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:

U.S. Callers Dial: 877-939-8828
International Callers Dial: 1-517-308-9385
Conference Number: PWXW7322399
Passcode: 9105668
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

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

Explore new streamlined pathway for software

- Launch an innovative Software 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
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- Publish draft guidance: Effect of the 21st Century Cures Act on existing digital health policies.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 Software as a medical device (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- Publish draft guidance: FDA review of products with some software functions that are devices and some functions that are not.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 and amend 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

- ✔
Multiple Functionality Draft Guidance

Key Draft Policy Proposed

(A) Does the other function impact the safety or effectiveness of the device function-under-review?; and

(B) Does the impact result in increased risk or have an adverse effect on performance?

<table>
<thead>
<tr>
<th>Function:</th>
<th>Premarket Oversight</th>
<th>Postmarket Oversight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device function under review (510(k), PMA, IDE, De Novo, or HDE)</td>
<td>Reviewed</td>
<td>General control requirements are applicable (except for IDE)</td>
</tr>
<tr>
<td>Device function that is 510(k) exempt</td>
<td>Not reviewed but assessed only for impact on the safety and effectiveness of the device function-under review</td>
<td>General control requirements are applicable</td>
</tr>
<tr>
<td>Device function for which no premarket review is sought and FDA does not intend to enforce applicable regulatory controls</td>
<td>Not reviewed but assessed only for impact on the safety and effectiveness of the device function-under review</td>
<td>General control requirements are applicable but not intended to be enforced</td>
</tr>
<tr>
<td>Non-device function</td>
<td>Not regulated but assessed only for impact on the safety and effectiveness of the device function-under review</td>
<td>Not regulated and therefore FDA requirements not applicable</td>
</tr>
</tbody>
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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

www.fda.gov
Concept: A Reimagined Approach Using FDA Pre-Cert

- Based on SaMD Risk + Pre-Cert level
- Streamlined Premarket Review
- Commercial Distribution & Real-World Use
- Real World Data Collection
- Regulatory Science
- Real-World Evidence
- Clinical Trials Outcomes research
- Patient Preference

FDA Pre-Cert level

Assess effectiveness feedback

DH FEEDBACK

DH

FDA Pre-Cert

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Developing the Program with Stakeholder Input

All stakeholders +
April Program Update

Developing a Software Precertification Program: A Working Model
(v0.1 - April 2018)

Introduction

The Software Precertification Program is intended to provide a more streamlined regulatory model more tailored than the current model to the rapid development and testing of software technologies without impacting patient safety.

Challenge Questions

Software Precertification Program

FDA proposes the following challenge questions for public input.

0.1 FDA recognizes stakeholder perspectives and priorities as important inputs into the development of the Precertification Program. How should anticipated stakeholder benefits in Table 1 in the program Working Model be revised, and what additional stakeholder perspectives should be included?

0.2 As a stakeholder, what would you want to know about the organizations that have been precertified and about the SaMD products that they manufacture?

Excellence Appraisal

FDA proposes the following challenge questions for public input. Although these questions are specific to excellence appraisal models and precertification status, they should be considered in:

- Pre-Cert 1.0
- First version of the program
- Program next steps for 2019

Scenario Testing:
- Scenario testing: Evaluate the degree to which program objectives are achieved, as well as lessons learned, in order to iteratively improve the components and the whole.
- Finalize Pre-Cert 1.0: Integrate stakeholder feedback, lessons learned, and other inputs into a cohesive set of deliverables.

Build - Test - Iterate | Integrate - Simulate - Pre-launch | Launch

<table>
<thead>
<tr>
<th>Pre-Cert Components</th>
<th>Working model - initial</th>
<th>Update</th>
<th>Update</th>
<th>Update</th>
</tr>
</thead>
</table>

Excellence Appraisal

- Excellence criteria: Objective indicators that demonstrate company commitment to creating safe and effective software as an integral device (SaMD).
- Evaluation metrics: How software is evaluated for safety.
- Success criteria: How companies pass, fail, lose, and receive the Pre-Cert.
- Program assurance: How companies qualify for and initiate evaluation, including pre-certification.

Review Determination

- Self-certification: How the Pre-Cert program meets SaMD-risk category, including alignment to other frameworks such as MDSAP-PreCyS, how FDA determines classification, how classification risk changes, criteria for re-certification, etc.
Four Key Program Components in Proposed Framework

- Streamlined Premarket Review
- Streamlined Review
- Risk Based (SaMD Risk + Pre-Cert level)
- Review Determination
- Real-world SaMD Performance
- Real-world Program Performance
- Real-World Performance
- Excellence Appraisal and Certification
- FDA Pre-Cert Level 2
- FDA Pre-Cert Level 1
Five Excellence Principles Proposed

1. **Patient Safety**
   - Demonstration of a commitment to providing a safe patient experience, and to emphasizing patient safety as a critical factor in all decision-making processes.

2. **Product Quality**
   - Demonstration of a commitment to the development, testing, and maintenance necessary to deliver SaMD products at the highest level of quality.

3. **Clinical Responsibility**
   - Demonstration of a commitment to responsibly conduct clinical evaluation and to ensure that patient-centric issues including labeling and human factors are appropriately addressed.

4. **Cybersecurity Responsibility**
   - Demonstration of a commitment to protect cybersecurity, and to proactively address cybersecurity issues through active engagement with stakeholders and peers.

5. **Proactive Culture**
   - Demonstration of a commitment to a proactive approach to surveillance, assessment of user needs, and continuous learning.
Eligibility

Any organization that intends to develop or market a regulated SaMD in the United States.

• FDA anticipates precertification at a business unit or center of excellence level, rather than at a corporate level.

Application

Eligible organizations or business units apply.

FDA confirms eligibility and acceptability.

FDA and applicant initiate process for precertification determination.

Appraisal

Applicant collects objective indicators related to the excellence principles.

Collected information demonstrating capabilities and maturity made available for appraisal.

Determination

FDA evaluates evidence and decides on approval and level of precertification.

Maintenance

• Automated tracking and monitoring of adherence to excellence principles.

• Proactive response to postmarket indicators.

• Details to be developed in future version.

Concept in the Working Model v0.1 – April 2018

Excellence appraisal and precertification

Scope of the component: The process for organization level precertification, including eligibility and application, evaluation against precertification criteria, and precertification status determination.

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Challenge Question 1.1 Excellence appraisal and precertification

How might an existing excellence or maturity appraisal framework used by an organization be leveraged to demonstrate the organization’s performance and success as outlined by the five excellence principles?

How should the FDA take into consideration...

• Certifications granted by external business excellence appraisal entities
• Maturity assessments made by external agencies
• Use of standards
• Accreditations
• Adoption of corporate level policies at a business unit level
• Adapting the appraisal model for start-up, new businesses
• Other...
How You Can Get Involved

Provide ongoing input through the public docket
bit.ly/docketjan18

Send questions about the program
FDAPre-CertPilot@fda.hhs.gov

Look for ongoing program updates
bit.ly/Precertupdates

#FDAPreCert

www.fda.gov
Review Determination

**Scope of the component:** The process and expectations for pre-certified organizations to determine when streamlined premarket review is applicable for each category of SaMD products.

**Concept in the Working Model v0.1 – April 2018**

1. Working to refine the SaMD International Medical Device Regulators Forum (IMDRF) Risk framework for application in the precertification program.

2. Preliminarily based on the risk category of SaMD product, determine when premarket review is necessary, including initial product availability, and major and minor product changes informed by:
   - Organization’s Pre-Cert status and level (Excellence Appraisal)
   - SaMD premarket requirements (Streamlined Review)
   - SaMD postmarket requirements (Real-World Performance)
We are exploring the refinement of the “IMDRF definition statement,” which is intended to provide a structured way in describing intended use for SaMD.

The IMDRF framework highlights the following components:

– The significance of the information provided by the SaMD to the healthcare decision; more specifically, how the SaMD dictates treatment or diagnosis, drives clinical management, or informs clinical management;

– The state of the healthcare situation or condition that the SaMD is intended for; more specifically, a description of the health state when the SaMD is intended for use, ranging from critical to serious to non-serious; and

– A description of the SaMD core functionality; more specifically, the critical features of the SaMD that are essential to the intended significance of the information provided by the SaMD to the healthcare decision in the intended healthcare situation or condition.

Questions...

• Within each of the three components, are there other factors that are currently included in describing the products’ intended use, and if so, what?

• Should the factors in the current components be further refined in order to provide clarity around the function and intended use of the SaMD and if so, how?
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#FDAPreCert
Streamline Review

**Scope of the component:** The process and expectation for a precertified organization and the FDA when it is determined that a streamlined premarket review is necessary to reasonably assure safety and effectiveness of a SaMD.

**Goals**

- Identify information necessary to reasonably assure safety and effectiveness to be reviewed
- Identify aspects that will be relied upon during pre-certification appraisal and the organizations engagement in real world performance data monitoring of their SaMD
- Identify an interactive process of conducting the review that yields best experience for FDA reviewers and organizations participating in the program

Concept in the Working Model v0.1 – April 2018
Challenge Question 3.1 Streamline Review

Given that one goal of this program is to significantly reduce the average premarket review timeline, what would be the best way for pre-certified companies to share product review information with us? Specifically:

Questions...

• What specific elements of review could be shifted to the company-specific excellence appraisal (as opposed to the product-specific review)?
• What are the features of a SaMD product that need to be assessed during device review?
• What product-specific content would be expected to be reviewed premarket?
• What specific postmarket real world data could be collected to support the assurance of safety and effectiveness for each product if an element is not reviewed premarket?
• What updates would FDA require, and at what interval, to provide continuous assurance of safety and effectiveness?
• Should there be a phased market authorization, where some elements are reviewed premarket and other elements are gathered through real world evidence to support full market authorization? What should happen to products that receive “preliminary” market authorization but fail to provide adequate evidence in the agreed upon timeframe?
How You Can Get Involved

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bit.ly/docketjan18

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Real-World Performance

**Scope of the component:** The process for developing real-world performance data (RWPD) elements and analytic methodologies needed for Pre-Cert Program activities.

**Concept in the Working Model v0.1 – April 2018**

<table>
<thead>
<tr>
<th>Level</th>
<th>Preliminary Pre-Cert Program Feedback: Use of aggregate organizational RWPD analysis as feedback to EA and SR components of the Pre-Cert Program</th>
</tr>
</thead>
<tbody>
<tr>
<td>Organization</td>
<td>Preliminary Inputs to Initial Precertification: Use of aggregate product RWPD as inputs into initial precertification</td>
</tr>
<tr>
<td>Product</td>
<td>Preliminary Inputs to Maintenance of Precertification: Use of aggregate product-level RWPD analysis as inputs into maintenance or modification of precertification status</td>
</tr>
<tr>
<td>Product</td>
<td>Preliminary Post-launch Product Monitoring: Post-launch monitoring of RWPD to ensure ongoing safety and effectiveness of a SaMD product</td>
</tr>
<tr>
<td>Product</td>
<td>Preliminary Product Claim Modifications: Use of RWPD in making and modifying SaMD product claims</td>
</tr>
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Challenge Question 4.4 Real-World Performance

Are the definitions for data types underlying RWPD accurate and comprehensive? Do the terms used in this section need to be modified or revised?

- **Real World Performance Data**: all data relevant to the safety, effectiveness and performance of a marketed SaMD product from a precertified manufacturer

- **Real World Health Data**: outputs and outcomes related to the intended use of the SaMD product

- **User Experience Data**: outputs derived from user experiences related to the real world use of a SaMD product

- **Product Performance Data**: outputs and outcomes demonstrating the accuracy, reliability, and security of a SaMD product
Questions & Answers
Pre-Cert Program Roadmap

2018

Pre-Cert Development

Jan

Dec

Build - Test - Iterate
Integrate
Pre-launch
Launch

2019

Pre-Cert 1.x
Pre-Cert 2.0

Jan

Dec

Public Input
Late Summer
Public Input
Late Fall
Public Input

Develop: Excellence Appraisal Model
Develop: Streamlined Review Approach
Develop: Real World Data (access, approach and analysis)

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Keep Engaging With Us

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Under the Heading: Specialty Technical Topics; Subheading: IT and Software

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