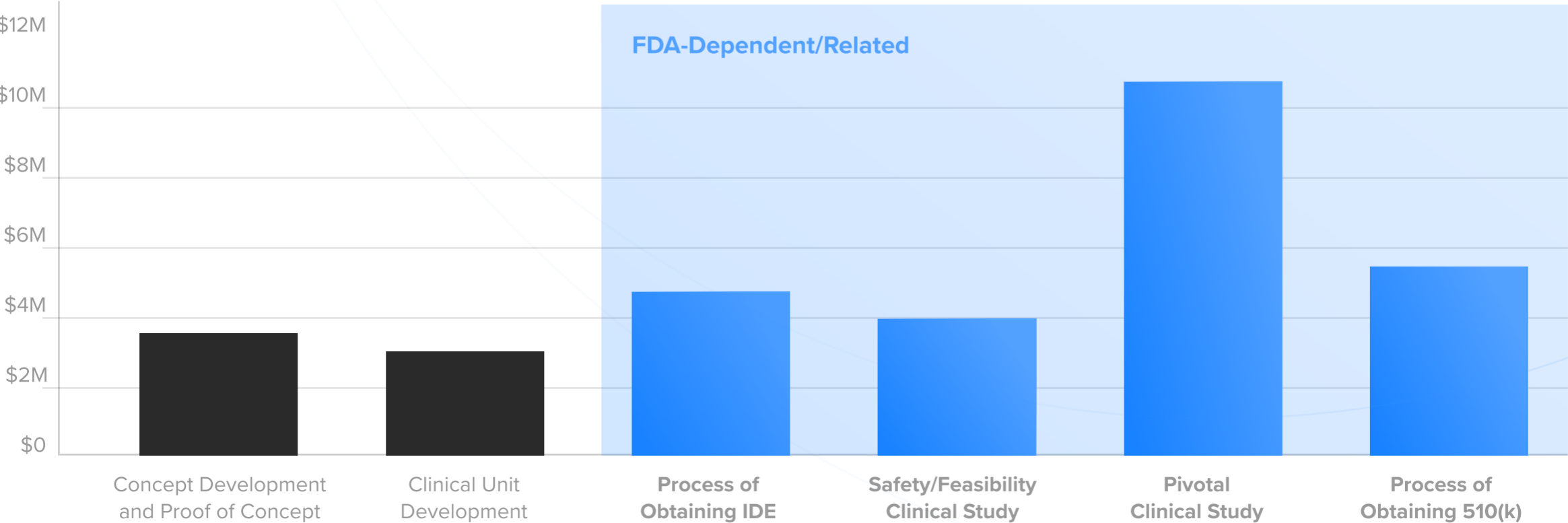
What are the development costs, notified body fees and time required for creating a medical device?

How can you be confident that cost projections are accurate and you'll stay within budget and time frame?

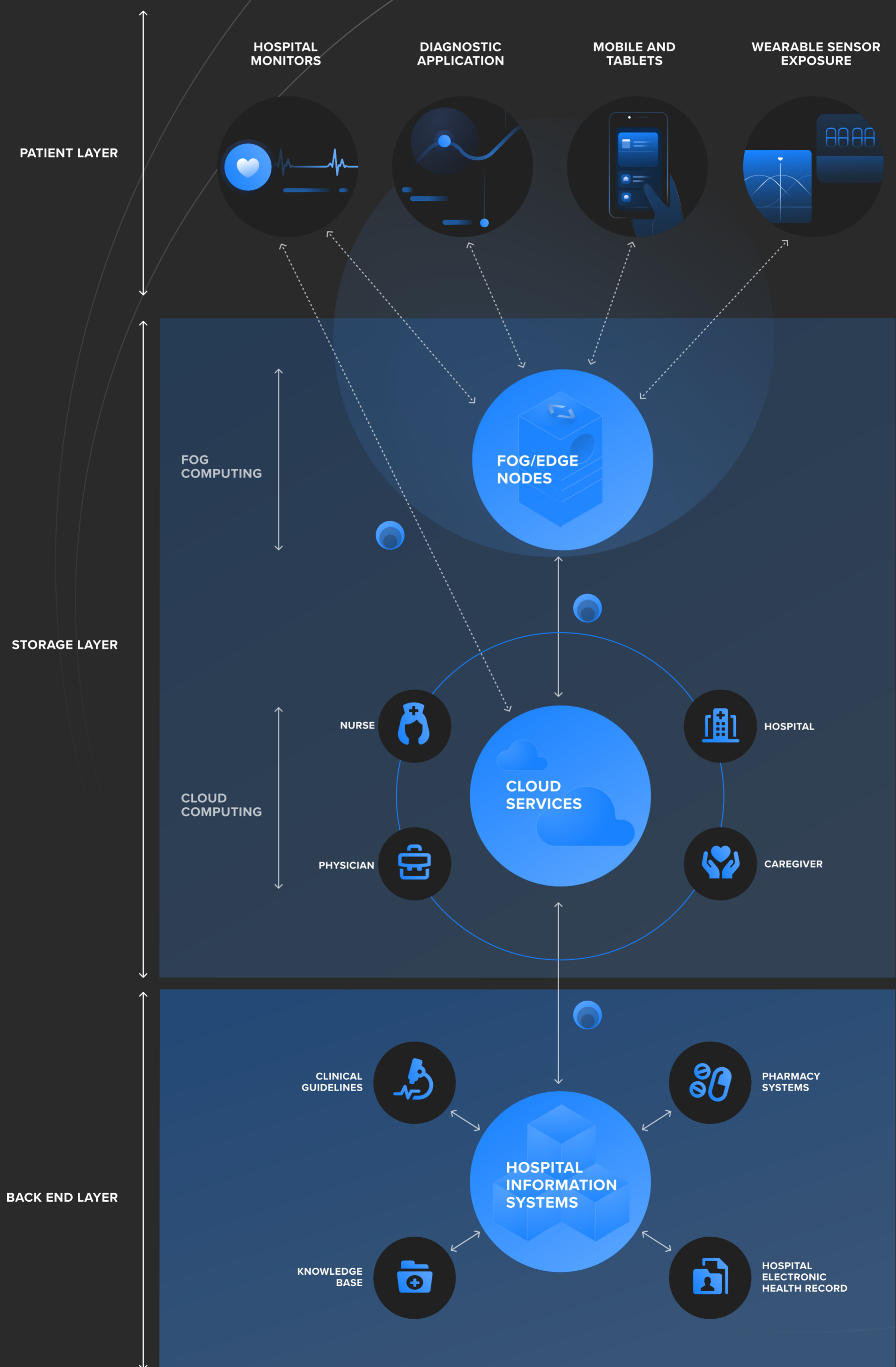
What types of know-how sets, tools and frameworks can be used to accelerate the regulatory process?

How to shift to the lower end of costs while maintaining product excellence, safety, efficacy and security?

Average Total Expenditure by Stage for 510(k) Product



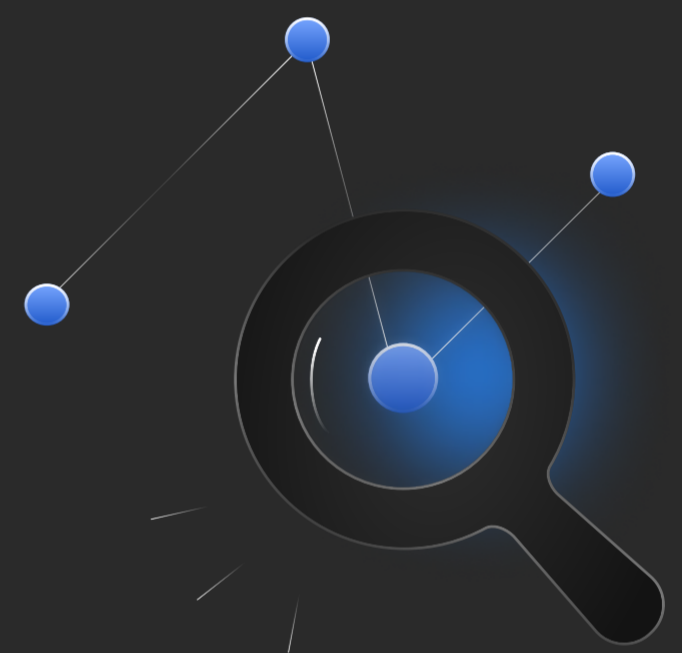
# Essential considerations for developing user-centric, secure and market-ready SaMD



**Successfully bringing a SaMD solution to market is much more complex than consumer digital healthcare products.** Before you start your product journey, here are the most important considerations for you to bear in mind:

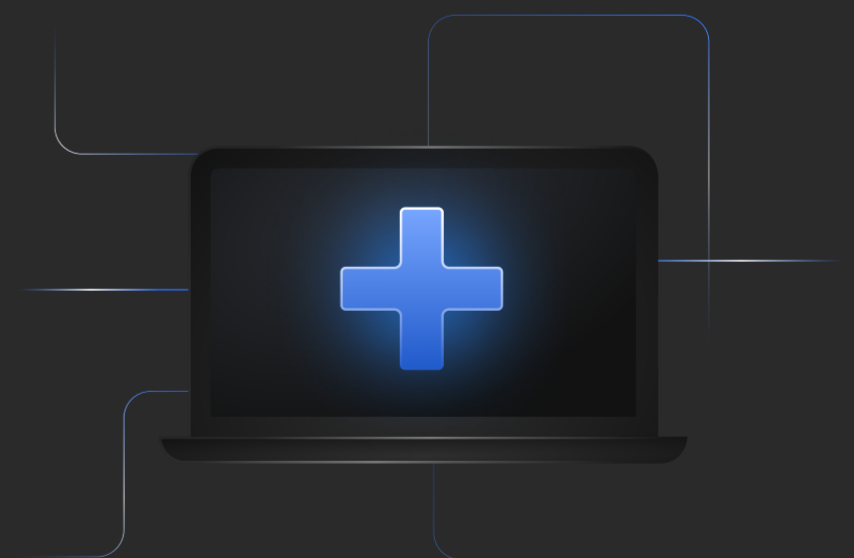
## **Regulatory strategy:**

Before doing anything you need to consider the regulatory regimes of the markets you plan to launch in. You'll need to craft an initial version of the intended purpose statement. Everything starts and ends with this statement, including how your product will be classified. From here, you'll have to consider medical indications and contraindications, user groups, body part/tissue groups, intended usage environment, functional principle, other intended uses and medical device limitations/device misuse.



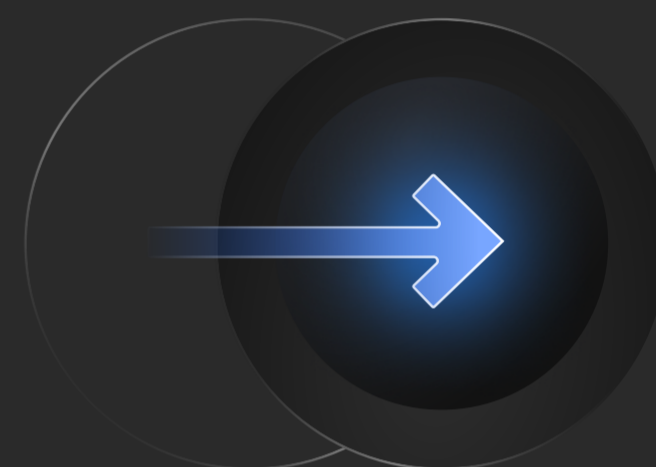
## **Data acquisition, storage, transmission:**

Data is the fuel of SaMD and the in-home care revolution. We have to think about how data will be created, stored and transmitted along with how healthcare businesses will extract value from it. Data is also critical for the training and validation of AI so you need to make sure you have enough of it available or can procure it when it is time to train your AI system. Even if you don't start with an AI system, with classic decision trees that evolve over time, you need to have enough quality data available.



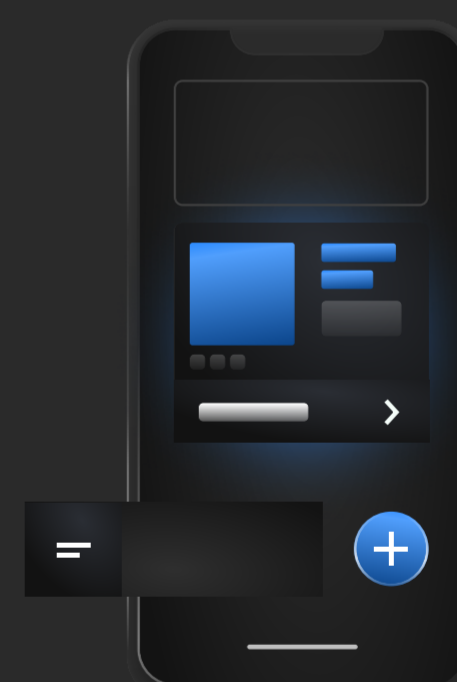
## Architectural Flexibility:

At Star, we consider how every solution we build will integrate into the larger technology ecosystem. When designing a medical device, you must think over the course of a 10+ year expected lifespan. It's essential that what you create can evolve over time to continue getting the most out of your investment.



## Usability and co-design:

Any technology, but especially SaMD, must remove friction and fit into workflows. We love technology that's invisible to the end user, such as the platform described earlier in the report. Of course, not all technology can work like this. Focusing on co-design and the specific needs of older users, particularly leveraging voice assistants and conversational user interfaces is essential for increasing accessibility. On the provider side, tools need to synthesize the vast troves of data into digestible and actionable insights.

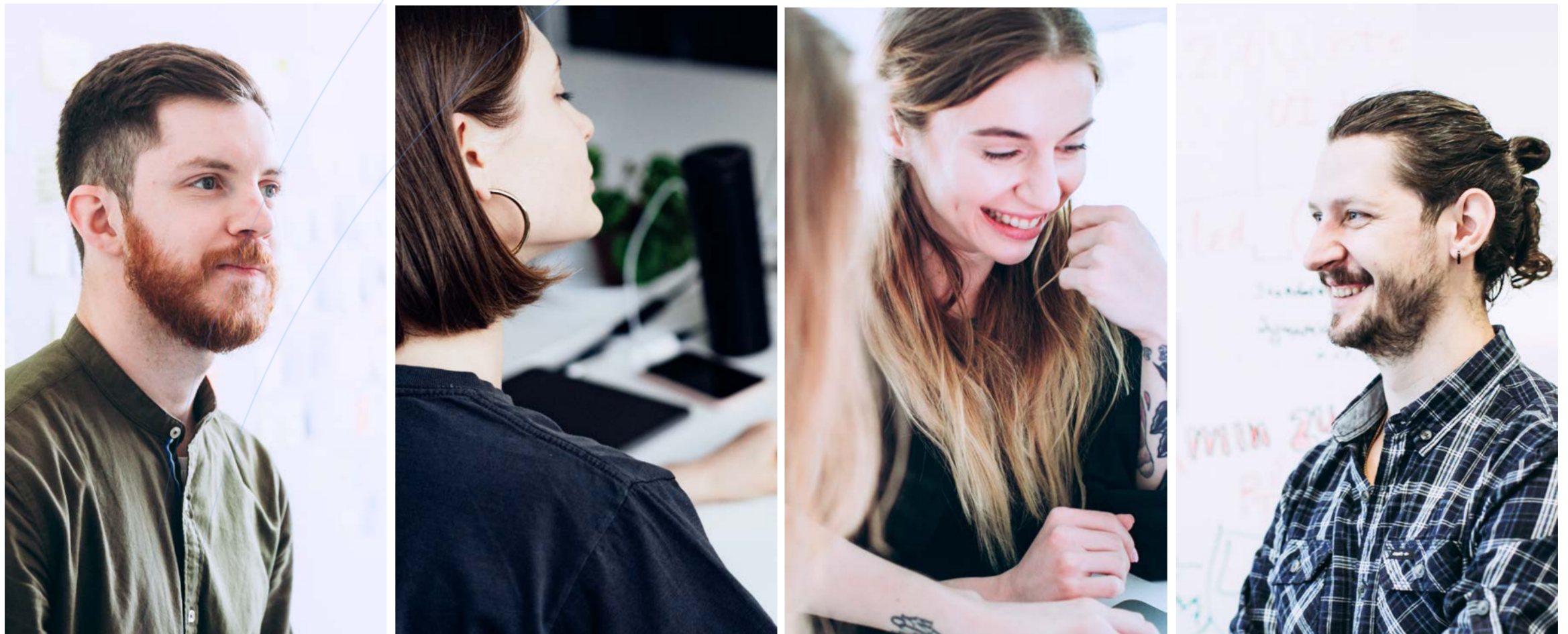


## Privacy and data protection:

Cyber-attacks have been rising significantly in recent years. With a shift to in-home care, we increase the amount of valuable data that's taken outside the "protected" 4-walls of existing healthcare systems. Interoperability and secure data access, sharing and storage must be a priority.



# Choosing the right MedTech and digital healthcare product development partner



## Software-based medical devices are transforming healthcare and fueling an infinite opportunity for healthcare businesses to deliver breakthrough solutions.

With the development of DTx, remote monitoring and other types of software as medical device products, patients have greater autonomy to self-manage care, contributing to improved health outcomes. Simultaneously, they reduce provider burden while informing clinical decision-making through high-quality data and synthesized insights. These among other advancements are facilitating aging-in-place technologies that facilitate the shift to in-home care.

There are so many opportunities to deliver value, many companies are trying to figure out their next move. Building SaMD is a complex process that involves regulatory, product and market considerations that will deeply shape the trajectory of your business.

## Star's HealthTech Practice can support you at every stage of your product development journey.

We offer a unique combination of end-to-end support from regulatory and product strategy through design, engineering and post-market maintenance and product evolution. And, with our custom QMS, our clients have the competitive advantage of immediate documentation, processes and tools necessary to streamline regulatory approval to get to market faster.

**Become a SaMD leader.** Get in touch with our HealthTech Practice to learn how.

Get in touch →



# See Star's HealthTech practice in action

We work with a wide variety of healthcare businesses from early-stage startups such as gMendel and One Concern to established enterprises including ZEISS and Constant Therapy.

**Learn more** in our case studies, podcasts and thought leadership articles.

**Learn more** →



## Geoffrey Parker

As Technology Director, Star HealthTech Practice, Geoff brings over 25 years experience designing and delivering software solutions. Dedicated to healthcare, life sciences and wellness industries, Geoff believes that technology should enhance our lives in a non-invasive manner. He enjoys working with clients to understand their business and user needs, and deliver secure, connected and engaging solutions that address the industry's regulatory requirements and deliver value to all stakeholders.



## Patrick Compton

As Senior Researcher, Star HealthTech Practice, Patrick Compton works with team leadership to ideate, craft and refine communications and content. He focuses on emerging technologies, product strategy and amplifying Star's core strengths as an end-to-end MedTech and digital healthcare development partner.