Digital health solutions and SaMD

Pharma’s five steps for success

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Digital health solutions and SaMD

For those looking to build digital health solutions, Software as a Medical Device (SaMD) is now an essential distinction to be aware of.

While all products classified as SaMD will be digital health solutions, not *all* digital health solutions are classified as SaMD, so it's important to be clear on where the distinction lies.

Put simply, SaMD is (as per the International Medical Device Regulators Forum), "software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device." Software does not however meet the definition of SaMD if its intended use is to drive a hardware medical device or simply fetch data.

Why SaMD is important now

The challenges facing pharma at present are numerous, according to Andrew Wright, Owner of H1 Consulting and former Vice President of Digital Medicine at Otsuka Pharmaceutical Companies:

- Pricing pressure
- How to deal with a post-COVID world
- The need to create value and innovation beyond just further drug discovery
- New commercial models
- The constant need for new patient solutions

SaMD is important in this context, because the types of digital health solutions pharma companies need to create to address these challenges fall increasingly into the classification of SaMD.

Pharma companies stand to gain most by embracing regulated digital health solutions that include SaMD components. While low-level, low-impact solutions, like digital health solutions that focus solely on patient education, onboarding, or initial engagement don't fall into the SaMD category, they no longer drive the value pharma really needs.

Making use of digital health solutions that qualify as SaMD offers the chance to differentiate pharma products in the market by working alongside medication in the management, treatment, and monitoring of diseases. This more than justifies addressing the greater regulatory burden of SaMD.

While the quality and regulatory environment for digital solutions is distinctly different to traditional medication, pharma should not be put off. The specialist regulatory expertise required is available through partnering with specialist digital health firms, and doesn't need to be built from scratch within the organization.

The benefits of SaMD for digital health

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While digital health solutions classified as SaMD are often more complex to develop, embracing these solutions offers a series of significant benefits, including:

Improving treatment outcomes, since SaMD solutions are more likely to play a direct role in the care of an individual compared with other unclassified digital health applications

Increasing confidence among clinicians, and thus increasing adoption as a result when compared with non-regulated digital health options

Providing greater reassurance to patients that these solutions are regulated, safe, and appropriate to use, building trust in digitally-delivered treatment elements

Differentiating pharmaceutical treatments by combining them with digital solutions that influence outcomes

Supporting holistic management of conditions by helping to manage symptoms and comorbidities

Furthering research and insights on disease trajectory by capturing standardized, real-world data across regions

Supporting reimbursement with real-world data, and improving engagement with payors and healthcare providers as a result

To fully realize these benefits, we've outlined our top five steps to help pharma succeed when embracing SaMD and delivering more in-depth digital health solutions.

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Five steps to successful SaMD

Define intended use early

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What is intended use?

The ‘intended use’ is a clear statement of intent of a given SaMD solution. It determines the regulatory process your product will need to go through, as well as the burden of evidence you’ll be required to submit to substantiate the claims you make about your product.

While it’s a familiar concept to pharma, the reality of development is very different for SaMD compared with traditional pharmaceutical products. Caroline Beaufour, Project Director at WeHealth™ Digital Medicine, the e-health division of the Servier Group, explains: “In pharma, intended use for drugs and medications is fixed during the clinical trial phase and only changes as a result of new clinical trials to validate its suitability for new indications. With digital health solutions, however – including SaMD – there will be changes based on patient and clinician feedback and experience, and as technology evolves.”

Why is it important?

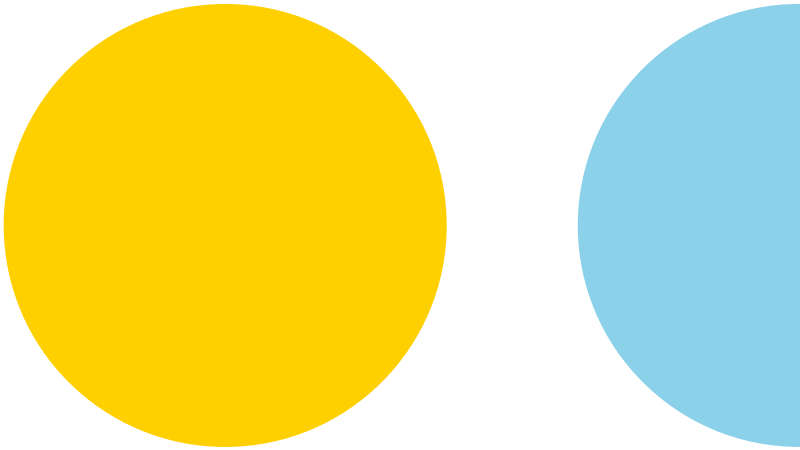
According to Jim O'Donoghue, President at S3 Connected Health, "Intended use is important because the specific regulatory classification and pathway your product must follow will significantly impact your planning and go-to-market approach: the difference between getting a class I and class II medical device to market could be nine months or more, for example." As such, it's important to clarify the intended use of your product as early as possible.

How should I go about it?

The intended use is determined by anything the manufacturer communicates about the use of a device, including in instructions for use or in promotional or sales materials. To prevent problems further down the line, it's important to be entirely accurate and consistent around the intended use itself, as well as how you *communicate* the intended use of your product.

"Intended use is important because the specific regulatory classification and pathway your product must follow will significantly impact your planning and go-to-market approach: the difference between getting a class I and class II medical device to market could be nine months or more, for example."

Jim O'Donoghue,
President of S3 Connected Health



Impact of intended use

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Intended use impacts a range of different considerations for pharma companies:

Business model

If the intended use of a solution means it must be classified as SaMD, it will cost more to create, commercialize, and operate. On the other hand, these costs can serve as a useful barrier to entry for competitors. If a solution is classified as SaMD due to clinical claims, those same clinical claims can also open avenues to reimbursement for pharma companies.

Overall solution

Intended use will impact how you develop the solution and what standards you follow. Once the solution is in the market it means you have regulatory responsibilities to monitor it, and ensure that it is being used and having the effect that is expected.

Service design

Intended use influences the claims that you will look to make, whether clinical claims, efficiency claims, or health economic claims. Any claims will influence how the solution is used in the delivery of care, and what obligation it places on clinicians using it.

Care pathway integration

Intended use determines exactly what the function of a solution is, and thus where it fits in the care pathway and who will operate it. Conversely, a lack of clarity can make the use case unclear, making it difficult to get clinical and patient adoption.

Post-launch management, surveillance, and operation

If intended use means a solution qualifies as SaMD, post-market surveillance is required. Exactly what needs to be monitored will be determined by both the stated intended use and the risk of patient harm.

Changing intended use

Digital health products can – and often do – go through multiple iterations. Should your SaMD go through multiple iterations, it's crucial to consider if new functionalities alter the original intended use of the product. If so, there could be significant implications:

Key takeaways for pharma

1. **Plan ahead** and be aware that responding to user needs may trigger changes in classification. A rigorous assessment of unmet needs before development really pays off here.

2. **Develop software that may eventually function as SaMD as if it were SaMD ready.** This means you have the option to develop the product into a SaMD later, without having to start the process again, saving time and money.

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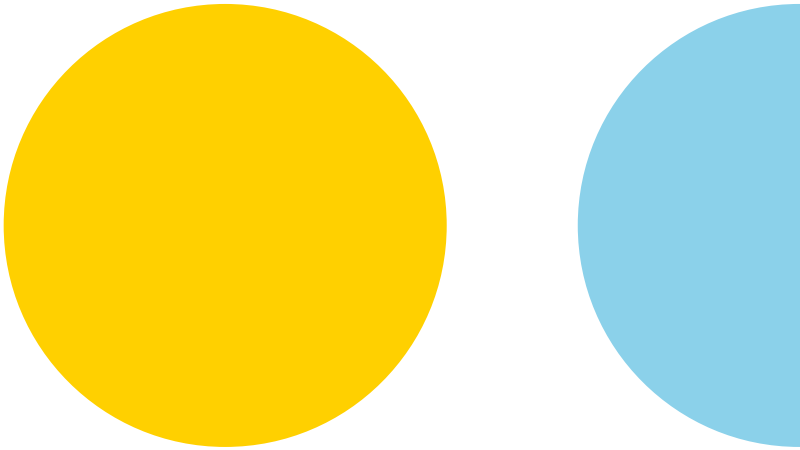

Choose where you'll launch first carefully

Why does it matter which market I launch in?

It's important to decide where your solution should launch first, because this will determine the specific regulatory guidelines under which your SaMD will be classified, as well as which reimbursement models – if any – are open for your product.

It's also important to consider data privacy regulations and how they differ between markets. For example, in the EU you will be subject to GDPR, while HIPAA will apply in the US. Local laws in each member state must also be considered, such as the California Consumer Privacy Act (CCPA) in California or Germany's Digital Healthcare Act (DVG).

How should I decide which market to launch in?

The best region to launch your solution in will vary based on your individual business needs and concerns.

Caroline Beaufour from Servier Group explains: “When choosing where to first launch their SaMD solution, pharma companies need to look beyond market size and drug prices, not simply prioritizing regions that are a commercial focus for them, but favoring countries based on the government’s maturity and open-mindedness to embracing digital health.”

With that in mind, Hans-Peter Frank, Founder and CEO of T-S-P Health GmbH – who has also held senior roles in pharma and medtech companies like Novartis, Pfizer, Fresenius Medical Care, and Vifor Pharma – outlines a selection of markets and why they may prove useful starting points for pharma companies:

The United States: Specific processes for SaMD

“The United States is attractive because the FDA has a specific department and resources to deal with SaMD, so the regulatory authorities are much more familiar with the challenges involved in the process.

“While it’s easier to leverage an existing medical device pathway for an SaMD solution than start completely from scratch, pharma companies will still need to find the right way to approach the relevant regulatory requirements.”

Singapore and South Korea: Gateway markets

“South Korea and Singapore are markets that are particularly open to SaMD and other innovative ways of demonstrating value. They’re something of a gateway market, and a valuable testing ground: if you succeed in these markets, it’s far easier to move onto others like EMEA and South America.”

Germany: Potential for reimbursement

“Germany has specific regulations for SaMD reimbursement managed by BfArM following the DiGA process; these have existed for the past year and a half. The possibility for reimbursement is no doubt attractive to pharma companies; however, as of May 2021, with only 15 such devices approved in the past 18 months (and 24 currently being processed), it’s still a slow process.”

Plan your regulatory roadmap

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Why do I need a regulatory roadmap?

According to Caroline Beaufour, “While pharma is well-versed in regulatory compliance in the context of a prototypical regulatory roadmap for medications, a particular skill set is required to tackle digital health regulations because versioning of the digital product is part of its life cycle management and has to be considered accordingly to regulations. It’s a totally different playing field.”

While the requirements for SaMD development are reasonably consistent due to the widespread use of standards such as ISO 13485 (quality management system), IEC 62034 (medical device software development) and ISO 14971 (medical device risk management), a regulatory roadmap should also consider items such as:

Regulatory roadmap considerations...

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- Market-specific approaches to SaMD classification, e.g. FDA's Clinical Decision Support Software guidance, EU MDCG guidance on qualification, and classification of software under the MDR.
- Whether or not a clinical investigation will be required to assess the safety and performance of the SaMD.
- Timeline and cost of various market approval pathways, e.g. EU CE marking including notified body assessment for higher than Class I SaMD, US 510(k), or potential De Novo for novel SaMD.
- The rapidly evolving approach to SaMD regulation, e.g. the recent FDA Artificial Intelligence/Machine Learning Based SaMD Action Plan and the EU proposal for a new regulation laying down the legal framework on AI.
- Additional requirements for SaMD reimbursement that are typically country-specific, e.g. requirements for Interoperability, Data Protection, Data Security, and Cybersecurity as required for DiGA approval in Germany.

"It's important to have this in place from the start, as the overall product development and approval timeline can vary significantly depending on the applicable regulatory classifications, from as little as a few months for unregulated devices, to more than two years for the most stringent categories."

Marzena Tabaka,
Quality Manager at S3 Connected Health

With that in mind, working to a clear regulatory roadmap is essential for ensuring you know exactly what is required, how it needs to be done, and how long it will take to roll out your SaMD solution.

It's not enough to think about the first version of your product alone. As mentioned above, changing intended use and/or classification at a later stage can be complex and costly, so you need to think about the entire roadmap throughout the product life cycle.

What does a regulatory roadmap look like?

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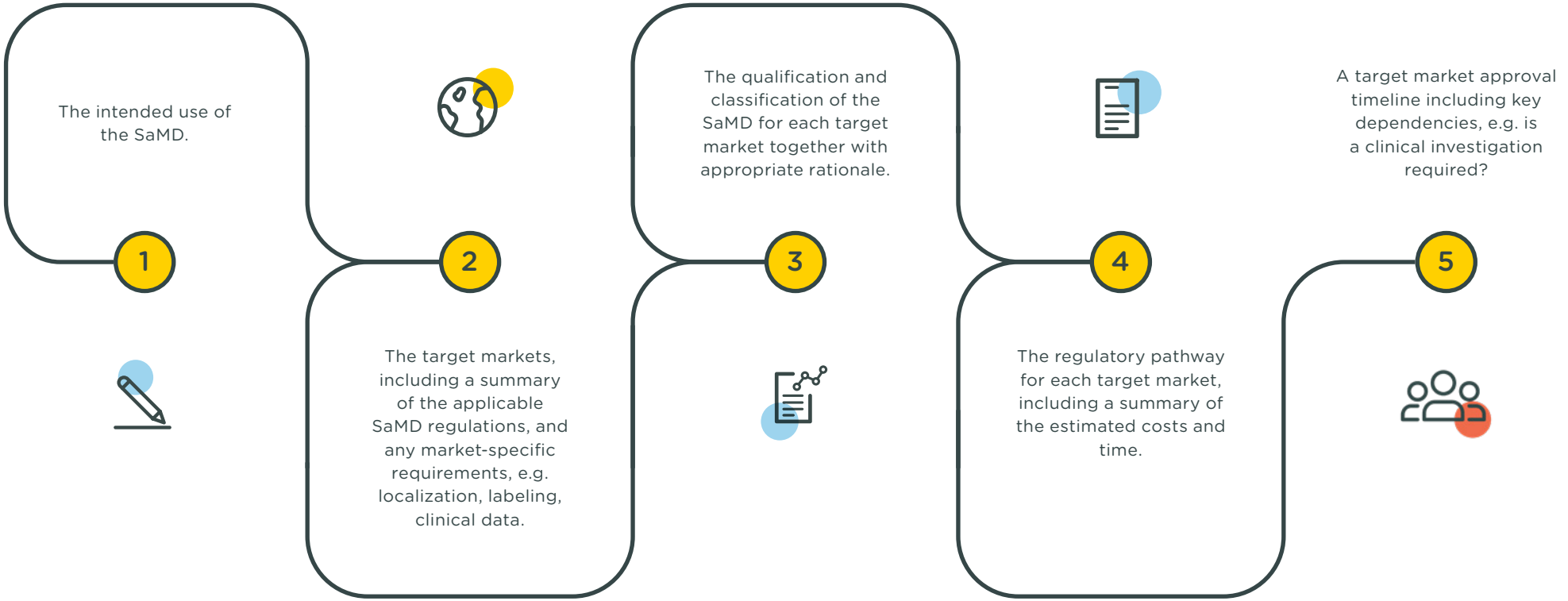
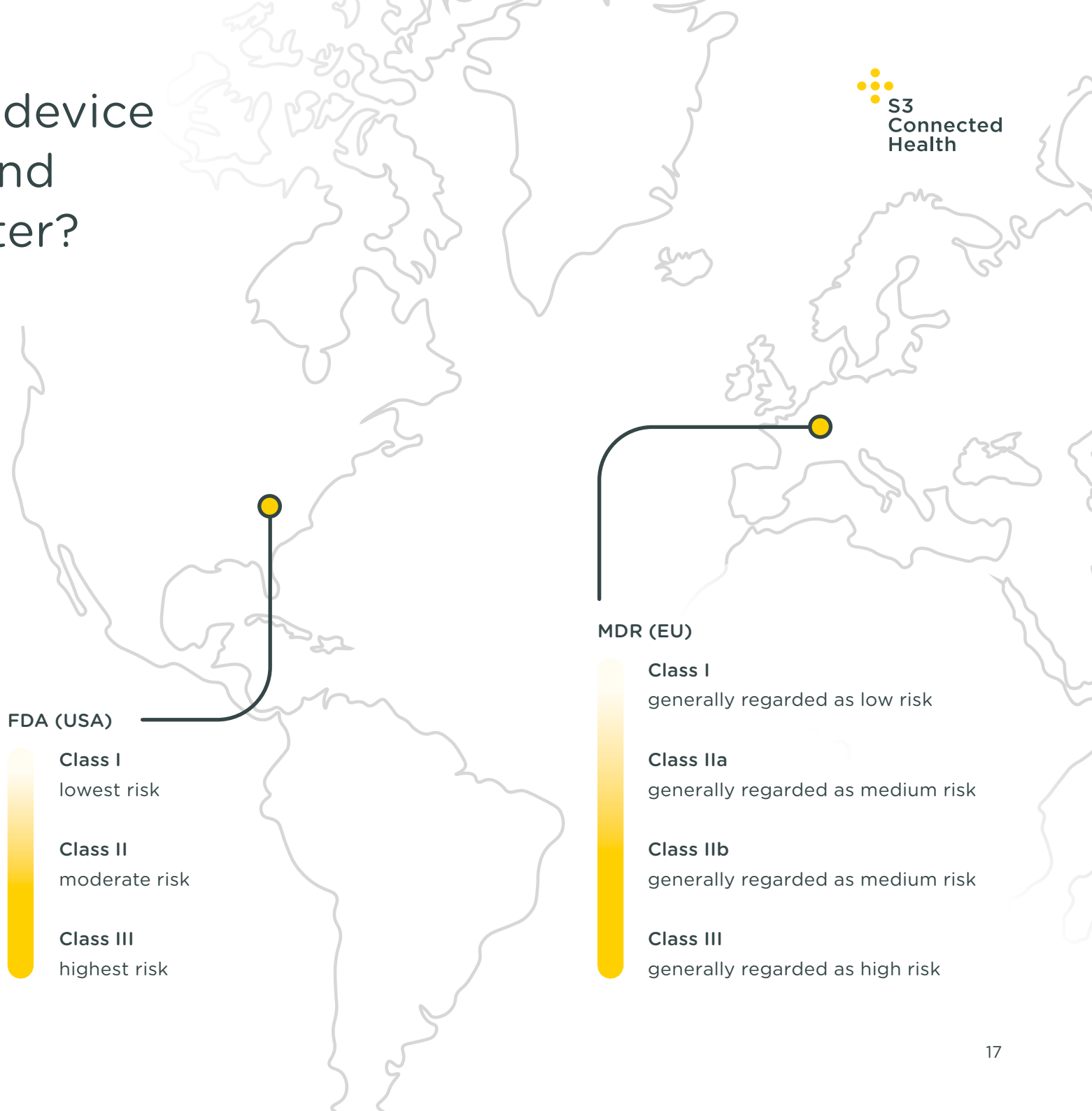
A regulatory roadmap should include the following:



What is medical device classification – and why does it matter?

SaMD classification is based on its intended use, the claims it makes, and the potential risks it presents to patients and users. Typically, the higher the classification, the more evidence required to validate your SaMD claims.

The diagram to the right offers a summary on how regulatory and evidential requirements increase depending on device classification:



FDA (USA)

Class I
lowest risk

Class II
moderate risk

Class III
highest risk

MDR (EU)

Class I
generally regarded as low risk

Class IIa
generally regarded as medium risk

Class IIb
generally regarded as medium risk

Class III
generally regarded as high risk

Consider the potential of platforms to reduce risk and accelerate your time to market

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What are platforms and how can they help?

Digital health platforms are technology infrastructures designed to be used across multiple solutions. They provide core services that are common across digital health solutions so that these don't need to be re-implemented each time. For SaMD solutions, the underlying platform should support key regulatory requirements around security, data management, and medical device regulations.

Platforms can be created internally by pharma, but, more commonly, pharma works with partners who have an existing platform, which can then be leveraged when building an SaMD solution.

Vitaliy Myskov, Mobile and Embedded Solutions Manager at S3 Connected Health says that, "By incorporating third-party components and existing platforms into their SaMD, pharma companies can speed up the development process and shorten the path to market. With less time spent on creating features that already exist, pharma companies can focus on the strategic aspects and core business logic of a given application."

By using third-party products created by those with a given expertise in the market, you can be assured of the end quality of the product.

What should I look for in a platform?

The goal of a platform is to reduce risk, cost, and time to market. Typically, however, a platform is only as good as the team using it to build the solution. Pharma companies should take a holistic view of the solution, leveraging the benefits of the platform while also considering the end-to-end regulatory, security, and data requirements.

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Example of a platform: S3 Connected Health's Affinial

Affinial is our cloud-based platform that sits at the core of the digital health solutions we create for our pharma partners. It serves as a foundation for a range of custom-built SaMD solutions involving patient applications, clinician portals, and wearable devices. Developed based on IEC 62304 and following our ISO13485 quality management system, solutions deployed on this platform are operated under our ISO 27001 certified information security system.

The Affinial platform

- Developed using IEC 62304
- Supports the creation of Class I,II, and III SaMD
- Supports integration of third-party services and devices
- Provides common services that are required for SaMD solutions
- Supports cybersecurity standards for medical devices
- Supports GDPR and HIPAA requirements for information management
- Reduces risk, cost, and time-to-market for SaMD solutions

Don’t try to do everything in-house

Why should I partner with a specialist firm?

Acquiring the expertise to develop, launch, and operate SaMD is a daunting task for most pharma companies. It’s also not the most efficient route to take. As Jim O’Donoghue explains, “Building all the quality systems, capabilities, and other functionalities internally can often take a number of years. With a need to show ROI as early as possible when venturing into digital health, this just won’t work for pharma companies.”

Outsourcing development alone won’t get the best results, either. But pharma companies without the relevant SaMD capabilities and ISO 13485 in place can still create SaMD solutions by picking a highly-qualified specialist partner, and even considering the option of the partner taking on the role of legal manufacturer.

The takeaway is clear: for the best results, don’t go it alone. As Hans-Peter states, “There’s an element of risk taking and trial and error in any new undertaking. But I’ve seen many pharma businesses attempt to manage the process of creating a SaMD solution by themselves, only to realize just how different it is from their current operating model, and have to start again. Truth be told, no pharma company does this successfully on their own.”

What impact does working with a specialist partner have?

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Partners can often manage the entire end-to-end process of creating a digital health tool, from defining the overall strategy and value proposition, to requirements management, proper clinician and patient engagement, intended use, development, clinical validation, registration, legal manufacturer services, and even commercial operation and evolution of product over time.

That's particularly valuable for pharma companies. Hans-Peter notes, "Working with a partner that manages the whole value chain offers a distinct advantage to pharma companies. No company wants multiple regulatory and compliance systems, and pharma companies are turning more and more to those who offer the whole package, rather than very specialized providers in fields like data visualization and data management.

"While these areas are important, first and foremost, you need to get your product out on the market as efficiently as possible. The best way to do this is by working with a partner that understands the whole process, from start to finish."

By leaning on a trusted partner, you can avoid common mistakes (and the large investment required to make them) and overcome any challenges that arise much more quickly. The end result is a faster time to market, greater value, and better outcomes for patients and clinicians.

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Hans-Peter Frank,
Founder and CEO of T-S-P Health GmbH,
CBO of Artha AG

What kind of partner should I look for?

According to Andrew Wright, “You need to have a partner with the right expertise and the right standards to minimize risk. Most pharma companies don’t have that internally, and so they’d be wise to work with companies that have considerable capabilities, experience, and proven bench strength, especially in the product development cycle, as they will have to continue to develop and tweak existing products throughout their lifetime.”

Partnering with a specialist firm is the best option for pharma, and pharma companies should look for a partner that can manage the entire end-to-end process and fill the expertise gaps in their organization, ensuring they avoid potential pitfalls the first time around.

But not all development partners are equal. With that in mind, here are some considerations pharma should bear in mind when searching for the right development partner:

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Partner checklist for digital health solutions and SaMD

- Can the partner company take regulatory responsibility and possibly become the legal manufacturer of the product?
- Do the teams in question (internal and external) have the right certifications? (ISO 13485 etc.)
- Can the partner be trusted to manage your data?
- Who’s going to be the data controller and data processor?
- Do the partner’s organizational culture, processes, and ways of working align with yours?

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Conclusion

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Building a digital health solution that's classified as SaMD offers many benefits for pharma.

Unlocking those benefits, however, can be complex, and with the shift in regulatory boundaries affecting what is and isn't SaMD, pharma needs to improve its understanding of what's involved, and what support they need.

That doesn't mean pharma companies need to know *everything* about SaMD. By knowing enough to create the right solution and select the right partner, pharma can leave the creation – and other complex elements of the process – to the relevant experts.

That said, time is of the essence. With most pharma companies interested in more complex solutions, and digital health tools becoming a key differentiator in the market, it's vital you take the right steps to prepare now and get ahead.

Contributors

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About S3 Connected Health

S3 Connected Health creates digital health solutions and digital therapeutics that improve the lives of people with acute and chronic conditions.

We have delivered award-winning, regulatory-compliant solutions across 20 therapy areas and in more than 50 countries. Our scalable and secure solutions improve disease management and capture real-world data to support access, reimbursement, and value-based care.

S3 Connected Health supports our partners in pharma at all stages of their journey; from discovery through to product creation and commercialization of digital health solutions that fit corporate and brand commercial strategies.

For more information visit
www.S3ConnectedHealth.com