

Digital Health Innovation Action Plan

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.

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.

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Food and Drug Administration (FDA)

Stakeholder(s):

Center for Devices and Radiological Health (CDRH) :

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.

Patients

Doctors :

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.

Consumers :

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.

Clinicians :

Software and technologies that assist in diagnosis, treatment options, storing and sharing health records, and managing workflow can enable more efficient clinical practice.

Communities :

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 Technologists :

Digital health technology has brought new market participants into the medical devices space, and those participants have brought new innovation and manufacturing processes.

Vision

Patients, consumers and other health care customers have timely access to high-quality, safe and effective digital health products.

Mission

To foster digital health innovation while continuing to protect and promote the public health.

Values

Connectivity: Digital health products that leverage connectivity can continually improve their safety and effectiveness through frequent modifications and updates.

Safety

Effectiveness

Cybersecurity: Those benefits are accompanied by challenges of cybersecurity and interoperability.

Interoperability

Accessibility: Use of software and use of consumer technology also make digital health products unusually accessible across international boundaries.

Quality: 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.

Trust

Efficiency: FDA recognizes that an efficient, risk-based approach to regulating digital health technology will foster innovation of digital health products.

Innovation

Iteration: 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.

Evolution: 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.

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

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1. Software

Update current policies and issue new guidance consistent with and providing clarity on the 21st Century Cures Act software provision.

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 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.

1.A. Guidance

Issue a new draft guidance with draft interpretations of several of the medical software provisions in the 21st Century Cures Act.

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.

1.B. Clinical Decisions

Issue a new draft guidance delineating clinical decision support software no longer under FDA's jurisdiction.

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.

1.C. Multifunctionality

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.

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 nondevice 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.

1.D. Software Changes

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 who 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.

Stakeholder(s):

Medical Device Manufacturers

1.E. SaMD

Finalize the International Medical Device Regulators Forum approach to clinically evaluating Software as a Medical Device (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.

Stakeholder(s):

International Medical Device Regulators Forum

IMDRF Management Committee :

In September of this year, FDA expects the IMDRF Management Committee to vote on the final docu-

ment 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. Oversight

Reimagine digital health product oversight.

The FDA is reimagining its approach to digital health medical devices.

2.A. Products

Foster the development of high-quality, safe, and effective digital health products, while assuring timely patient access.

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.

2.A.i. Precertification

Develop a precertification program.

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.

2.A.i.a. Customer Input

Leverage customer input to reduce the time and cost of market entry for software developers.

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.

Stakeholder(s):

Customers :

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--planfor-digital-health-devices-software-precertification-pilot>. FDA has discussed the idea of a precertification program in previous forums and invites further input from all stakeholders throughout this pilot.

Software Developers

Digital Health Technology Developers :

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.

CDRH Staff :

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 :

Firms may be able to take advantage of the National Evaluation System for health Technology (NEST), a national evaluation system to generate evidence

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Stakeholders (continued)

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.

2.A.ii. Third-Party Certification

Consider the role of third party certification.

FDA is also considering the role of third party certification in facilitating FDA determinations about pre-certification.

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3. Expertise

Grow 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.

3.A. Cadre

Build a cadre of experts with a deep understanding and experience with software development and its application to medical devices.

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.

Stakeholder(s):

Software Development Experts

Medical Device Experts

3.B. Entrepreneurs

Launch an Entrepreneurs in Residence program.

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.

Stakeholder(s):

Entrepreneurs

Thought Leaders

Administrative Information

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