
FDA
U.S. FOOD & DRUG
ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH
DIGITAL HEALTH PROGRAM
Health Care
Doctor
Hospital
DIGITAL HEALTH INNOVATION ACTION PLAN
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Digital Health Innovation Action Plan

Introduction

FDA's Center for Devices and Radiological Health (CDRH) puts patients at the forefront of our vision—we are driven by timely patient access to high-quality, safe and effective medical technology.

From mobile medical apps and fitness trackers, to software that supports the clinical decisions doctors make every day, digital technology has been driving a revolution in health care.

This Digital Health Innovation Action Plan outlines our efforts to reimagine FDA's approach for assuring that all Americans, including patients, consumers and other health care customers have timely access to high-quality, safe and effective digital health products. This plan lays out the CDRH's vision for fostering digital health innovation while continuing to protect and promote the public health, including:

- Issuing guidance to provide clarity on the medical software provisions of the 21st Century Cures legislation;
- Launching an innovative pilot precertification program to work with our customers to develop a new approach to digital health technology oversight (FDA Pre-Cert for Software); and
- Building FDA's bench strength and expertise in CDRH's digital health unit.

Background

Digital health technologies can empower consumers to make better-informed decisions about their own health and provide new options for facilitating prevention, early diagnosis of life-threatening diseases, and management of chronic conditions outside of traditional care settings. Software and technologies that assist in diagnosis, treatment options, storing and sharing health records, and managing workflow can enable more efficient clinical practice. With advances in analytics, medical software can help address public health crises, such as the opioid epidemic devastating many American communities, by providing immediate information on nearby treatment options and emergency help.

Digital health technology has brought new market participants into the medical devices space, and those participants have brought new innovation and manufacturing processes. Digital health products that leverage connectivity can continually improve their safety and effectiveness through frequent modifications and updates. Those benefits are accompanied by challenges of cybersecurity and interoperability. Use of software and use of consumer technology also make digital health products unusually accessible across international boundaries. Because they can

impact the health of millions of Americans, the U.S. public should be able to trust that these products are high-quality and do what they are supposed to do.

FDA recognizes that an efficient, risk-based approach to regulating digital health technology will foster innovation of digital health products. FDA's traditional approach to moderate and higher risk hardware-based medical devices is not well suited for the faster iterative design, development, and type of validation used for software-based medical technologies. Traditional implementation of the premarket requirements may impede or delay patient access to critical evolutions of software technology, particularly those presenting a lower risk to patients.

For the American people to see the full potential of digital health technologies, FDA must lean forward and adapt our processes.

What we've already accomplished

FDA has consistently focused its regulatory efforts on higher risk functionality and attributes, and we believe consumers and health care providers should expect the same level of safety and efficacy in those higher risk digital health devices as they do from other types of medical devices. FDA's CDRH has extensive experience with software that is a medical device[1] and software embedded in medical devices.

We recognized the need for a new approach for digital health oversight, so we created a Digital Health Program that is helping advance this technology by establishing new relationships and fostering collaboration with digital health developers, patients, and providers. In addition, this program is tasked with developing and implementing regulatory strategies, policies, and processes in this area—and then providing transparency and clarity on those policies and processes.

Over the past five years, the Digital Health Program has developed several practical policies and approaches towards certain digital health products, balancing the benefits and risks to patients. For example:

- We focused our oversight on mobile medical apps to only those that present higher risk to patients, while choosing not to enforce compliance for lower risk mobile apps;
- We confirmed our intention to not focus our oversight on technologies that receive, transmit, store or display data from medical devices[2];
- We chose not to focus our oversight on products that only promote general wellness;

[1] Referred to as "Software as a Medical Device" or SaMD. Software embedded in a medical device is referred to as "Software in a Medical Device" or SiMD.
[2] Also known as Medical Device Data Systems (MDDS).

- We provided clarity on our expectations on cyber security and collaborated with stakeholders to form a community to exchange cyber security information; and
- Working with our customers and other federal agencies, we published the Food and Drug Administration Safety and Innovation Act (FDASIA) Health IT report proposing a new framework for Health IT.[3]

These policies were designed to allow lower risk beneficial technologies to be readily available to Americans while assuring connected products continue to be high-quality, safe and effective. We created a mechanism to respond to queries from digital health developers, including mobile apps makers, to provide dedicated policy support and clarify published policies.[4]

Improving the international regulatory environment for digital health products is also critical to fostering innovation domestically and increasing the availability of products that benefit the health of Americans and people of other nations. FDA leads an international effort to converge on regulatory principles for Software as a Medical Device (SaMD) through the International Medical Device Regulators Forum (IMDRF)[5]. FDA, as a member of the IMDRF, has adopted converged principles on SaMD terminology, a risk classification schema, application of quality management system principles tailored to software, and more recently working towards a guidance on application of clinical evaluation for SaMD.

Action Plan

FDA can help encourage digital health innovation by redesigning our policies and processes and modernizing our tools so that they match the needs of digital health technology, and providing clarity on those policies and processes so that manufacturers and developers know what they need to do. We have designed this Action Plan to set forth what we see as the next steps that we will take over the coming year.

1. Issuing new guidance implementing legislation

The 21st Century Cures Act, enacted in December 2016, reflected, and, in some cases, expanded policies we had already begun to implement.

Under the 21st Century Cures Act, certain medical software, including certain software that supports administrative functions, encourages a healthy lifestyle, serves as electronic patient

[3] Available at https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhreports/ucm390588.htm.
[4] Since 2013 FDA has responded to over 900 inquiries.
[5] IMDRF is a group of medical device regulators from Australia, Brazil, Canada, China, European Union, Japan, Russia, Singapore, and the United States that work together to accelerate international medical device harmonization and convergence.

records, assists in displaying or storing data, or provides limited clinical decision support, is no longer considered to be and regulated as a medical device.

While FDA had already taken a more hands off approach to lower-risk digital health technology, including software, we will update current policies and issue new guidance to be consistent with and provide greater clarity on the 21st Century Cures Act software provision, as described below.

A. **General 21st Century Cures Implementation Guidance.** FDA intends to issue a new draft guidance with draft interpretations of several of the medical software provisions in the 21st Century Cures Act, explaining their effect on pre-existing FDA policy, including policy on:

   - Mobile medical applications;
   - Medical device data systems, used for the electronic transfer, storage, display, or conversion of medical device data;
   - Medical image storage devices, used to store or retrieve medical images electronically;
   - Medical image communications devices, used to transfer medical image data electronically between medical devices;
   - Low-risk general wellness products; and
   - Laboratory workflow.

   Our goal is to issue this draft guidance for public comment by the end of 2017.

B. **Clinical Decision Support Software**. FDA intends to issue a new draft guidance that delineates the clinical decision support software that is no longer under FDA's jurisdiction. Our goal is to issue this draft guidance for public comment during the first quarter of 2018.

C. **Multifunctionality.** FDA intends to issue draft guidance on FDA oversight of products with both software functions that fall under FDA's medical device oversight and software functions that do not. Consistent with the 21st Century Cures Act, FDA will assess a non-device software function to the extent that it impacts the software function subject to FDA review, including impacts on safety and effectiveness. Our goal is to issue this draft guidance for public comment during the first quarter of 2018.

D. **Finalize guidance on Deciding When to Submit a 510(k) for a Software Change to an Existing Device.** In August 2016, FDA put forward a draft guidance to help manufacturers of medical devices subject to premarket notification requirements[6] who

[6] These are also known as "510(k) requirements" because section 510(k) of the FD&C Act requires premarket notification.

intend to modify software that is or is part of the medical device determine whether that modification necessitates premarket submission and clearance of a new 510(k). The document includes guiding principles as well as a simple to follow flow chart, with the aim of setting clear, practical, and transparent regulatory expectations. Our goal is to issue this final guidance before the end of 2017 that incorporates public comments on the draft.

E. **Finalize the International Medical Device Regulators Forum approach to clinically evaluating SaMD**. The IMDRF published a proposed document on the clinical evaluation of SaMD, which FDA issued as a draft guidance document for public comment in October 2016. In September of this year, FDA expects the IMDRF Management Committee to vote on the final document for adoption. If the final document is adopted by IMDRF, FDA intends to issue a final guidance document adopting the internationally converged principles, as appropriate.

2. Reimagining digital health product oversight

The FDA is reimagining its approach to digital health medical devices. We aim to develop pragmatic approaches to optimally foster the development of high-quality, safe, and effective digital health products, while assuring timely patient access. FDA intends to develop a precertification program that could replace the need for a premarket submission for certain products and allow for decreased submission content and/or faster review of the marketing submission for other products.

The first step is a pilot program to develop a new approach toward regulating this technology – by looking first at the software developer or digital health technology developer, not the product.

Under this firm-based approach, CDRH could "pre-certify" eligible digital health developers who demonstrate a culture of quality and organizational excellence based on objective criteria, for example, that they can and do excel in software design, development, and validation (testing). Pre-certified developers could then qualify to be able to market their lower-risk devices without additional FDA review or with a more streamlined premarket review.

This streamlined premarket review could include reduced submission content, faster review of that content by CDRH staff, or both. In addition, firms that take advantage of their "pre-cert" status could collect real-world data postmarket that might be used, for example, to affirm the regulatory status of the product, as well as to support new and evolving product functions. Firms may be able to take advantage of the National Evaluation System for health Technology (NEST), a national evaluation system to generate evidence across the total product lifecycle of medical devices by strategically and systematically leveraging real-world evidence, and applying

advanced analytics to data tailored to the unique data needs and innovation cycles of medical devices. The goal of NEST is to generate better evidence for medical device evaluation and regulatory decision-making throughout the device innovation cycle.[7] FDA is also considering the role of third party certification in facilitating FDA determinations about pre-certification.

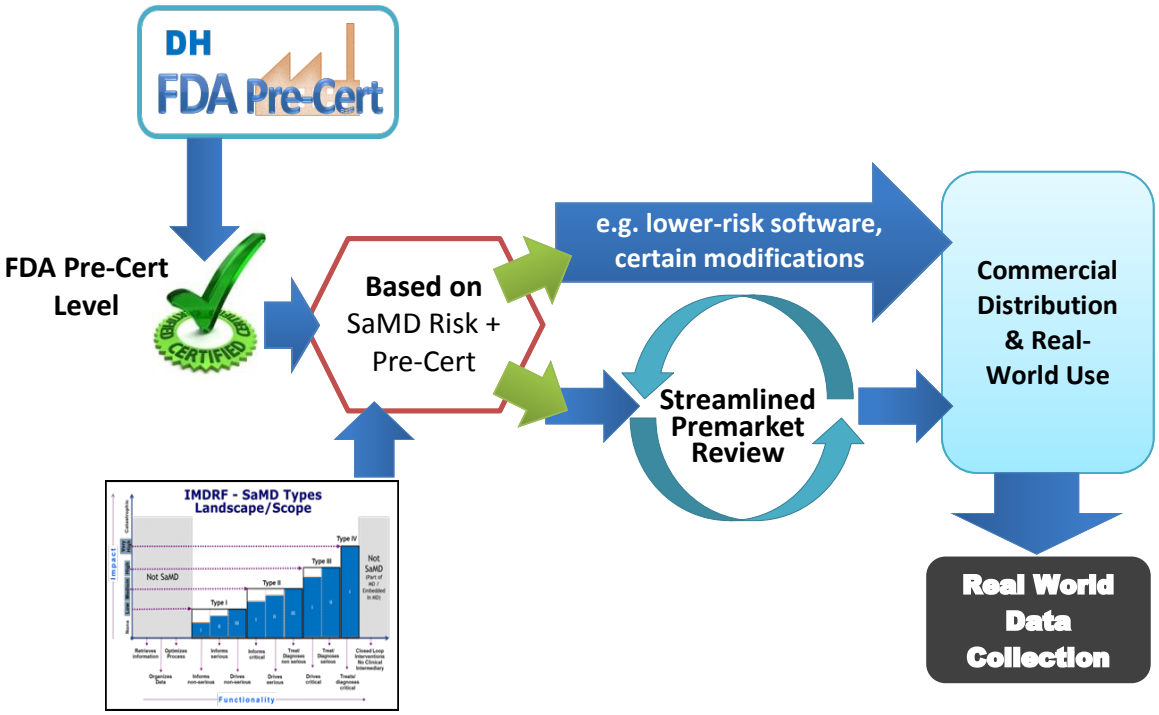

Figure 1. High level concept of the reimagined approach using FDA Pre-Cert for Software

The purpose of FDA's Software Pre-Cert pilot is to leverage customer input to develop a program that can help reduce the time and cost of market entry for software developers that FDA determines reliably manufacture high-quality, safe and effective digital health devices while providing appropriate patient safeguards. Applying such an approach could improve support for continued innovation, allow for more rapid availability of new and updated software, and better focus FDA resources on higher-risk developers and products.

The Federal Register notice announcing the Software Pre-Cert Pilot Program with more details about participation and FDA's goals can be found at https://www.federalregister.gov/documents/2017/07/28/2017-15891/fostering-medical-innovation---plan-for-digital-health-devices-software-precertification-pilot. FDA has discussed the idea of a

[7] For more on NEST, see https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhreports/ucm301912.htm.

precertification program in previous forums and invites further input from all stakeholders throughout this pilot.

3. Growing our expertise

We are growing our digital health expertise within FDA by hiring new staff for our Digital Health Program within CDRH, as supported by additional user fee funding.

Our goal is to build a cadre of experts with a deep understanding and experience with software development and its application to medical devices. This new staff will work with reviewers, compliance officers, and others within the FDA to improve the quality, predictability, consistency, timeliness, and efficiency of decision making on individual products and firms.

We are also launching an Entrepreneurs in Residence program this fall, to take advantage of input from thought leaders and others with real experience in software development to build and structure the digital health function within CDRH as it – and the market – grows.

Customer service and feedback

Finally, we know how important customer service is—and we know we need customer feedback to get our digital health action plan right. We are planning a public workshop to discuss reimagining the paradigm in January of 2018. We also encourage input through the public docket (FDA-2017-N-4301) at www.regulations.gov.