



Preparing for the Regulatory Challenges Wrought by Software as a Medical Device

As the digital health ecosystem proliferates, medical device manufacturers need to protect themselves from regulatory risk caused by a single line of wrong or misplaced code contained in SaMDs. Here's how to get started.

EXECUTIVE SUMMARY

We live in a world incessantly disrupted by digital. For every physical activity or object, there is a digital component. Take a basic necessity, such as walking. It is now shaped by digital: Individuals can track their steps, count calories burned and recalibrate their exercise regimen to ensure a healthier lifestyle.

Digital's impact in the personal health space is so enormous that it has given birth to new devices such as wearable computers, health apps and sensors, which not only can provide insights to take actions that improve well-being, but also enable individuals to connect, communicate and share health status in real time with family, friends and health professionals. This gaining and sharing health-related insights in digital form in real or near-real time has propelled the "digital health" movement - central to which is software.

In the digital health scenario, software is not only tied to hardware as an embedded component but also has the ability to be hardware agnostic (think apps), where it can interconnect and integrate with other devices on internal and public data networks. It also can be executed and deployed over the cloud, and hence can enable multiple possibilities to access and execute specific health-related tasks. However, these possibilities entail risks to life and as such are a key item for medical device companies' regulatory watch agendas.

This is not to say that software used today in medical devices is not regulated. It is. But because software is embedded into hardware, medical device manufacturers often do not plan for scenarios such as:

- Over-the-air updates and mass distribution.
- Different behavior or response on varied hardware platforms.
- Operating system version dependency for subsequent releases.
- Copies installed multiple times at multiple locations.
- Frequent uninstall and reinstallation in the case of lag, latency or crash.

If any of the aforementioned scenarios occurs, there is a direct threat to life - which is not acceptable. So rules are required to govern these scenarios. And these rules take the form of regulatory frameworks and guidance designed to ensure that when a manufacturer creates a product or service as an app in a smartphone, or enables a smartphone to be used as an independent medical device like a blood glucose meter, there is no risk to life.

And in line with this view, the International Medical Device Regulators Forum (IMDRF), which includes the U.S. Food and Drug Administration (FDA) as a member, has released guidance¹ on software as a medical device (SaMD) for public consultation before publishing the final version, expected in March 2017.

This white paper is intended to help medical device manufacturers understand SaMD, evaluate its impact on quality management systems (QMS) and embrace the shift in their business environment. One caveat: This white paper should not be considered or perceived to be legal advice. Rather, it presents directional guidance and offers new business models to help medical device companies transform and remain relevant in the digital health age.

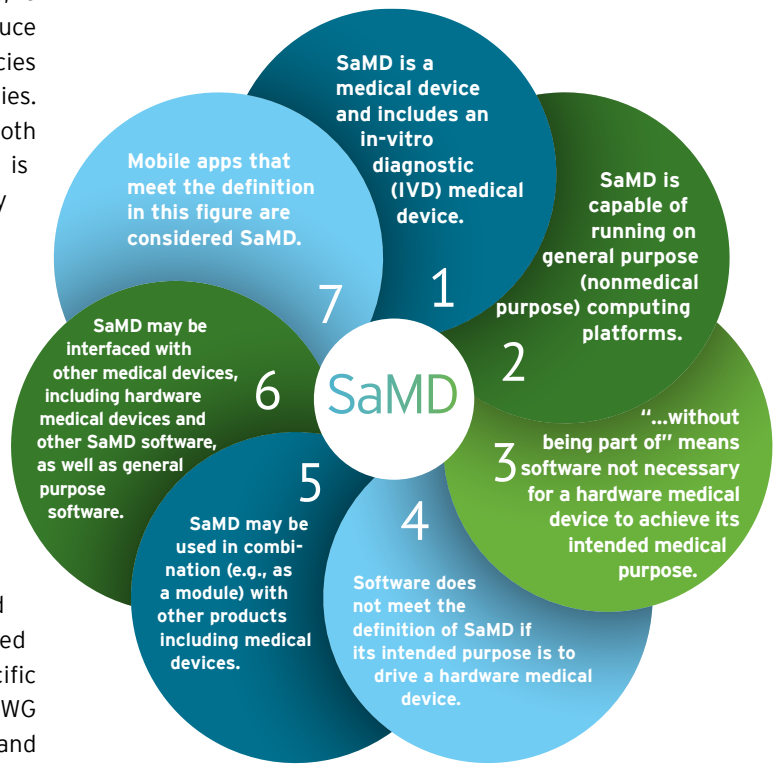
SAMD: BEYOND ACRONYMS

Let's set the context right. The IMDRF, formerly the Global Harmonization Task Force (GHTF), is chartered to promote harmonization and reduce differences in medical device regulatory policies among regulatory agencies across geographies. To do so, it is incorporating inputs from both industry and regional bodies. Hence, IMDRF is managed by committee, comprising regulatory officials from Australia, Brazil, Canada, China, the European Union, Japan, Russia, and the U.S. (the FDA, as mentioned above).

As part of its activities, and to address ever-changing scenarios where software has transformed digital health beyond its initial embed in hardware, the IMDRF formed an SaMD Working Group (WG). This WG focuses on software's evolving role in digital health, and has established foundational principles, a harmonized vocabulary and a list of acknowledged specific considerations applicable to SaMD. The WG works to further address the concerns and unique challenges of manufacturers and regulators, as reflected in the issued draft guidance on SaMD (which has been released for comment by participating members).

The IMDRF SaMD WG defines² SaMD as "software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device." Figure 1 expands on these purposes and offers examples within the context of SaMD's defining principles.

Figure 1: SaMD Definitional Principles



It is important to note that for SaMD, the term "intended use/intended purpose" is the objective intent of the manufacturer regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer.³

MEDICAL DEVICE GOVERNING CLASSES

The FDA defines⁴ a medical device as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory that is:

- Recognized in the official National Formulary, or the U.S. Pharmacopoeia, or any supplement thereof.
- Intended for use in the diagnosis of disease, or other conditions, such as the cure, mitigation, treatment, or prevention of disease, in humans or animals.
- Intended to affect the structure or any function of the body of humans.

Further, the FDA classifies medical devices in three classes:⁵

- **Class I:** Devices that are deemed to be low risk and are therefore subject to the least regulatory controls.
- **Class II:** Higher-risk devices than Class I which require greater regulatory controls to provide reasonable assurance of safety and effectiveness.
- **Class III:** Generally the highest-risk devices which are therefore subject to the highest level of regulatory control. Class III devices must typically be approved by the FDA before they are marketed.

For SaMD, those classifications remain the same except with the addition of a novel category, Class IV:⁶

- **Class IV:** These devices which are vital to avoiding death or serious deterioration of health issues.

Class IV is currently limited to SaMDs; there is no hardware classification at this time.

As SaMD's availability, uniqueness and application vary frequently, further breakdown is required to clearly differentiate the four categories.

There are two key criteria that help to break down SaMD classifications (as shown in Figure 2, next page):

- **Significance of the information provided by SaMD to the healthcare decision.** This is classified into categories such as:
 - » To treat or to diagnose.
 - » To drive clinical management.
 - » To inform clinical management.
- **State/impact of the healthcare situation or condition.** This is classified into categories such as:
 - » Critical.
 - » Serious.
 - » Nonserious.

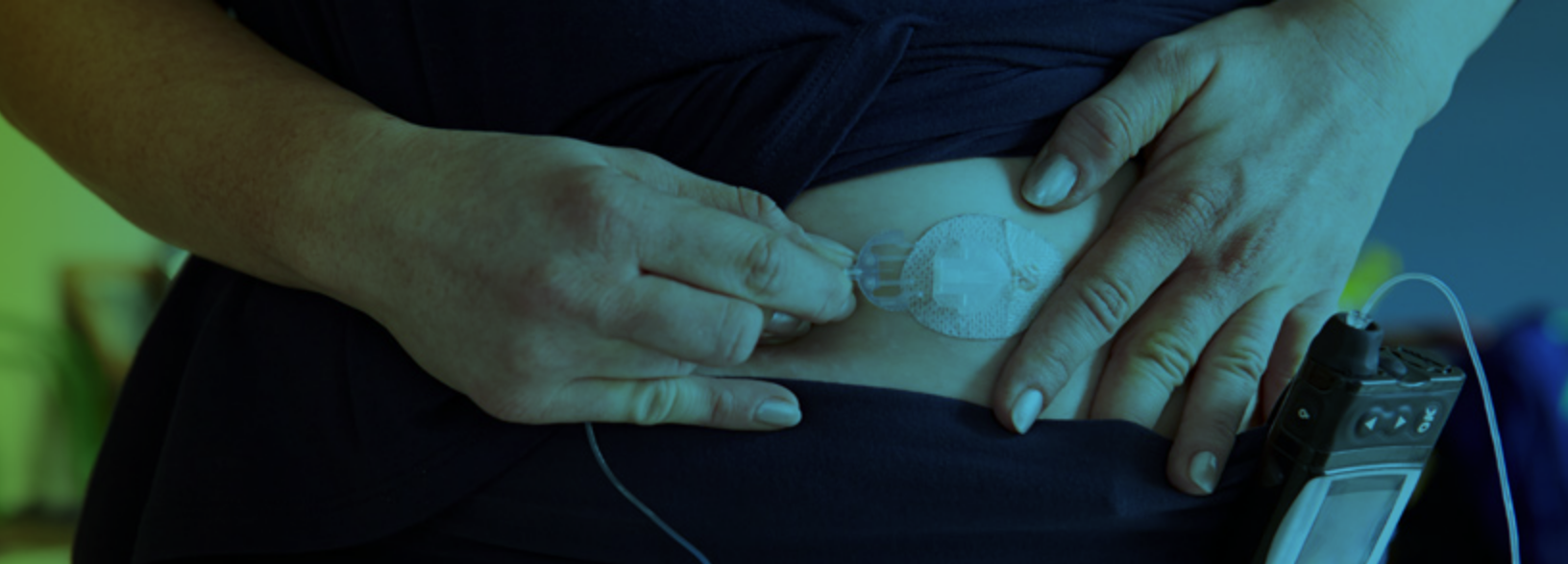


Figure 2. SaMD Classification

State of Healthcare situation or condition	SIGNIFICANCE OF INFORMATION PROVIDED BY SaMD TO HEALTHCARE DECISION		
	TREAT OR DIAGNOSE	DRIVE CLINICAL MANAGEMENT	INFORM CLINICAL MANAGEMENT
CLINICAL	CLASS IV.i	CLASS III.i	CLASS II.i
SERIOUS	CLASS III.ii	CLASS II.ii	CLASS I.ii
NON-SERIOUS	CLASS II.iii	CLASS I.iii	CLASS I.i

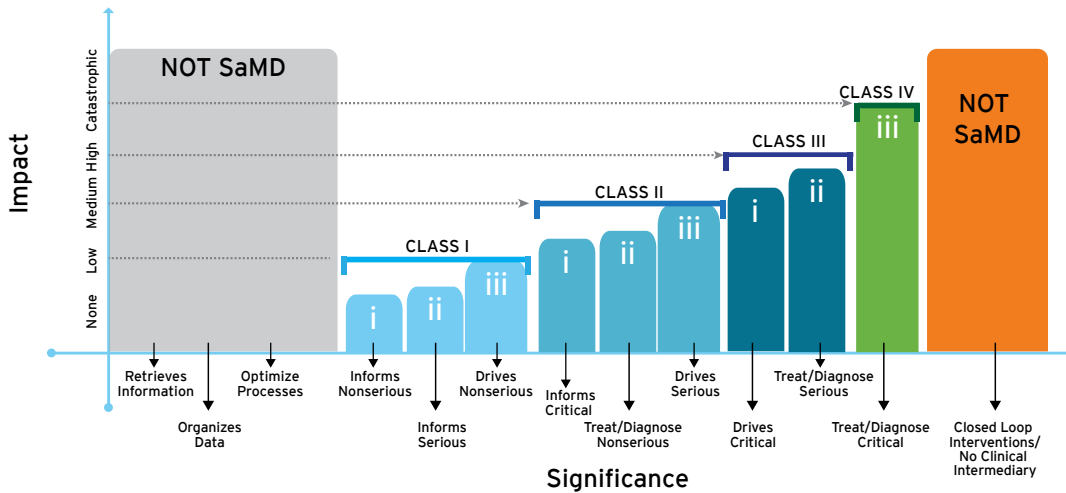
i represents significance of information provided by SaMD.

A complete holistic view, with reference from the draft guidance,⁷ is represented in Figure 3 (next page).

Want examples of what an SaMD is *not*? Here are some:

- Digital copies of medical dictionaries, emergency care information, surgical training videos, etc.
- Apps used only to log, record, track, evaluate, or make decisions or suggestions related to developing or maintaining health and wellness, as long as those decisions or suggestions are not intended for curing, treating, seeking treatment for mitigating, or diagnosing a specific disease or health condition.
- Apps that automate general office operations
- Software/apps as part of an “embedded item” with hardware not part of SaMD classification.
- Apps that allow healthcare providers to communicate in a secure and protected method (e.g., using a Health Insurance Portability and Accountability Act (HIPAA) compliant app to send messages between health care providers in a hospital).
- Apps that perform simple calculations routinely used in clinical practice (e.g., determining body mass index).

Figure 3. Holistic View: SaMD Device Class, Significance & Impact



ALIGNING QMS WITH DIGITAL HEALTH NEEDS

QMS in medical devices focuses on three primary parameters:

- Safety and efficacy.
- Risk management.
- Design protocols.

These elements govern the product development process throughout the device lifecycle. And there are clear rules and regulations to help manufacturers build the intended medical devices.⁸ However, the challenge with current regulations is that they are more focused on software that is embedded in dedicated hardware and is part of the diagnostic or treatment process while in the hands of a specialist.

The situation with SaMD is different. Software now powers mobile apps or software products/platforms that are deployed on the cloud, are not dependent on hardware and can be improved with frequent updates.

A recent report⁹ noted that there are more than 165,000 mobile health apps as of today, and this number is going to only increase significantly in coming months. It is fair to assume that not all of these mobile health apps will originate from traditional medical device manufacturers. Instead, most are likely to be the brainchild of a software company looking to enter the digital health space.

And in an effort to build a competitive product focused on consumer features and a comfortable user interface, there is a strong possibility that the three key parameters - safety and efficacy, risk management and design protocols - could be overlooked. This means that a mobile app manufacturer may be following the software development lifecycle process but may not be fully aware of QMS for medical devices. Hence, there is a risk.

Because mobile apps are critical to digital health, their evolution is changing the way health products and information are built and delivered. As a result, multiple QMS challenges have arisen for SaMD manufacturers, including the following:

“A mobile app manufacturer may be following the software development lifecycle process but may not be fully aware of QMS for medical devices.”

- How should an SaMD address an update issue in the event of poor network zones where the only update option is via insecure wireless technology?
- With frequent operating system version updates, the support of earlier versions is eventually decommissioned. How would an SaMD manufacturer address this?
- How would users be informed about updates or decommissioning of support? What communication channels should be used?
- What happens to data in the event of decommissioning or an update? What are the risks and backup mechanisms?
- How should an SaMD manage and address complaints, incidents, support, and technical issues and inquires? What are the control and governance mechanisms?

CONTENDING WITH DIGITAL HEALTH'S SHIFTING BUSINESS MODELS

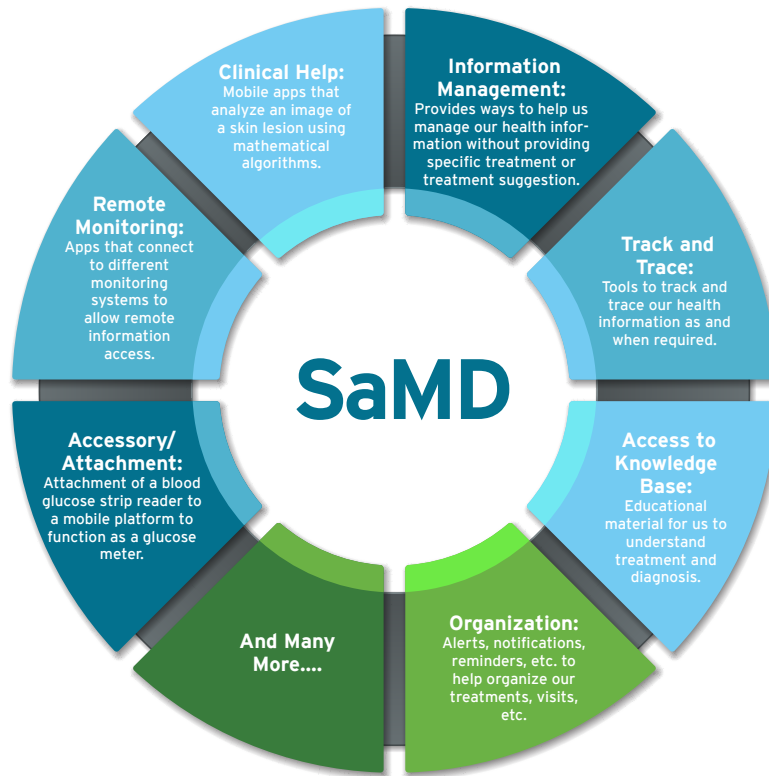
Digital health is having a major impact in the medical health industry. A recent report found that funding of digital health deals in 2016 alone amounted to a total of \$2.6 billion.¹⁰

These results clearly show not only the direction but also the attention digital health is receiving. Figure 4 (next page) offers a selective view of the landscape such deals cover.

Not only are these deals causing a shift in traditional medical device companies' business models and the business landscape, but it is raising four key concerns for industry players:

- **The shift in the operating model** is now compounded by the emergence of digital apps that could eat into revenues. The traditional market will soon be surrounded by new players that do not operate in silos. Sticking to the old formula of building a device and hoping for the best is not sufficient for success. Rather, plugging into the digital health ecosystem is equally important for maintaining market relevance.
- **The shift in time to market** wrought by digital has shattered the myth that only hardware or embedded focused medical devices can make money. The flood of digital apps in the marketplace, as well as their ability to deliver basic services via more frequent updates, has challenged traditional players to keep pace.

Figure 4. SaMD Landscape Offerings: Where the Money Is



- **The shift in the married-to-a-platform approach** has opened doors to cross-platform compatibility; hence, support for digital apps must be provided for most of the leading platforms.
- **The shift in customer acquisition** is from a model in which medical device makers deploy manpower to sell their device to the use of a digital platform to quickly reach a large and growing customer base. If a product can be launched with a digital companion, then marketing can be quickly and cost-effectively enhanced. No longer will device makers need an army of representatives visiting hospitals. Now, even hospitals can order online and have trial versions shipped to their door.
 - » **Case in point:** The first continuous glucose monitoring (CGM) mobile system for diabetes management was recently approved by the FDA.¹¹ The “non-adjunctive” indication enables

the use of the CGM system as a replacement to painful fingerstick glucose testing for diabetes treatment decisions. Fingersticks are needed only once every 12 hours to calibrate. The FDA’s approval of the mobile CGM system as the first and only medical device for non-adjunctive indication represents a new era in diabetes management.

Moreover, the FDA also cleared 36 digital health apps in 2016,¹² sending a clear message that it is time for the industry to rethink traditional models and embrace digital health.

LOOKING FORWARD

As the industry transitions to SaMD, we believe medical device manufacturers must consider the following:

- Offering a digital twin to conventional devices is more of a necessity than merely nice to have.

- Consumers on mobile devices demand access to information; therefore, medical device manufacturers need to draw the balance between what to expose and what not to expose.
- Privacy laws and storage of information are becoming more pertinent than ever.
- SaMD business models are taking money from traditional players, and going digital is the survival key for life sciences organizations.
- SaMD models are likely to be impacted by cybersecurity laws and challenges that could pose a threat to their business and revenues.
- Embedded medical devices will still be in demand as they are required for treatment and diagnosis of critical conditions. However, consumers will want information to be delivered on demand to their mobile devices.

Epilog

2016 has been a year of multiple releases by the FDA - some in draft form, others as final guidance. With its draft guidance to allow patients to gather their health data directly from

medical device manufacturers in addition to their health providers,¹³ the message has been a consistent one of alignment with the digital health regulatory environment. We expect to see new regulations with revisions to existing rules to accommodate digital's sweeping impact.

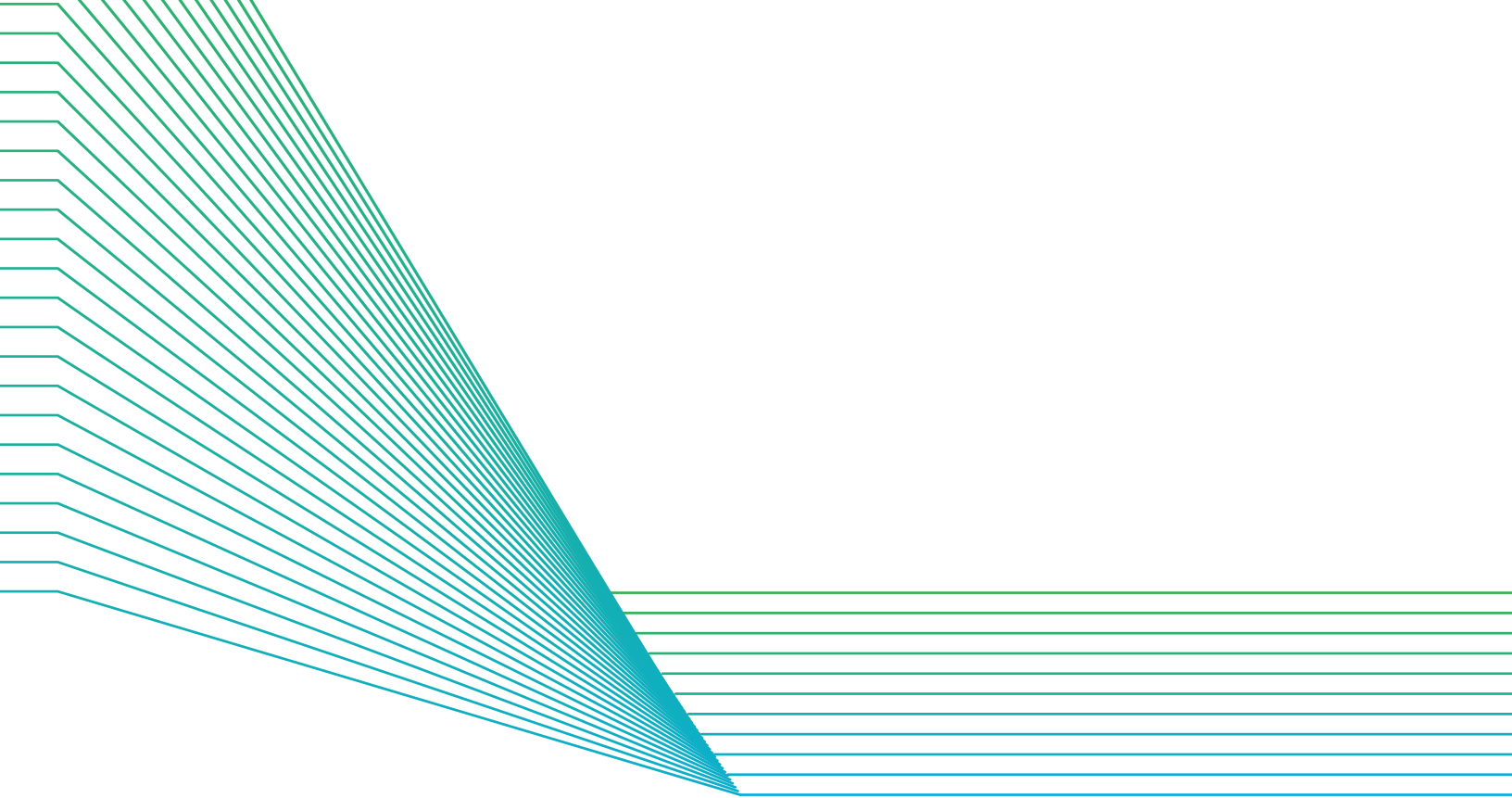
SaMD will forever change the landscape and set a course for good. At the same time, there are new threats such as cyberattacks, and manufacturers must focus on patient safety and life while maintaining or extending their devices' robust product features and functionality.

Rules governing SaMD will be in effect by March 2017. This should serve as a wake-up call for all manufacturers to speak the same language, along with providing the clinical evidence required to extend their SaMD from the U.S. market into geographies such as Brazil, Russia, China, etc. SaMD is also changing the rules for insurance providers and mobile device manufacturers. A recent example of building a collaborative mobile health platform in the wellness space has set an industry precedent.¹⁴ This deal has helped build a foundation to deliver on SaMD's long-term potential.



FOOTNOTES

- ¹ “Software as a Medical Device: Clinical Evaluation,” Federal Register notice, Oct. 14, 2016. <https://www.federalregister.gov/documents/2016/10/14/2016-24805/software-as-a-medical-device-clinical-evaluation-international-medical-device-regulators-forum-draft>
- ² “Software as a Medical Device (SaMD): Clinical Evaluation,” SaMD WG proposal, Aug. 5, 2016. <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM524904.pdf>
- ³ Ibid.
- ⁴ Medical device definition, U.S. FDA. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051512.htm>
- ⁵ “Classify Your Medical Device,” U.S. FDA. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/>
- ⁶ Op cit. footnote no. 2.
- ⁷ Op cit. footnote no. 2.
- ⁸ Overview of Device Regulation, U.S. FDA. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm#qs>
- ⁹ “New report finds more than 165,000 mobile health apps now available, takes close look at characteristics & use,” *iMedicalApps*, Sept. 17, 2015. <http://www.imedicalapps.com/2015/09/ims-health-apps-report/>
- ¹⁰ Heather Mack, “All the digital health funding MobiHealthNews covered in 2016,” *MobiHealthNews*, Dec. 26, 2016. <http://www.mobihealthnews.com/content/all-digital-health-funding-mobihealthnews-covered-2016>
- ¹¹ “FDA Approval of Dexcom’s Non-Adjunctive Indication Triggers a New Era in Diabetes Management,” Dexcom press release, Dec. 20, 2016. <http://investor.shareholder.com/dexcom/releasedetail.cfm?ReleaseID=1005071>
- ¹² Heather Mack, “Thirty-six connected health apps and devices the FDA cleared in 2016,” *MobiHealthNews*, Dec. 30, 2016. <http://www.mobihealthnews.com/content/thirty-six-connected-health-apps-and-devices-fda-cleared-2016>
- ¹³ “Dissemination of Patient-Specific Information From Devices by Device Manufacturers; Draft Guidance for Industry and Food and Drug Administration Staff,” FDA Federal Register notice. <https://www.federalregister.gov/documents/2016/06/10/2016-13787/dissemination-of-patient-specific-information-from-devices-by-device-manufacturers-draft-guidance>
- ¹⁴ “Samsung and Cigna Release New Health and Fitness Application,” Samsung press release, May 18, 2015 <https://news.samsung.com/global/samsung-and-cigna-release-new-health-and-fitness-application>



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