



Reimagining digital health regulation:

An agile model for regulating
software in health care

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A digital revolution in health care

Over the last decade, software has begun to permeate and transform virtually every industry—and health care is no exception.

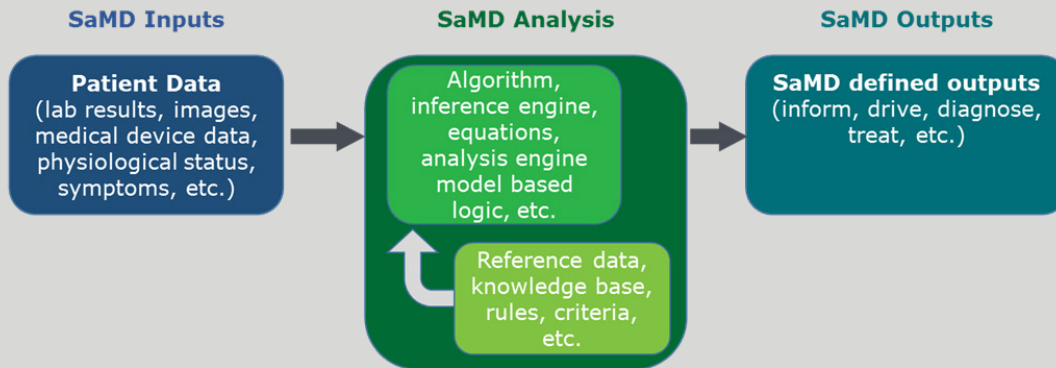
The software that drives market disruptors, including smartphones, social media, and the sharing economy, has fundamentally changed the way we live, work, and play. It's also powering game-changing developments in exponential medicine, including 3D printing, point-of-care diagnostics, robotics, bioinformatics, synthetic biology, genomics, and more.

Software is changing how clinicians practice medicine, how consumers manage their own health, and how patients and providers interact. One revolutionary development in digital health technology is software that can perform complex medical functions—software as a medical device (SaMD). SaMD can diagnose conditions, suggest treatments, and inform clinical management (see sidebar).

What is SaMD?

SaMD is software that performs one or more medical functions. While the software may be embedded in a piece of hardware (as is often the case) it's the software itself that performs the medical function. Figure 1 describes high-level SaMD inputs, analysis, and outputs.

Figure 1: High-level SaMD components



Source: Food and Drug Administration, "Software as a Medical Device (SaMD): Clinical Evaluation"

The International Medical Device Regulators Forum (IMDRF), of which the US Food and Drug Administration (FDA) is a member, describes SaMD as software that may work on general-purpose (non-medical) computing platforms; may be used in combination with other products including medical devices; and may interface with other medical devices or other general-purpose hardware and software that provide input to SaMD.¹

Software that is integral to the function of hardware—for example, software that helps an MRI's magnets turn or animates an X-ray control panel—isn't SaMD. Neither is software that simply retrieves information, organizes data, or optimizes processes (Table 1).

Table 1: What is and is not SaMD?

SaMD	Not SaMD
Software that can determine the proper drug dose for a patient, given personalized patient data	Software that operates a pacemaker
Software that can detect and diagnose a stroke by analyzing MRI images	Software that drives or controls an infusion pump’s motors
Software that can track the size of a mole over time and determine the risk of melanoma	Electronic health record (EHR) systems
Software that draws on data from other digital devices to determine risk factors associated with epileptic seizures	Software in the machines that assemble medical devices

Source: Deloitte Analysis

Additionally, not all health software is regulated by the FDA; such applications are considered outside this paper’s scope. According to draft FDA guidance released in December 2017, “Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act”² and “Clinical and Patient Decision Support Software,”³ general wellness applications, such as those that track heart rate and exercise routines, are not subject to FDA review. Neither is lower-risk decision support software that allows the health care provider, caregiver, or patient to independently review the basis of a treatment recommendation. A hypothetical application that provides recommendations for insulin dosage based on blood sugar level readings, for example, would not be subject to FDA review, so long as the recommendations are consistent with FDA-approved labeling for the insulin.

SaMD offers myriad health benefits. One of the most important is that it allows patients to play a more active role in their own health care. For example, WellDoc’s BlueStar captures blood-glucose information and offers individualized coaching to help diabetic patients manage their treatment and medication.⁴

Powered by artificial intelligence (AI)-enabled algorithms in some instances, some SaMD can also outperform the accuracy of diagnoses by trained clinicians. In Great Britain, the National Health Service (NHS) is teaming with Google’s DeepMind to help doctors spot the early signs of sight-threatening eye diseases. Google’s British-based AI division will use machine learning to analyze more than one million anonymous eye scans, creating computer algorithms that can detect early warning signs that clinicians—even seasoned ones—might miss. The hope is that this collaboration may lead to earlier detection and treatment of common eye diseases such as age-related macular degeneration and diabetic retinopathy, the latter being the fastest-growing cause of blindness around the world.⁵

The FDA historically has regulated SaMD the same way as hardware-based medical devices such as heart stents. However, according to the FDA’s Digital Health Program, this approach is “not well suited for the faster, iterative design, development, and type of validation used for software-based medical technologies.”⁶ A stent, for example, remains untouched by the device maker once it’s released into the market and implanted into the patient. In contrast, software developers have the ability to make continuous, post-launch changes to their products remotely. These changes may be related to security or feature updates, or product evolutions based on user data.

In another example, the Google DeepMind algorithm may soon be able to detect early signs of eye disease six months before clinicians can. And as this device is used on more people, its ability to detect abnormalities may become more precise and sophisticated, allowing even earlier detection—perhaps as much as a year before clinicians can. But there is a caveat: To update the algorithm’s functionality, the device maker may need to release a product update, thus transforming the product that was previously approved by the FDA. The current regulatory process emphasizes thorough vetting before products are released into the market, without much continuous evaluation after.

Additionally, many SaMD creators are software developers who have never dealt with the FDA. They may find the regulatory process challenging to navigate, which could create barriers to bringing products to market and, potentially, dissuade them from developing SaMD offerings in the first place. To encourage medical innovation among these new players, the FDA may need to clarify and simplify the regulatory process. According to FDA Commissioner Dr. Scott Gottlieb, digital health may allow people to “better manage chronic diseases, which could result in less trips to the doctor for check-ups, or better awareness of illness, like prompts to a parent with a sick child on when they need to see a provider.”⁷ Encouraging digital health innovation may be an important goal for the FDA and health care stakeholders at large.

Finally, SaMD can continually collect and analyze data on medical images, physiological status (e.g., body temperature), lab results or whatever it is the SaMD algorithm processes. This ability, which lies at the heart of SaMD, raises concerns about cybersecurity and protection of patient data. The FDA released guidance on cybersecurity in medical devices in December 2016,⁸ but the potential to collect, analyze, and store patient data has caused some advocacy organizations, such as the American Hospital Association,⁹ to call on the FDA for even more transparency around data handling and security requirements for protecting patient data. By creating a new regulatory review process in which device manufacturers and patients are willing to share real-world data (RWD), the agency can more effectively monitor these products as they evolve and ensure that they remain safe and effective.

The exponential advancement of digital health technologies presents a clear imperative for a new regulatory framework that addresses the key differences between these products and traditional medical devices. Developing a process for effective SaMD regulation could be the first step to creating a new regulatory paradigm for the entire digital health space, and for other regulated industries in which software has become prevalent and disruptive.

Some members of the SaMD ecosystem have begun discussing and iterating ways to improve SaMD regulatory review. This paper synthesizes various ideas developed by a number of individuals and working groups into an integrated, high-level framework that can be used to inform digital health software regulation. Our goal is to catalyze the larger digital health and SaMD community to contribute to this proposed framework and to become active participants in reimagining a regulatory process for software in health care.

FDA's SaMD transformation progress

Over the last five years, the FDA has begun work to develop and clarify risk-based policies to better communicate requirements and align its regulatory approach with the evolving nature of digital devices. In mid-2017 the FDA announced its Digital Health Innovation Action Plan¹⁰ and began implementing plan commitments by hiring digital health staff, launching its digital health software Precertification Pilot Program¹¹ (Pre-Cert Pilot Program) (see sidebar), and releasing three new guidance documents—two of which distinguish between device types that are low-risk and, therefore, no longer required to undergo pre-market review,¹² and one which outlines new guidelines for evaluating SaMD applications.¹³

The FDA Pre-Cert Pilot Program

The FDA's Pre-Cert Pilot Program aims to develop a new approach for a risk-based and accelerated review of digital health products by “looking first at the software developer or digital health technology developer, not the product.”²³ Since launching the program, the FDA has selected nine pilot participants representing a diverse range of SaMD developers (Figure 2); started collecting data to evaluate organizational excellence key performance indicators (KPIs) and measures; conducted initial site visits with pilot participants; and held a two-day public workshop—“Fostering Digital Health Innovation: Developing the Software Precertification Program”—in January 2018 to engage “the tenth pilot participant” (the larger SaMD community) in the Pre-Cert Pilot Program.²⁴

Figure 2: FDA Pre-Cert Pilot Program companies

- **Apple (Cupertino, California)**
- **Fitbit (San Francisco, California)**
- **Johnson & Johnson (New Brunswick, New Jersey)**
- **PEAR Therapeutics (Boston, Massachusetts)**
- **Phosphorus (New York, New York)**
- **Roche (Basel, Switzerland)**
- **Samsung (Seoul, South Korea)**
- **Tidepool (Palo Alto, California)**
- **Verily (Mountain View, California)**

Source: Food and Drug Administration, "FDA Selects Participants for New Digital Health Software Pre-Certification Pilot Program" <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm577480.htm>

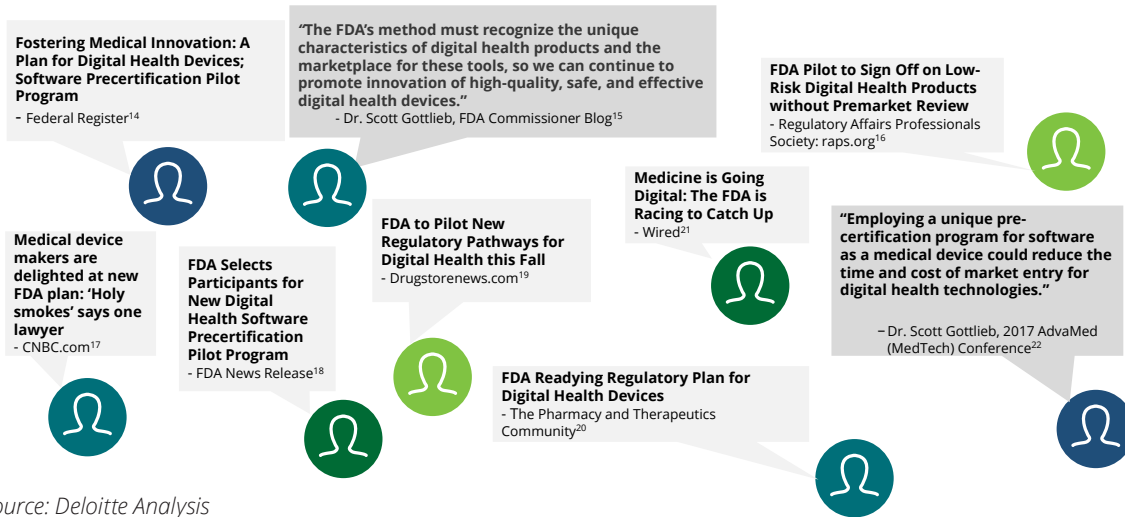
During the workshop's first day, the FDA introduced the imperative for designing a new regulatory process for SaMD. The agency also moderated panels to share the perspectives of the Pre-Cert Pilot companies, FDA Digital Health team, health care stakeholders, industry trade groups and associations, and representatives from existing excellence model/certification organizations. During the second day, workshop attendees participated in exercises to identify key drivers, indicators, outcomes, and measures for "excellent" organizations, as well as considerations for aggregating metrics into Pre-Cert scorecards.

One issue discussed during the health care stakeholders' panel was patient confusion between "FDA-approved" and "FDA-cleared" devices. Some expressed concern that calling products "FDA pre-certified" may add to this confusion. Additionally, participants grappled with how an "organization" should be defined for FDA Pre-Cert purposes. Many large companies may be comprised of multiple "organizations" and some companies may partner with many different entities to develop a final product, raising questions about which "organization" would be evaluated during the FDA Pre-Cert process. Finally, panel participants discussed whether excellence metrics/KPIs should be prescribed by the FDA, how the score should be weighted and grouped (i.e., whether there should be FDA Pre-Cert tiers), and how to make the process accessible across diverse SaMD developer organizations.

The two-day workshop provided a significant opportunity for SaMD stakeholders to work directly with the FDA and contribute their ideas, expertise, and experience to help define the Pre-Cert Program. Yet even with all the progress to date, considerable work remains to further define KPIs, determine the Pre-Cert scoring approach, and implement a Pre-Cert scorecard that truly reflects an organization's level of excellence.

The release of the Digital Action Plan and subsequent efforts by the FDA to modernize SaMD regulation have sparked discussion in the news media and across the SaMD ecosystem, and different players have weighed in on these recent developments (Figure 3).

Figure 3: Significant digital health announcements and headlines



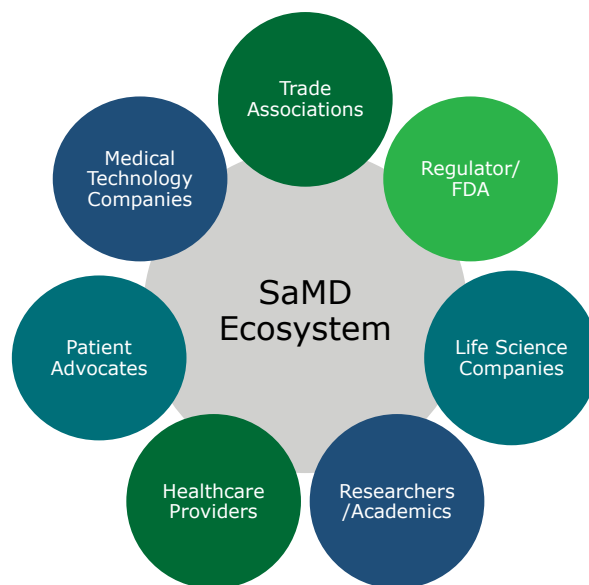
Source: Deloitte Analysis

Principles and solutions for a new regulatory framework

Developing a new regulatory framework, let alone implementing it, is no small feat. Still, the unique characteristics of SaMD and the new players it has brought into the medical technology ecosystem suggest that a reimagined regulatory pathway could be greatly beneficial to numerous health care stakeholders.

To determine what this pathway might look like, Deloitte hosted a convening session on February 22-23, 2017. Attendees included key players in the SaMD ecosystem: representatives from the FDA, medical technology corporations and start-ups, patient advocacy groups, health care providers, other life sciences companies, trade associations, and medical researchers (Figure 4).

Figure 4: Key players in the SaMD ecosystem



Source: Deloitte Analysis

Lively conversation about the unique challenges of regulating SaMD led to a better understanding of the problem, as well as ideas on how to solve it. The group brainstormed design principles for a new regulatory paradigm, identified qualities that make an organization excellent (see Figure 5 for graphic notes of the brainstorming session), and debated the degree of regulatory hurdle, represented by a “friction score” to bring different types of products to market.

The friction score, based on a scale from 1 to 5 (with a score of 5 meaning a higher regulatory hurdle) is a Deloitte-developed tool to help determine from the convening session participants how much real-world data companies should be required to provide to the FDA to receive clearance to market their product. We gave groups of participants different SaMD product risk profiles (low- to high-risk) and organization scenarios, and asked them to provide a “friction score” to represent how much regulatory rigor and data should be required to clear that SaMD. In aggregate, convening session participants agreed that products that pose a lower risk to patient safety should be approved with less regulatory hurdle than products that pose a greater risk to patient safety. (This paper’s Pre-Cert section includes a deeper discussion on the risk categorization framework).

Figure 5: Design principles and organizational excellence



Source: The Deloitte Greenhouse™ Experience

Following the convening session, we drafted an initial version of this paper and collected feedback from session members. Additionally, we created a rapid prototype of an Integrated Online Collaboration Capability—built in Salesforce.com—to demonstrate, test, and collect feedback on the FDA PreCert and SaMD product submission and review processes. Overall, the feedback was very positive, with considerable excitement about the potential of the new SaMD regulatory process. For example, respondents said the prototype made it easier to visualize and understand how a company’s FDA Pre-Cert Program score or Pre-Cert standing could be connected to the overall regulatory process for SaMD. We also received constructive feedback and concerns, which we have addressed.

This finalized paper outlines a potential framework for regulating SaMD with an agile, collaborative approach that could achieve the following goals:

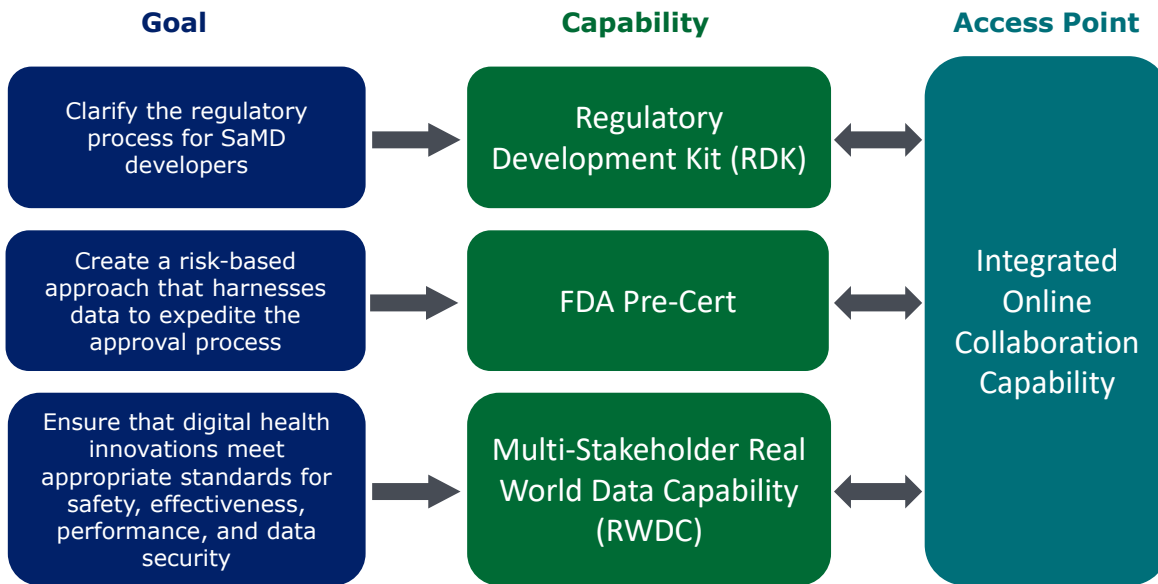
1. **Clarify the regulatory process** to make it easier to navigate and encourage innovation among all SaMD manufacturers.
2. **Create a risk-based process** that harnesses data to expedite the pre-market approval of SaMD and ensure device safety, effectiveness, and performance throughout its life cycle.
3. **Create a secure, encrypted RWD capability** for the FDA to access and analyze selected RWD across SaMD organizations and from other public or private sources.

Reimagining digital health regulation

With these goals in mind, we collected and synthesized all ideas (some of which were developed by other working groups), built on the concepts, and developed a regulatory framework that rests on three core capabilities (Figure 6):

- The Regulatory Development Kit (RDK)
- FDA Pre-Cert
- The Multi-Stakeholder Real World Data Capability

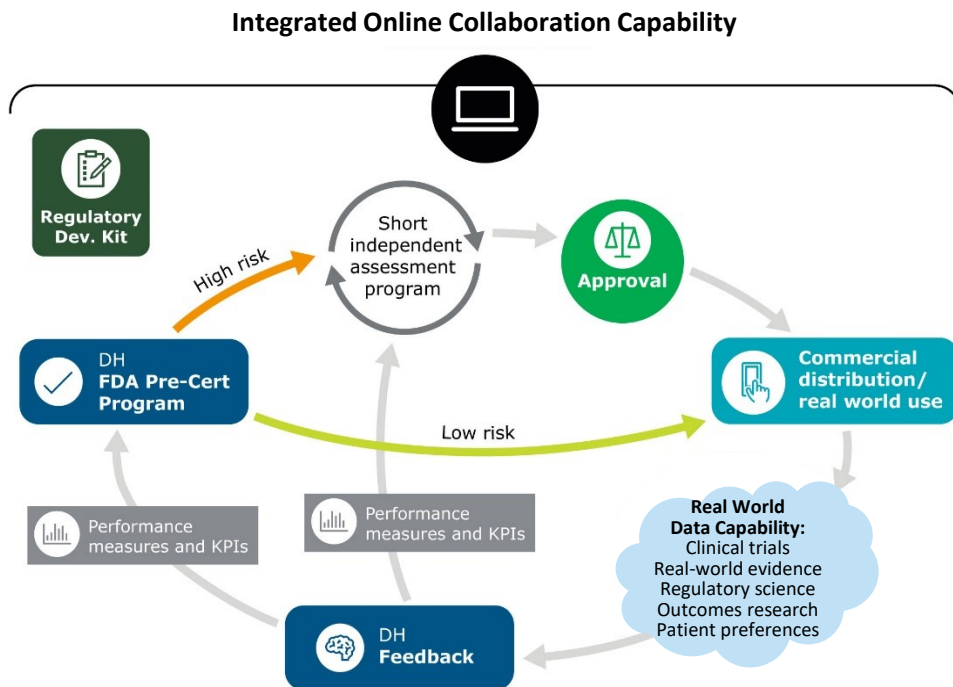
Figure 6: Principles and capabilities guiding the new SaMD regulatory framework



Source: Deloitte Analysis

Ideally, the new regulatory framework for SaMD would include ongoing collaboration among key stakeholders: SaMD developers seeking product approvals, the FDA, and the patients who stand to benefit from new digital health technologies. As depicted in Figure 6, a secure, cloud-based, Integrated Online Collaboration Capability could house the RDK, FDA Pre-Cert, and RWD capability and enable organizations to securely submit applications to the FDA. The FDA, in turn, could use it to conduct the regulatory review, notify organizations of their application status, and share regulatory decisions (Figure 7). The capability could be accessible to all SaMD ecosystem stakeholders. Each user would have a unique ID and password, allowing proprietary data to be protected and limited to those who should have access, and making other data that is of interest to the general public available to all. For example, a SaMD developer alone would have access to its Pre-Cert application and be able to track its SaMD application on its path to market, while all users could have access to data on which SaMDs have been approved, and whether there have been adverse patient events.

Figure 7: The integrated online collaboration capability



Source: Deloitte Analysis of Food and Drug Administration, "Digital Health Innovation Action Plan" <https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/UCM568735.pdf>

For those interested in the challenges, accomplishments, and overall progress of the new SaMD regulatory initiative, the online collaboration capability could display statistics on user adoption of the Pre-Cert program, types of SaMD approved, number of SaMD products approved and rejected, number and types of product recalls, summary information on Pre-Cert quality outcomes, summary information on post-market adverse events, and overall SaMD product quality. Organizations using the online capability could also add or exchange additional regulatory information (e.g., clinical trial data, product safety data) with the FDA; address requests for additional data and answer questions from the FDA during the regulatory review phase; highlight deadlines and expectations from the FDA back to the SaMD developer; and view results of the FDA's performance as it relates to product submission, market launch, ongoing surveillance, and annual reporting. Such exchanges could increase FDA awareness of emerging safety issues, help improve regulatory decision-making, identify areas for process improvement, and create opportunities to update guidance and standards based on actual performance.

Framework components for regulating SaMD

As mentioned earlier, three capabilities—the Regulatory Development Kit (RDK), FDA Pre-Cert, and the Multi-Stakeholder Real World Data Capability—comprise the core components of the proposed framework for modernizing SaMD regulation.

Regulatory Development Kit

While SaMD products are not new, there are many new players in the SaMD space, including tech giants and start-ups that see opportunities to contribute their talents and expertise to digital health but may be unfamiliar with FDA regulatory processes. However, new players aren't the only ones who may require regulatory assistance. Given the speed with which the FDA is evolving to better regulate iterative devices all SaMD developers likely could benefit from

timely information on FDA requirements and guidance on how to interact with the agency to get their products to market. An important step forward is to make the regulatory process easier for SaMD developers to understand and navigate.

Enter the Regulatory Development Kit (RDK). The FDA has been considering creating a RDK to help digital health technology developers easily understand and meet the agency's regulatory requirements. As such, it could be useful to outfit the RDK with a module that functions similar to a software program that guides individuals through a step-by-step process to complete their federal and state income tax forms—in this case, the RDK could guide users through the regulatory process. The RDK could contain tools to clarify requirements and expectations at each stage of the process; provide templates to accelerate development of required documentation; and supply answers to frequently asked questions about data standardization, security requirements, and legal and clinical information. The RDK also could contain an expert-monitored wiki for users to share leading practices. In short, the RDK could provide the health care industry with a simple, user-friendly guide to the SaMD regulatory process, thus encouraging future product innovation and proliferation.

Of note, the city of Boston created a similar tool to streamline its construction permitting and inspections process. Making the process quicker, easier, and more user-friendly enabled the city to issue 21 percent more permits and reduce the number of days in review by 10 percent.²⁵ The RDK could fill a similar need by providing a user-friendly tool that makes the SaMD regulatory approval process faster, easier to navigate, and more efficient.

FDA Pre-Cert

The FDA has limited resources with which to evaluate new SaMDs before they are introduced into the market. According to Bakul Patel, FDA Associate Director for Digital Health, the volume of FDA pre-market approval applications for SaMD has the potential to increase exponentially as technology advances spawn development of more software-based health care solutions.²⁶ A risk-based approach to regulatory review could allow the FDA to accelerate review for lower-risk SaMDs and focus its attention and limited resources on reviewing SaMDs that pose greater potential risk of causing patient harm.

One proposed regulatory review option—an FDA Pre-Cert Program to facilitate expedited SaMD approvals—is inspired by the TSA Pre✓ model (see sidebar). The FDA Pre-Cert Program would be a risk-based, expedited, and predictable approval process for organizations that demonstrate a commitment to a culture of quality and organizational excellence (CQOE). Entry into this new pathway would be contingent on the SaMD developer providing access to key pieces of pre- and post-market information to provide continued confidence in the product's safety, efficacy, and performance. Two factors could be used to determine the pre- and post-market requirements for each SaMD review (1) the SaMD organization's standing in the FDA Pre-Cert Program; and (2) the risk categorization of the SaMD being evaluated. Organizations that demonstrate a commitment to organizational excellence could expect to spend relatively less (or no) time in pre-market review than their non-Pre-Cert peers with similarly risky products; however, higher-risk products may have more requirements than lower-risk ones.

What is TSA Pre✓?

The Transportation Security Administration (TSA) is charged with keeping passengers and freight transportation secure in the United States. After 2001, airport security tightened, making flying more time-consuming and inconvenient for many.

To improve the efficiency of airport security, TSA developed a Pre✓ program. Obtaining TSA Pre✓ certification requires individuals to share more personal information than an airline passenger normally would; the process includes a background check, fingerprinting, and an in-person interview. In return, passengers with Pre✓ approval proceed through a separate (and usually, shorter) security line and receive less scrutiny (i.e., they are not required to remove shoes and belts, and present laptops and liquids for inspection).²⁷

Pre-Cert eligibility: Measuring an organization’s commitment to excellence

FDA Pre-Cert eligibility would be determined based on a company’s ability to demonstrate a culture of quality and organizational excellence (CQOE). The proposed CQOE framework is comprised of two core components, organizational perspectives and excellence outcomes (Figure 8).

Figure 8: Culture of Quality and Organizational Excellence (CQOE) framework

Each outcome of organizational excellence can be measured using data from multiple perspectives.



Source: Deloitte Analysis

- 1. Organizational perspectives** are areas that the FDA could evaluate to determine a SaMD organization’s quality and commitment to excellence. Our framework proposes the organizational perspectives of talent, software development life cycle (SDLC), enterprise, partnership ecosystem, and patient engagement. The perspectives, which link to the FDA’s proposed excellence outcomes (described below), would be self-reported and measured through a standard set of (yet-to-be-determined) KPIs and measures; quantified through an overall aggregate CQOE score; and displayed via an organizational excellence scorecard, with Bronze, Silver, and Gold levels reflecting a company’s overall commitment to quality. The organizational perspectives would indicate the likelihood of a company’s ability to create devices that meet the FDA’s standards for excellence.
- 2. Excellence outcomes** are results that show a SaMD organization’s products meet the FDA’s standards for excellence and quality. These excellence outcomes include providing a safe patient experience, being clinically responsible, delivering high-quality products, being conscious of cybersecurity, and having a proactive culture (Figure 8).

One of the key goals of the recently launched FDA Pre-Cert Pilot Program is to collect organizational information from participants and to identify and test potential organizational excellence KPIs and measures that will underlie the new SaMD regulatory paradigm. It is also important to consider the appropriate balance of transparency and flexibility in the KPIs and measures used to assess an organization’s CQOE. FDA-prescribed KPIs and measures for assessing each excellence outcome could provide greater transparency into what each company is expected to demonstrate to gain Pre-Cert standing but they also may require organizations of different sizes, industries, cultures, and product types to be evaluated against the same measures. Alternatively, the FDA could provide a list of KPIs and measures from which organizations could choose a subset to measure themselves. The FDA also could allow organizations to propose new KPIs and measures, so long as they can sufficiently justify how the measure demonstrates alignment with at least one

of the excellence outcomes. The FDA could even permit organizations to reference other excellence certifications (e.g., Capability Maturity Model Integration from the CMMI Institute) they have achieved as a way to supplement the KPIs and measures they submit.

Because the data used to assess organizational perspectives would be self-reported, it raises the risk of a company submitting inaccurate or falsified information to gain Pre-Cert status. To address this situation, the FDA could incorporate automated audit techniques using advanced audit and AI methods to identify and prevent fraud.

Ongoing assessment of product safety and effectiveness

Whether the organization is established or new, large or small, all market entrants will have the opportunity to apply and qualify for Pre-Cert. Even organizations that already have SaMD products in the market could be evaluated on the safety and effectiveness of those products and be eligible for Pre-Cert. The FDA could continuously track these measures through the Real World Data Capability and incorporate the results dynamically into the CQOE score and respective Pre-Cert level. The FDA also could monitor products through publicly available data on software bugs and error reports, customer feedback, software updates, app store information, social media, and GitHub.

CQOE scores and corresponding Pre-Cert levels wouldn't be static: they could go up or down based on performance and effectiveness data gathered through the RWDC, app store reviews and other data already being gathered on the device. If a CQOE score were to fall below a defined Pre-Cert threshold (e.g., moving from Pre-Cert Gold to Silver), the organization may lose certain Pre-Cert benefits, such as expedited reviews for less-risky SaMD products, or it may no longer be eligible for FDA Pre-Cert status until it is able to demonstrate a commitment to excellence through a new Pre-Cert assessment and resolution of any product issues.

SaMD risk categorization

An important consideration for an FDA Pre-Cert and expedited review pathway is evaluating the level of risk posed by a SaMD. One potential model is the SaMD Risk Categorization Framework developed and published by the International Medical Device Regulators Forum (IMDRF) (Figure 9).²⁸ While different from existing medical device classification (e.g., Class 1, 2, 3), it plays a similar function in enabling the FDA to risk-stratify submissions and focus resources on products that pose the greatest risk to patient safety.

Figure 9: IMDRF SaMD Risk Categorization Framework

Criticality of health care situation or condition	Significance of SaMD information to health care decisions		
	Treat or diagnose	Drive clinical management	Inform clinical management
Critical	IV	III	II
Serious	III	II	I
Non-serious	II	I	I

↑ Increasing criticality

← Increasing significance

Source: International Medical Device Regulators Forum, https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM524904.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery

In the IMDRF risk-categorization framework, the rows indicate the criticality of the health condition the SaMD is designed to address; the columns indicate the significance of the information the device provides in the health care decision-making process. As we move from the bottom right (Category I, a device that informs clinical management for non-serious conditions) to the top left (Category IV, a device that treats or diagnoses patients in critical condition), the risk profile increases along both axes.

During the convening session, we provided a sample SaMD scenario to align with each combination of SaMD criticality and significance. We then asked participants to provide a “friction” score (a score from 1 to 5, with 5 indicating more “friction”), or the amount of rigor they believed the FDA should require that companies undergo when their device is under review. In the sample scenarios, participants were told whether or not a company had the CQOE designation. In general, discussions around data yielded two outcomes:

1. Participants believed that devices that were classified as higher significance/criticality should require more data to be provided to and reviewed by the FDA, resulting in a higher friction score; and
2. Organizations with a culture of quality and organizational excellence (CQOE) should be permitted to get a new SaMD to market through a faster and less-rigorous mechanism compared with companies that do not have CQOE.

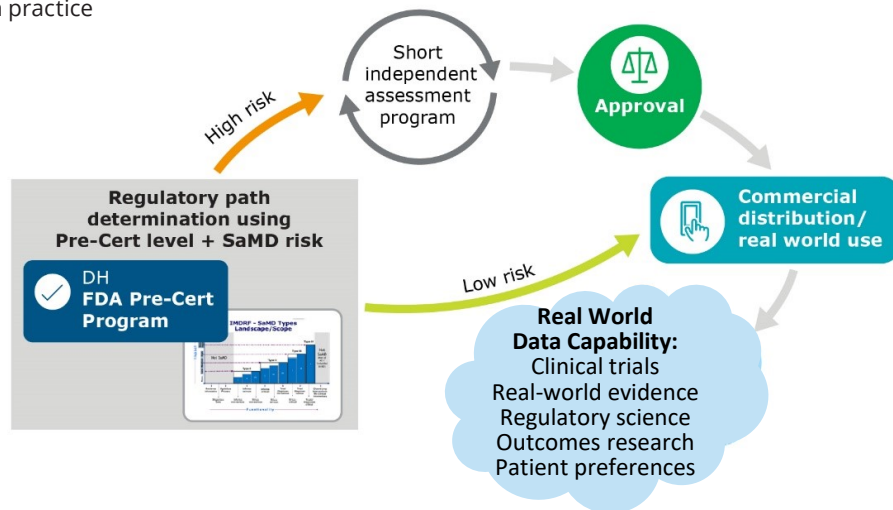
Higher-risk devices (Category IV) may require a thorough clinical evaluation through clinical trials or retrospective analysis of existing clinical information to ensure safety, effectiveness, and performance. However, even Category IV devices could be eligible for FDA Pre-Cert expedited review, depending on specific product attributes, such as the clinical efficacy and safety evidence provided to support approval, as well as a company’s Pre-Cert level and other product attributes that can potentially pose a safety risk to patients. For example, a company with the highest CQOE score and Pre-Cert level (e.g., Gold) might be able to submit a Category IV device within the same timeframe and with the same burden of requirements as a Category III device with a less favorable CQOE score and Pre-Cert level (e.g., Silver).

Low-risk devices (Category I) could skip the review altogether, per FDA guidance,²⁹ and Category II devices may similarly be eligible to skip review or undergo an expedited review process wherein the manufacturer could simply submit an application and go straight to market without waiting for approval but with a commitment to share RWD to enable FDA to monitor all SaMD products post-market.

A combination of the organization’s Pre-Cert standing and the device’s individual risk categorization would determine the amount of pre-market review required for each SaMD. An organization’s Pre-Cert standing would be dynamic and change over time based on real world post-market performance of products and audits of the organizational excellence metrics and KPIs provided by the organization.

Figure 10 shows how the Pre-Cert level (e.g., Bronze, Silver, Gold) in combination with the SaMD risk categorization (e.g., Category I-IV) determines whether the product is formally reviewed by the FDA based on the evidence (high risk) or whether the product goes directly to market (low risk). In both cases, the FDA would use the RWDC to monitor the SaMD products post-market.

Figure 10: FDA Pre-Cert in practice



Source: Deloitte Analysis of Food and Drug Administration, “Digital Health Innovation Action Plan” <https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/UCM568735.pdf>

Step-by-step: How FDA Pre-Cert could work

1. CQOE assessment. A company seeking Pre-Cert status for its SaMD begins by creating an online account and providing the FDA access to evaluate the company's CQOE through organizational perspectives and excellence outcomes data, and the performance of the company's SaMD products already on the market, if applicable. The CQOE score determines its Pre-Cert level (e.g., Bronze, Silver, Gold). The more a company can demonstrate its commitment to a "culture of quality and organizational excellence" the higher the Pre-Cert level it may achieve.
2. Product categorization. The FDA categorizes the company's SaMD according to the IMDRF risk categorization framework.
3. Pre-Cert determination. The CQOE score, in combination with the device's SaMD risk category, determines the product's ultimate path to market. Those companies that qualify for Pre-Cert may be able to get into a shorter approval queue, provide less data to FDA in the pre-market stage, or skip other steps in the approval process.
4. Post-market surveillance. All SaMD products in categories I to IV remain under post-market surveillance. The company's CQOE score and Pre-Cert level may change based on post-market surveillance data.

The Multi-stakeholder Real-world Data Capability (RWDC)

One of SaMD's important characteristics is that products connect to the Internet and have the potential to continuously collect valuable RWD, including clinical and nonclinical patient information, administrative data about the SaMD's operating system, patient-reported health outcomes data, customer satisfaction data, geospatial data, and software-defect data (Figure 11). SaMD can analyze the collected data to iterate on the device, helping make it more accurate, intelligent and patient-centered.

Some RWD, such as app store customer reviews, are publicly available but need to be consolidated into a format that is conducive to analysis. Other RWD may include proprietary information about the SaMD's algorithm, making it important to restrict access. Also, sensitive patient information must be protected. Central to the SaMD data collection, analysis, and management could be development of a technical RWD capability stood up by the joint efforts of multiple stakeholders.

Figure 11: Sources of RWD that can contribute to the evaluation of Pre-Cert eligibility



Organizational Data Collection

Applicant-Level Data Collected via CQOE Assessment.



Patient Data Collection

Patient Reported Outcomes Data.



FDA Data and Archives

Information from FDA Information Systems of Record and Archives.



Passive Data Collection

Publicly Available Data Collection and Mining – Digital Exhaust from App Store, GitHub, Social Media Feeds, etc.

Source: Deloitte Analysis

RWD capability

There are multiple ways to store, analyze, and use RWD while mitigating stakeholder data security concerns. Approaches range from highly distributed to extremely centralized, and they can be especially effective when individual companies, industry stakeholders, patients, and appropriate governing bodies work collaboratively to develop a solution.

One example is the Medical Device Innovation Consortium’s (MDIC) National Evaluation System for health Technology (NEST). NEST is a voluntary network of data partners assembled to “apply an inclusive, patient-centered approach to increase the responsible use of [Real World Evidence] across the total product life cycle (TPLC) for a diverse set of stakeholders in a cost-effective and sustainable manner.”³⁰

The FDA has described NEST as “a cooperative network of partners working to use data, advanced methodologies, and good governance to improve the state of medical device evidence generation,” and considers it a top agency priority.³¹ NEST’s data partners include the FDA, device industry, clinician groups, payers, health systems and patient groups (figure 12). Some individuals at the convening session recommended that NEST develop a secure database for storing the RWD provided by each SaMD. Whether through NEST or another multi-stakeholder solution, an RWD capability would need to be designed and implemented for our framework.

Moving the RWD of every SaMD into one central repository would be a significant undertaking requiring coordination across all participating organizations. It also would require costly and complex technical infrastructure to house this centralized data. As such, another alternative may be for SaMD companies to provide regulators with secure access to their cloud-based data. Encryption and blockchain technologies could be used to provide regulator access without jeopardizing data security. The data obtained through the RWD capability could allow the FDA to more actively monitor SaMD applications for safety and efficacy, even as the applications change and evolve.

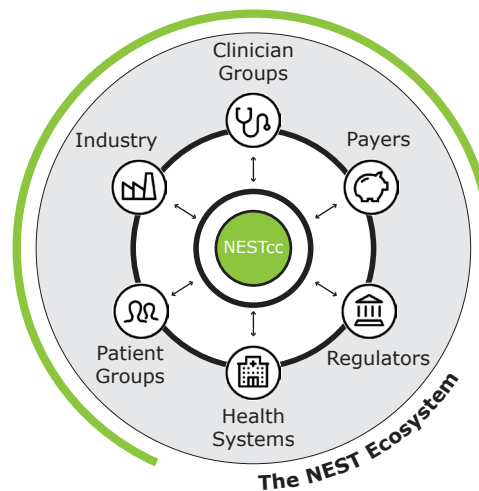
Many questions remain regarding the multi-stakeholder RWD capability. Which pre- and post-market SaMD RWD would be required to be accessible? Would the data need to be in a standardized format for analysis? How could sensitive company and patient data be accessed by the FDA while remaining protected? How can we build on current consent practices to make sure patients understand how their SaMD data is being used and stored? These questions, and others, will need to be answered as the new SaMD regulatory process is developed, as they will define FDA’s ability to track safety, efficacy, and performance after each SaMD is cleared for market use.

Next steps

As SaMD technology becomes cheaper, more accessible, and more sophisticated, it is likely to play an increasingly important role in health care delivery, personalized medicine, and medical research. To realize its full benefit, however, regulation of these products will need to radically change to accommodate new SaMD manufacturers and the technology’s rapid evolution, and to harness SaMD’s ability to capture RWD to create a collaborative, innovative SaMD community.

The FDA has made recent, significant progress in addressing the issue of software regulation in health care, with the goal of standing up a new regulatory process for SaMD by the end of 2018.³² Still, the success of this regulatory transformation will require input and contributions from the larger SaMD ecosystem. In this paper, we have outlined one potential framework for the overall regulatory transformation of digital health, but a great deal of work lies ahead. We call upon the larger SaMD ecosystem to contribute their thought leadership and expertise to the following efforts (Table 2).

Figure 12: NEST is one potential solution to collecting RWD.



Source: Medical Device Innovation Consortium, NEST, “Who We Are” <https://nestcc.org/about/who-we-are/>

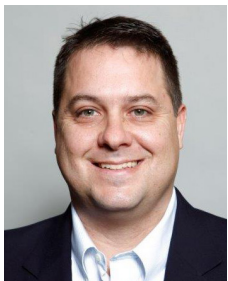
Table 2: Proposed next steps by capability area

Capability	Proposed next steps
RDK	Create and contribute to an open SaMD community that develops a draft RDK – including software development tools, techniques, code, training guides, best practices for organizational governance and quality systems, and mechanisms for curating content.
FDA Pre-Cert	Develop consensus on the appropriate menu of KPIs and measures for evaluating an organization's CQOE score, Pre-Cert level and overall commitment to excellence.
	Develop consensus on what data would be required for those companies eligible for Pre-Cert.
	Develop methodologies for testing potential KPI measures against their ability to predict the excellence outcomes of patient safety, clinical responsibility, high product quality, cybersecurity consciousness, and proactive culture.
	Develop methodologies to ensure Pre-Cert doesn't prioritize large companies over small companies and start-ups.
RWD Capability	Develop an automated audit process to validate that KPIs and measures provided by organizations are accurate and substantiated.
	Identify the core RWD elements to which FDA should require access from SaMD developers for device post-market surveillance, as well as RWD elements that could be leveraged directly by the FDA from its internal sources, patient sources, and publicly available sources.
	Create a RWD business model that builds trust between the SaMD ecosystem participants and delivers the right incentives to participate (e.g., more data equals lower regulatory hurdles; leads to accelerated market entry).
Other	Develop a secure, encrypted RWD capability for the FDA to access and review selected RWD across SaMD organizations and from other public or private sources.
	Create a prototype for the Integrated Online Collaboration Capability to continue to test out and improve the concepts described in this paper.
	Explore ways to infuse continuous learning in the new SaMD regulatory process to improve organizational excellence to elevate the bar for quality products.
	Attend public workshops and provide perspectives for consideration to the FDA.

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