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THE FDA 'S
NEW APPROACH
TO DIGITAL HEALTH

The purpose of the Software Pre-Certification Program is to streamline the regulatory process for companies with a history of developing and testing quality products.
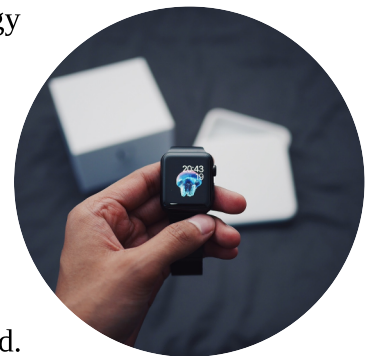
Recognizing that their traditional approach to moderate and higher-risk, hardware-based medical devices is not well suited for the more rapid and iterative design, development, and validation phases used for software products, the FDA has created a new Digital Health Innovation Action Plan.

One important piece of this plan is the "Software Pre-Certification (Pre-Cert) Pilot Program". This pilot program, which began on September 1, 2017, is a voluntary program that will enable the FDA to develop a tailored approach toward regulating digital health technologies by looking first at the software developer and/or digital health technology developer, rather than the product. The purpose of this is to streamline the regulatory process for companies with a history of developing and testing quality products. Once pre-certified, that developer would be empowered to make software iterations and changes as needed.

The nine participants that have been selected for the Software Pre-Cert Pilot Program are: Apple, Fitbit, Johnson & Johnson, Pear Therapeutics, Phosphorous, Roche, Samsung, Tidepool, and Verily. According to the FDA, these participants were chosen as they "represent a wide range of companies and technology in the digital health sector, including small startups and large companies, high- and low-risk medical device software products, medical product manufacturers and software developers."

QUESTIONS FOR
THE FDA

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

Why is the FDA trying to develop a new regulatory approach for software as a medical device?

In order for Americans to see the full benefits of digital health products, we need a regulatory framework that accommodates the distinctive nature of digital health technology, its clinical promise, and the compressed cycle of product iterations. The FDA's traditional approach to medical devices is not well-suited to these products. A new pragmatic approach must recognize the unique characteristics of digital health technology and the marketplace for these tools, so we can promote the public health by supporting the innovation of high-quality, safe, and effective digital health devices.

What types of products are within the scope of the program?

The program only includes software that meets the definition of device in 201(h) of the FD&C Act. We have chosen to keep the scope narrow to software as a medical device to stay focused while developing the program.

Why is the FDA focusing on software for this pilot?

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Is the FDA committed to this pilot program and new approach to digital health?

Yes. This pilot is important and is a priority for the agency. The Software Pre-Cert Program is reflective of the FDA's commitment to promoting the public health by fostering innovation, allowing patients to experience the benefits of advances in software development by facilitating access to high quality, safe, and effective digital health products.

What are some key goals of the Software Pre-Cert Program?

This pilot is an important first step to help us explore and evaluate which elements might be appropriate for a future pre-certification program. Right now, we are aiming to develop an FDA Digital Health Software Precertification (Software Pre-Cert) Program that:

- Enables a modern and efficient regulatory framework that allows software iterations and changes to occur in a timely fashion;
- Provides an easy to follow process for obtaining and maintaining precertification, allowing organizations to continue the customized processes they use to embed a culture of quality and organizational excellence, with minimal translation for regulatory purposes;
- Ensures high quality, safe, and effective software throughout the life of the product, while reducing regulatory burden and regulatory uncertainty, to improve patient and provider access to safe and effective digital health products.
- Is scalable to organizations of all sizes, enabling measurement of "Key Performance Indicators" (KPIs) independent of organization size, deployment strategies, or computing platforms; provides credit for what a company is doing "right";
- Leverages existing certifications or evaluations that show conformance with best practices and/or recognized industry standards; and
- Learns and adapts (i.e., adjust/tweak/evolve scorecard elements and key dimensions and measures) based on the effectiveness of the program and is sufficiently flexible to withstand the variation and evolution of software development and management processes in use to today or that may exist in the future.

Will startups and smaller companies be eligible for the Software Pre-Cert Program?

The pilot program includes both small and large organizations. The FDA recognizes the diversity in the digital health space and plans to design the program in a way that is scalable, so that precertification would be achievable for organizations with a culture of quality and organizational excellence, regardless of size. In this pilot, we are working to identify, examine, and evaluate key performance indicators that are applicable to small organizations as well as large ones.

FDA U.S. FOOD & DRUG ADMINISTRATION

The FDA is seeking public input from a variety of stakeholders, including medical device developers, and encourages comments on their docket **here.**

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