FDA’s Software Precertification Program

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FDA’s Software Precertification Program

Frederick R. Ball, Partner, Duane Morris LLP and Treasurer, FDLI Board of Directors
Effects of Moore’s Law

1. The accelerating pace of change...

- Agricultural Revolution: 8,000 years
- Industrial Revolution: 120 years
- Light-bulb: 90 years
- Moon landing: 22 years
- World Wide Web: 9 years
- Human genome sequenced

2. ...and exponential growth in computing power...

- Computer technology, shown here climbing dramatically by powers of 10, is now progressing more each hour than it did in its entire first 90 years.

3. ...will lead to the Singularity

- Apple II: At a price of $1,298, the compact machine was one of the first massively popular personal computers.

Image Credit: Time Magazine
Digital tools can provide consumers with valuable health information.

Consumers who are better informed about health make better decisions.

What qualifies as a digital health product?

What digital health technologies need regulation?

www.fda.gov/digitalhealth
Digital Health Technology

Digital health technology is the convergence of computing power, connectivity, sensors, and software used in healthcare.

→ Used as a medical product;
→ Incorporated into a medical product (include a pharmacologic product);
→ Used to develop a medical product;
→ Used to study a medical product;
→ Used as a companion or adjunct to a medical product, including diagnostics and therapeutics.
Goals for a Tailored Regulatory Framework

**Fostering Responsible Digital Health Innovation**

- Enhance patients access to high quality digital medical products
- Enable manufacturers to rapidly improve software products with minor changes
- Maintain a reasonable assurance of safety and effectiveness
- Minimally burdensome
The Need for a Tailored Approach

While maintaining reasonable assurance of safety and effectiveness

Today’s Device World (Hardware-based)

Product Development Timeline
• Months to years +
• Less frequent modifications

Postmarket Data
• Limited availability and access to real world data (522, PAS, MDRs, MedSun)

FDA Premarket Program Volume:
• Stable (~3,500 510(k) submissions / 2200 pre-submissions)

Digital Health Device World (Software-Based)

Product Development Timeline
• Weeks to months (incremental, iterative) +
• Frequent modifications

Postmarket Data
• Potential for high availability and access to rich real world data (benefits and risks)

FDA Premarket Program Volume:
• Potential for exponential increase in volume of submissions

www.fda.gov/digitalhealth
FDA Pre-Cert Program

An organization-based streamlined regulatory approach for

Software as a Medical Device (SaMD) that relies on a demonstrated

Culture of Quality and Organizational Excellence
Concept: A Reimagined Approach Using FDA Pre-Cert

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
  - Regulatory Science
  - Real-World Evidence
  - Clinical Trials Outcomes research
  - Patient Preference

FDA Pre-Cert level

DH Feedback

FDA Pre-Cert effectiveness feedback
## Five Excellence Principles Proposed

<table>
<thead>
<tr>
<th>Principle</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>Patient Safety</strong></td>
<td>Demonstration of a commitment to providing a <em>safe patient experience</em>, and to emphasizing patient safety as a critical factor in all decision-making processes.</td>
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<tr>
<td><strong>Product Quality</strong></td>
<td>Demonstration of a commitment to the development, testing, and maintenance necessary to deliver SaMD products at the highest level of quality.</td>
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<tr>
<td><strong>Clinical Responsibility</strong></td>
<td>Demonstration of a commitment to responsibly <em>conduct clinical evaluation and to ensure that patient-centric issues</em> including labeling and human factors are appropriately addressed.</td>
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<tr>
<td><strong>Cybersecurity Responsibility</strong></td>
<td>Demonstration of a commitment to <em>protect cybersecurity</em>, and to proactively address cybersecurity issues through active engagement with stakeholders and peers.</td>
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<tr>
<td><strong>Proactive Culture</strong></td>
<td>Demonstration of a commitment to a <em>proactive approach</em> to surveillance, assessment of user needs, and continuous learning.</td>
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Reimagining the Regulatory Approach

While maintaining reasonable assurance of safety and effectiveness

Today’s Device World (Hardware-based)

Go-To-Market

- Pre-Market Organization-Level Data
- Pre-Market Product-Level Data
- Post-Market Data

CURRENT PATHWAY

Digital Health Device World (Software-Based)

- Leverages real world performance data
- Shortens the timeline for premarket product review
- Adds appraisal of company’s culture of excellence

PRE-CERT PATHWAY
FDA’s Software Precertification Pilot Program

✓ **Building** a working model with continuous public input.
✓ **Working** with nine participating companies (large and small).
✓ **Testing** v1.0 throughout 2019 to ensure the same level of **safety** and **effectiveness** of products as compared to our traditional approach.
Our Goals For a New Model

How can a pre-certification program address the evolving needs of SaMD products?

Enable a tailored, pragmatic, and least burdensome regulatory oversight that

1. **Assesses** organizations to establish trust that they have a culture of quality and organizational excellence such that they can develop high quality SaMD products;

2. Leverages **transparency** of organizational excellence and product performance across the entire lifecycle of SaMD;

3. Uses a tailored **streamlined** premarket review;

4. Leverages unique postmarket opportunities available in software to **verify** the continued safety, effectiveness, and performance of SaMD in the real world.
1. A description of the **Total Product Lifecycle approach**

2. Revisions to **Excellence Appraisal** (EA) descriptions for levels of Pre-Cert and FDA’s intention to conduct appraisals in 2019;

3. Revisions to SaMD product-level elements for **review determination**;

4. A proposed list and descriptions of review elements for **streamlined review**, and an updated review process to apply to all submission types;

5. An updated description of the process for developing a **Real World Performance** analysis plan, examples of analytic types/sources, and how the types of RWP collected & the duration of collection may vary.
FDA intends to implement Pre-Cert Pilot Program under the De Novo Pathway so that Excellence Appraised sponsors may:

1. **Submit a “Pre-Cert De Novo”** to receive device classifications through De Novo Pathway by submitting all applicable required information to FDA at different times (i.e., during the Excellence Appraisal, Review Determination, and Streamlined Review);

2. **Submit a Review Determination pre-sub** to confirm a SaMD sponsor is excellence appraised and is eligible for 510(k) under device classification created by Pre-Cert De Novo;

3. **Submit “Pre-Cert 510(k)”** under device classification created by Pre-Cert De Novo containing product-level information on modifications while leveraging EA data to satisfy some required elements of a 510(k) submission.
2019 Test Plan

FDA intends to perform testing of the Pre-Cert program model before establishing it as an alternative premarket pathway for SaMD:

The Test Plan will assess whether **Excellence Appraisal** (EA) and **Streamlined Review** (SR) components together produce an **equivalent basis** for determining reasonable assurance of safety and effectiveness, as compared to the traditional paradigm.

1. **Retrospective Testing:** Internally FDA is conducting retrospective tests of SaMD submissions that FDA previously reviewed.

2. **Prospective Testing:** FDA is working with Pilot Participants who volunteer submissions to apply both the proposed Pre-Cert pathway and the traditional review process;

3. **Evaluation of Findings:** Demonstrate that the evidence collected through EA and SR processes align to satisfy regulatory requirements for safety and effectiveness.
The Test Plan will assess whether Excellence Appraisal and Streamlined Review components together produce an equivalent basis for determining a reasonable assurance of safety and effectiveness, as compared to the traditional paradigm.

Determining Equivalency

Today’s Device World (Hardware-based)
- Pre-Market Organization-Level Data
- Pre-Market Product-Level Data
- Post-Market Data

Traditional Review Method

Go-To-Market

Digital Health Device World (Software-Based)

Streamlined Review
- Leverages real world performance data
- Shortens the timeline for premarket product review

Excellence Appraisal
- Adds appraisal of company’s culture of excellence

The Test Plan will assess whether Excellence Appraisal and Streamlined Review components together produce an equivalent basis for determining a reasonable assurance of safety and effectiveness, as compared to the traditional paradigm.
2019 Test Approach

Excellence Appraisal
Pre-Cert team conducts excellence appraisal

Streamlined Review
Pre-Cert team identifies and extracts elements for SR

Review Team (Pre-Cert Pathway)
Review team makes a determination of reasonable safety and effectiveness based on review of the Excellence Appraisal results and the Streamlined Review elements

Pre-Cert Team
Evaluates and refines Pre-Cert Model based on the comparison of findings of both review teams

Traditional Review Method
Review team evaluates submission

DeNovo Premarket Submission
Pilot participant company submits a product for review.

Review Team (Traditional)

Regulatory Decision
OHT Leadership makes the final regulatory decision on the product
Developing the Program with Stakeholder Input

All stakeholders

The FDA continues to seek input on the Pre-Cert working model from the public through the public docket. Your input will help shape the next steps that we take to build the Pre-Cert program.
We’re building our Digital Health Center of Excellence to develop more efficient ways to ensure the safety and effectiveness of technologies like smart watches with medical apps. Our Software Precertification Pilot Program is allowing us to test a new approach for product review.

Dr. Scott Gottlieb, FDA Commissioner
April 2, 2019
2019 FDLI Annual Meeting

Lesley R. Maloney, Pharm.D.
Head, U.S. Regulatory Policy, Roche Diagnostics
REIMAGINE
FDA Software Precertification Pilot Program

Perspectives From A Pilot Participant
FDA Software Precertification Pilot Program

Perspectives From A Pilot Participant

• **2018**: Focused on providing input to the draft Working Models
  – Review Determination
  – Streamlined Review
FDA Software Precertification Pilot Program

Perspectives From A Pilot Participant

• 2018: Focused on providing input to the draft Working Models
  – Review Determination
  – Streamlined Review

• 2019: Individual companies test Working Model v1.0
  • Preparing for FDA to conduct an Excellence Appraisal
  • Fit-for-purpose quality management system (QMS)
  • Continued development of our SaMD for traditional submission
Global Interest in Software Regulation

Driving Toward Global Convergence

Global Organizations

IMDRF
WHO
Challenges

• Confusion between qualification and classification
• Mapping IMDRF risk classifications to local jurisdictions
• How to appropriately review software in a streamlined manner
• Extent of FDA’s legal authority
Digital health solutions connect the dots...
creating an ever-expanding healthcare ecosystem to support more informed health decisions and improved patient outcomes.
FDA’s Software Precertification Program

Ian Pearson, Senior Associate, Jones Day
FDA Software Pre-Cert: Startup Perspective

Mobile Medical Apps  
Medical Software  
Artificial Intelligence
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New Regulatory Paradigm

**Traditional Device Regulation**
- Medical Device Amendments added to FDCA in 1976
- Meant to address hardware-based products at the time
- Slower development cycles and technology design changes

**Unique Aspects of Digital Health**
- Digital health has brought new market participants
- Software development differs from hardware
- New safety issues (e.g., cybersecurity, data privacy, connectivity, AI, etc.)
Enacted in December 2016, Section 3060 of the Cures Act removes certain types of medical software from FDA’s regulatory jurisdiction, including software intended to:

1. Support administrative functions;
2. Encourage a healthy lifestyle;
3. Serve as an electronic patient record;
4. Transfer, store, convert formats, or display device data and findings; or
5. Provide clinical decision support

- See FDA draft guidance 2017: Clinical and Patient Decision Support Software
FDA Software Pre-Certification Pilot Program

- The Pre-Cert Pilot Program is intended to be a tailored approach to regulating software by focusing regulatory oversight on developers rather than the product
  - Will allow manufacturers to “demonstrate a culture of quality and organizational excellence”
  - Leveraging of real-world data and regulatory history
- If adopted, this developer-targeted review would be a significant departure from FDA’s historic approach of evaluating each individual product
- Pilot participants include:
Software Pre-Cert: Program Outline

Source: FDA.gov
Startups: Unique Concerns

- Unclear Pathway
- Funding
- Investors
- ROI
- Novel Products
- Competition
- Evolving Landscape
- Budget
- Resources
- Timelines
- Information Overload
- Unclear Pathway
The Startup Perspective

**LIKES**
- Acknowledgment
- Agency Responsiveness
- Focused Review
- Shorter Timelines

**CONCERNS**
- Legal Authority
- Scalability
- Burden
- Information Sharing
- Staffing
- Cost
The Path Forward
Any Questions?