Welcome to today’s FDA/CDRH Webinar

Thank you for your patience while we register all of today’s participants.

If you have not connected to the audio portion of the webinar, please do so now:

Dial: 800-988-9674
International: 1-773-756-4812
Passcode: 2374123
Conference Number: PWXW4874924
Digital Health
SOFTWARE PRECERTIFICATION PILOT PROGRAM

www.fda.gov
Digitization Across the Health Care Continuum

Moving health care from the Clinic to the Patient.
Understanding patient’s behavior and physiology “In the wild”.
Focusing on prevention for early/smaller interventions.

Leveraging computing power, sensors, connectivity and software.
Enable “patient centered” public health as digitization touches every aspect of health care.

Foster trust in innovative technologies as an enabler of a new health care paradigm.

Partner with customers to be "digital-future ready".
Smart Regulation Principles

Platform Independent
Promote Innovation
Promote Patient Engagement
Protect Patient Safety

Functionality Focused
Narrowly Tailored

Risk Based
Digital Health Foundational Policies

- RF Wireless - guidance
- Mobile medical app (MMA)
- FDASIA Health IT report
- Premarket Cybersecurity
- MDDS/image storage and communication
- MMA update
- General wellness
- Accessories
- Post-market cybersecurity

Interoperability

2013 2014 2015 2016 2017
International Convergence on Software as a Medical Device (SaMD)

IMDRF goal - a converged SaMD framework and associated controls.

A prioritized building blocks strategy

2013
- Foundational vocabulary

2014
- Risk framework based on impact to patients

2015
- QMS control
- Translating Software development practices to regulatory QMS

2016/2017
- Application of clinical evaluation

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21 Century Cures Act – Codifies FDA Policies

The new law amended the definition of “device” in the Food, Drug and Cosmetic Act to exclude certain software functions intended...

• (A) for administrative support;
• (B) for maintaining or encouraging a healthy lifestyle;
• (C) to serve as a electronic patient records;
• (D) for transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results and certain other related information; and
• (E) to provide recommendations to health care professionals for clinical decisions, where the user can independently review the basis of the recommendation.
Rapidly Evolving Situation

Current Regulatory Paradigm

- Premarket timeline suited for hardware based products
- Deterministic risks, known responsibilities, physical products
- Current program volume – 3,500 510(k) submissions / 2200 pre-submissions

Unique Aspects of Digital Health

- Software development timelines + software development practices + rapid iterations
- Emerging issues – (cybersecurity; distributed responsibilities, non-physical products)
- Potential for exponential increase in volume of submissions
An Opportunity to Foster Digital Health Innovation and Further Public Health

Considering current FD&C act authorities and implementing regulations
Digital Health Innovation Action Plan

An Integrated Approach

- Refine policies & provide guidance
  - Issue guidance conforming to software provisions of the 21st Century Cures legislation
  - Revise regulations for products that are not devices post 21st Century Cures

- Explore new streamlined pathway for software
  - Launch an innovative pilot Precertification (Pre-Cert) program to build a new approach to digital health technology, working with our customers and leveraging internationally harmonized principles for software regulation

- Building bench strength and expertise
  - Build Digital Health unit with right technical expertise
  - Launch digital health Entrepreneurs-in-Residence program for building the new paradigm
Digital Health Innovation Action Plan

**Refine policies & provide guidance**

**Publish draft guidance**: Effect of the 21st Century Cures Act on existing digital health policies.

**Publish final guidance**: Design considerations and premarket submission recommendations for interoperable medical devices.

**Publish final guidance**: Deciding when to submit a 510(k) for a software change to an existing device.

Finalize the International Medical Device Regulators Forum approach to clinically evaluating SaMD.

**Publish draft Clinical Decision Support Software guidance** that delineates the clinical decision support software that is no longer under FDA’s jurisdiction

**Publish draft guidance**: FDA review of products with some software functions that are devices and some functions that are not.

**Withdraw regulations for products that are no longer devices based on the effect of the 21st Century Cures Act on existing digital health policies.**

2017

2018
An agile and learning regulatory paradigm that is:

- Aligned with software development timelines
- Aligned with industry practices and real world experience
- Aligned with global regulators

An opportunity to work together with customers to build and prepare for a digital health future
Concept

FDA Pre-Cert for Software

A company based streamlined regulatory approach for Software as a Medical Device that relies on a demonstrated Culture of Quality and Organizational Excellence
Concept: A Reimagined Approach Using FDA Pre-Cert

FDA Pre-Cert level

Based on SaMD Risk + Pre-Cert level

Streamlined Premarket Review

Real World Data Collection

Commercial Distribution & Real-World Use

e.g. lower-risk software, certain modifications
FDA Pre-Cert for SaMD

A voluntary program that allows manufacturers of Software as a Medical Device (“SaMD”) to demonstrate their embedded Culture of Quality and Organizational Excellence (CQOE) to ultimately participate in a streamlined and predictable FDA regulatory pathway.

**Purpose/Goal**
Allows manufacturers of SaMD with FDA Pre-Cert status (demonstrated culture of quality and organization excellence):

- To have the ability to get SaMD to market faster;
- To iterate based on real world experience;
- To have an excellent regulatory experience; and
- To have regulatory predictability.

**Public health/innovation outcomes**
1. Companies strive for excellence rather than compliance;
2. Promotes high quality and effective innovation;
3. Transparent FDA Pre-Cert status increases user confidence beyond regulatory oversight; and
4. Allows FDA to focus resources on higher risk digital health products.

**Example of CQOE scorecard elements of interest where a company shows commitment towards ...**

- Providing safe patient experience
- Delivering highest product quality
- Being clinically responsible
- Being cybersecurity responsible
- Being proactive v/s reactive

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A possible framework to measure excellence

PERSPECTIVES

Organizational resource
KPI that demonstrates outcome measures in leadership, employee training, organizational support, infrastructure, employee empowerment, etc.

Customer
KPI that demonstrates outcome measures in revenue, marketing, support, etc.

Learning and growth
KPI that demonstrates outcome measures in product support, innovation, employee training, stakeholder engagement, etc.

Internal process
KPI that demonstrates outcome measures in product engineering, management support, risk management commitment, efficiency, revenue, etc.

Aggregate KPI

Providing safe patient experience
Being clinically responsible

Delivering highest product quality
Being cybersecurity responsible

Being proactive v/s reactive
FDA Pre-Cert Goals

1. Enables a modern and efficient regulatory framework that allows software iterations and changes to occur in a timely fashion;

2. Is an easy to follow process for obtaining FDA Pre-Cert and is easily maintained by the FDA and industry;

3. Ensures high quality and safe and effective software throughout the life of the product by enabling companies to demonstrate their embedded culture of quality and organization excellence (CQOE);

4. Enables measurement of “Key Performance Indicators” (KPI) independent of organization size, deployment strategies, or computing platforms and provides credit for what a company is doing “right”; 

5. Enables for scalability, variation and evolution of software development and management processes in use today or others that may exist in the future; and

6. Is a program that learns and adapts (i.e., adjusts/tweaks/evolves scorecard elements and key dimensions and measures) based on the effectiveness of the program.
A Learning Regulatory Paradigm

DH FDA Pre-Cert

FDA Pre-Cert level

Based on SaMD Risk + Pre-Cert level

Streamlined Premarket Review

e.g. lower-risk software, certain modifications

Commercial Distribution & Real-World Use

Real World data Collection

Real-World Evidence

Regulatory Science

Clinical Trials

Outcomes research

Patient Preference

Evidence Commons

DH FEEDBACK

Effectiveness feedback
Empowering Developers and Software Makers

SaMD Regulatory Development Kit

- The RDK would function and have components similar to a Software Development Kits ("SDK") that enables SaMD manufacturers to efficiently and successfully develop high quality safe and effective products; and

- The RDK would aid in access to relevant regulatory resources and considerations that focus on protecting patient safety and complying with regulatory expectations.

A toolkit for digital health entrants that is usable in an interactive manner (not a paper-only guidance document or checklist);

Comprehensively includes regulatory intent, expectations and principles across the SaMD lifecycle;

Relies on and references existing resources and documents (e.g., FDA guidance, standards, etc.); and

Amplifies regulatory objectives of patient safety and the intent of the regulatory requirements.
Key Building Blocks

- Regulatory Development Kit

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Software Precertification Pilot Program
Scope of the Pilot

- Manufacturers developing or planning to develop software as a medical device (SaMD) as defined by IMDRF.
- Limited to maximum of 9 pilot participants.
- Software function not excluded from medical device definition by 21<sup>st</sup> Century Cures Act.

<table>
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<th>Software is a SaMD when ...</th>
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<td>- Software’s output on its own has a medical purpose as defined by FD&amp;C act;</td>
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<td>- Can run on any computing platform regardless of the location of the platform such as generic PC on a network, mobile phone, generic computer located within a hardware medical device, cloud infrastructure.</td>
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<td>- Can receive/use input from any general purpose peripheral of a computer or a sensor that is not specifically intended for a medical purpose;</td>
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<td>- Can receive/use data generated by other medical devices or in-vitro devices as input;</td>
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<td>- Does not control, or alter functions or other parameters of another medical device.</td>
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**IMDRF SaMD Definition**

*Software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device*
From Concept to A Program: An Iterative Approach

A streamlined Regulatory Program for Software

In COLLABORATION with Pilot Participants + Stakeholders

Concept and framework
# Key Pilot Program Goals

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<tr>
<th>Program component</th>
<th>Deliverable/outcomes of Pilot</th>
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<tr>
<td><strong>Pre-certification components</strong></td>
<td>Leverage industry measures to benchmark CQOE elements</td>
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<td>Develop and evaluate measure criteria</td>
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<td>Develop levels of certification correlated to SaMD risk type</td>
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<td>Prototype mechanism for companies to collect measures for pre-certification as part of their business operations</td>
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<td>Develop and test mechanics to obtain and maintain certification</td>
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<td><strong>Pathway decision criteria</strong></td>
<td>Develop criteria using IMDRF SaMD risk framework and levels of certification</td>
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<td>Develop and test mechanism/tools for pathway determination</td>
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<td><strong>Independent assessment flow</strong></td>
<td>Develop optimal submission method and content</td>
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<td>Explore options for decreasing / aligning to Pre-Cert status</td>
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<td><strong>Post market evidence collection</strong></td>
<td>Identify use scenarios and collection scope and methods</td>
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<tr>
<td><strong>Feedback</strong></td>
<td>Identify appropriate metrics and KPIs to measure effectiveness of the program</td>
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Pilot Participation

- Applications open August 1, 2017 and will remain open throughout the duration of the program.
- Companies submit statement of interest including agreement to selection qualities.
- Phased approach expected to run from September 2017 through September 2018.
- 1st phase targeting participation with 3 companies.

**Statement of Interest Selection Qualities**

- Company must be in the process of developing or planning to develop a software product that meets the definition of a device in 201(h) of the FD&C Act.
- Company has an existing track record in developing, testing and maintaining software products demonstrating a culture of quality and organizational excellence (CQOE) measured and tracked by Key Performance Indicators (KPIs) or other similar measures.
- While participating in the pilot, the company must agree to:
  - Provide access to CQOE measures, KPIs or similar measures.
  - Collect real-world postmarket performance data and provide it to FDA.
  - Be available for real-time consultations with FDA.
  - Be available for site visits from FDA officials.
  - Provide information about the firm’s quality management system.
Expected Pilot Participants Spectrum

Organization size

Large → small

Large

Industry

Traditional (medical device + IVD)

New entrant to MedTech

New entrant to MedTech

Best in class

Shown by known track record / market success in software

Best in class

SaMD risk profile

Low → high

Low

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Pilot Roles and Responsibilities

**CDRH Staff role**

- Work collaboratively with the participating company
- Work alongside with entrepreneurs in residence candidates
- Available to answer questions or concerns that may arise
- Maintain confidentiality of commercial and proprietary information

**Pilot participants role**

- Actively help develop criteria for precertification and process
- Dedicate resources to partner with FDA staff
- Provide access to KPIs or similar measures
- Engage in sharing their experiences with the Pre-Cert pilot to improve the program

**Participant will also ...**

- Collect real-world postmarket performance data and provide it to FDA.
- Be available for real-time consultations with FDA.
- Be available for site visits from FDA officials.
- Provide information about the firm’s quality management system.
Pilot Overview

- Collect statements of interest
  - Applications accepted beginning August 1, 2017
  - Program will begin September 1, 2017
  - Enrollment ongoing throughout the duration of the program

- Select no more than 9 participants
  - Best meet selection criteria
  - Reflect broad spectrum of software developers
  - Include companies that develop a range of both low and high risk software devices

- Develop program elements
  - Conduct Site visits
  - Refine precertification elements in collaboration with participants
  - Share findings and solicit public input

Interested parties should email their statement of interest with subject line “Pre-Cert Pilot: statement of interest” to FDAPre-CertPilot@fda.hhs.gov
Key Points

• Pilot is an important first step to help us explore elements of the program
• Program is part of the FDA’s ongoing efforts to develop pragmatic approaches to balance benefits and risks of digital health products
• Collaborate and learn from companies and stakeholders who perform high-quality software design, testing and maintenance
• Pilot participants will engage with the FDA to explore:
  – Elements of a precertification program that may replace the need for premarket submission in some cases; and
  – May allow for decreased submission content and/or faster review of marketing applications in other cases.
Questions?

For questions related to Digital Health, please contact the Digital Health Team: digitalhealth@fda.hhs.gov

For general question, please contact the Division of Industry and Consumer Education: DICE@fda.hhs.gov

Slide Presentation, Transcript and Webinar Recording will be available at: http://www.fda.gov/training/cdrhlearn
Under the Heading: Specialty Technical Topics

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