Digital Health

SOFTWARE PRE-CERT PILOT PROGRAM KICK-OFF MEETING

www.fda.gov
Agenda

• Introductions (10 min)
• Pre-Cert Pilot Goals and Objectives (20 min)
  – FDA Perspective (5 min)
  – Pilot Participant Perspective (15 min)
• Pre-Cert Pilot Program Logistics (10 min)
  – Points of Contact
  – Engagement Plan and Schedule
• Site Visits and Data Collection: Excellence Principles and Common Validating Perspectives (25 min)
• Questions and Discussions (20)
• Next Steps (5 min)
FDA Pre-Cert Pilot Overview

A company-based, streamlined regulatory approach for Software as a Medical Device that relies on a demonstrated Culture of Quality and Organizational Excellence
• 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".
An agile and learning regulatory paradigm that is:

- Aligned with software development timelines
- Aligned with industry practices
- Aligned with global regulators
FDA Pre-Cert Concept

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

DH FEEDBACK

FDA Pre-Cert level
Pre-Cert Program Objectives

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. Not static -- 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.
## FDA: Key Deliverables

<table>
<thead>
<tr>
<th>Program component</th>
<th>Deliverable/Outcomes of Pilot</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pre-certification Framework</strong></td>
<td>Measures to benchmark CQOE elements</td>
</tr>
<tr>
<td></td>
<td>Criteria to evaluate measures</td>
</tr>
<tr>
<td></td>
<td>Levels of certification correlated to SaMD risk type</td>
</tr>
<tr>
<td></td>
<td>Prototype mechanism for companies to collect measures for pre-certification as part of their business operations</td>
</tr>
<tr>
<td></td>
<td>Mechanics for obtaining and maintaining certification</td>
</tr>
<tr>
<td><strong>Regulatory Pathway Decision Criteria</strong></td>
<td>Develop criteria using IMDRF SaMD risk framework and levels of certification</td>
</tr>
<tr>
<td></td>
<td>Develop and test mechanism/tools for pathway determination</td>
</tr>
<tr>
<td><strong>Processes for Streamlined Regulatory Review</strong></td>
<td>Explore optimal review method and content</td>
</tr>
<tr>
<td></td>
<td>Explore options for review method content to Pre-Cert status</td>
</tr>
<tr>
<td><strong>Post-Market Evidence Collection</strong></td>
<td>Identify use scenarios and collection scope and methods</td>
</tr>
<tr>
<td><strong>Program Feedback and Evaluation</strong></td>
<td>Identify appropriate pre-cert program metrics and KPIs to measure effectiveness of the program</td>
</tr>
</tbody>
</table>
From Concept to A Program: An Iterative Approach

A streamlined Regulatory Program for Software

In COLLABORATION with Pilot Participants + Stakeholders

Concept and framework
Pilot Participant: Perspective

Suggested content

• **Overview:**
  – *State of Software in Healthcare*
  – *Company’s role in healthcare*

• **Participating in the pilot**
  – *Objectives*
  – *Expectations*

• **In the final state of the Software Pre-Certification Program**
  – *What values you expect should be delivered for public health?*
  – *What efficiencies will be afforded?*
• Discussion
  –Aligning goals and expectations
FDA Pre-Cert Pilot Engagement
FDA Team Structure & Governance

FDA Site Visit Team (5-7 Members)
1. Bakul Patel, Associate Director, Digital Health
2. Point of Contact - Marisa Cruz/Cathy Bahr/John Murray
3. Pre-Market office
4. Post-Market Surveillance
5. Compliance
6. Entrepreneur-in-Residence

POC Key Responsibilities:

- Serves as primary liaison between Pilot Participants and FDA Tactical Team
- Facilitates site visit, including exchange of information prior to and following visit
- Leads review and analysis of company-provided data, including synthesis and aggregation for purposes of public presentation or disclosure
# Pilot Participant Engagement Plan

<table>
<thead>
<tr>
<th>Activity Topic</th>
<th>Lead</th>
<th>Outcomes</th>
</tr>
</thead>
</table>
| Kick-Off Meeting             | FDA        | • Set frequency of engagement  
                                   • Review product roadmap  
                                   • Assign FDA POC for PP |
| CQOE Collection Plan         | FDA + PP   | • Review of PP CQOE measures  
                                   • Set agenda for site visit |
| CQOE Collection              | PP         | • Collect CQOE measures  
                                   • Establish mechanism for data sharing |
| Consolidate CQOE Measures    | FDA + PP   | • Aggregate and normalize CQOE measures across PP ** |
| Update CQOE / KPI            | FDA + PP   | • Update Pre-Certification Framework ** |
| Determine Pre-Cert Status    | FDA        | • Establish Pre-Cert status |
| Public Meeting               | FDA + PP   | • Set agenda for public meeting  
                                   • Determine findings to be shared at public meeting ** |
| Product Review Plan          | FDA + PP   | • Product categorization  
                                   • Set post-market data collection plan ** |
| Product Review               | FDA + PP   | • Product review |
| Pilot Participant Debrief    | FDA + PP   | • Aggregate lessons learned **  
                                   • Refine CQOE measures **  
                                   • Refine product review pathway |

** opportunities to share publicly
Staged Area of Focus

<table>
<thead>
<tr>
<th>Development Stage</th>
<th>Pre-Cert</th>
<th>Streamlined Review</th>
<th>Post-Market Surveillance</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Develop and Publish Pre-Cert Concept</td>
<td>Aggregate Data</td>
<td>Aggregate Data</td>
<td>Aggregate Data</td>
</tr>
<tr>
<td></td>
<td>Refine Framework</td>
<td>Refine Framework</td>
<td>Refine Framework</td>
</tr>
<tr>
<td></td>
<td>Share Publicly</td>
<td>Share Publicly</td>
<td>Share Publicly</td>
</tr>
<tr>
<td>Pilot Participants</td>
<td>Site Visits</td>
<td>Site Visits</td>
<td>Site Visits</td>
</tr>
<tr>
<td></td>
<td>Review and Feedback</td>
<td>Review and Feedback</td>
<td>Review and Feedback</td>
</tr>
<tr>
<td>Stakeholders</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Review and Feedback</td>
<td>Validate</td>
<td>Validate</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Review and Feedback</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

www.fda.gov
• Questions?
• Clarifications?
• Discussion
Pre-Certification Framework: Principles of Excellence
Excellence Principles

**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.

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

**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.

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

**Proactive Culture**
Demonstration of a commitment to a proactive approach to surveillance, assessment of user needs, and continuous learning.
Company Specific –
Common Validating Perspectives

Customer Prospective
How does our consideration of customer needs and customer satisfaction support our commitment to the excellence principle?

Process Prospective
How do we ensure our processes support our commitment to the excellence principle?

Organizational Resource Perspective
How do we empower employees to meet the excellence principle by providing necessary tools, training, and infrastructure?

Learning and Growth Perspective
How will we employ continuous learning and improvement to support our commitment to the excellence principle?
Scorecard Framework

Excellence Principles

- Product Quality
- Proactive
- Patient Safety
- Clinically Responsible
- Cyber Responsible

Common Validating Perspectives

- Process Prospective
- Organizational Resource Perspective
- Customer Prospective
- Learning and Growth Perspective

Key Performance Indicators

How will we employ continuous learning and improvement to support our commitment to the excellence principle?

Library of qualitative and quantitative measures that evaluate excellence
## Bridging to KPIs: Appraisal Questions

<table>
<thead>
<tr>
<th>EP</th>
<th>CVP</th>
<th>Appraisal Questions</th>
<th>KPI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Safety</td>
<td>Organizational Resource</td>
<td>How do employees identify, report, and act on patient safety issues?</td>
<td></td>
</tr>
<tr>
<td>Customer</td>
<td></td>
<td>Does your organization contact your customers regarding patient safety issues?</td>
<td></td>
</tr>
<tr>
<td>Learning and Growth</td>
<td></td>
<td>How does your organization identify future development or skills needs with regards to patient safety?</td>
<td></td>
</tr>
<tr>
<td>Process</td>
<td></td>
<td>How does your organization validate corrective actions to prevent patient safety issues and inform patients/customers about potential issues?</td>
<td></td>
</tr>
</tbody>
</table>
## Bridging to KPIs: Appraisal Questions

<table>
<thead>
<tr>
<th>EP</th>
<th>CVP</th>
<th>Appraisal Questions</th>
<th>KPI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Quality</td>
<td>Organizational</td>
<td>What tools do employees have available to identify and track product quality issues?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Resource</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Customer</td>
<td>How does your organization monitor customer reports of product quality issues?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Learning and</td>
<td>How do you leverage real-world evidence in improving product quality?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Growth</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Process</td>
<td>How are quality risks in marketed products identified and managed?</td>
<td></td>
</tr>
</tbody>
</table>
## Bridging to KPIs: Appraisal Questions

<table>
<thead>
<tr>
<th>EP</th>
<th>CVP</th>
<th>Appraisal Questions</th>
<th>KPI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Responsibility</td>
<td>Organizational Resource</td>
<td>How do you ensure that employees responsible for clinical evaluation have the knowledge, skills, and experience to understand clinical benefits and risks?</td>
<td></td>
</tr>
<tr>
<td>Customer</td>
<td></td>
<td>How does your organization incorporate customer perspectives into product development and modification?</td>
<td></td>
</tr>
<tr>
<td>Learning and Growth</td>
<td></td>
<td>How does your organization utilize learning from external sources regarding clinical risks and benefits relevant to product design or process improvements?</td>
<td></td>
</tr>
<tr>
<td>Process</td>
<td></td>
<td>How does your organization identify weaknesses or gaps in the process of clinical evaluation?</td>
<td></td>
</tr>
</tbody>
</table>
## Bridging to KPIs: Appraisal Questions

<table>
<thead>
<tr>
<th>EP</th>
<th>CVP</th>
<th>Appraisal Questions</th>
<th>KPI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cybersecurity Responsibility</td>
<td>Organizational Resource</td>
<td>How is leadership made aware of cybersecurity issues that arise in product design, development, and validation?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Customer</td>
<td>How does your organization assess customer needs and concerns related to cybersecurity?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Learning and Growth</td>
<td>How do employees throughout the organization learn about cybersecurity issues?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Process</td>
<td>How does your organization monitor process optimization and improvement activities for cybersecurity?</td>
<td></td>
</tr>
</tbody>
</table>
## Bridging to KPIs: Appraisal Questions

<table>
<thead>
<tr>
<th>EP</th>
<th>CVP</th>
<th>Appraisal Questions</th>
<th>KPI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proactive Culture</td>
<td>Organizational Resource</td>
<td>How is the value of operational and product improvement efforts measured?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Customer</td>
<td>How does your organization communicate with customers about new or emerging issues?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Learning and Growth</td>
<td>How often are employees rewarded for proactively identifying and taking action on opportunities for improvement?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Process</td>
<td>How are the goals and vision for a proactive corporate culture communicated to the organization?</td>
<td></td>
</tr>
</tbody>
</table>
Questions and Considerations

• Would you refine the excellence principles and/or common validating perspectives to better reflect your understanding of excellence in an organization? How?

• How do you use the common validating perspectives to demonstrate commitment to the excellence principles?

• How does your organization use metrics to evaluate your performance against these excellence principles?
Pre-Cert Site Visit: Objectives

* To experience and understand methods and processes for establishing and demonstrating a culture of quality and organizational excellence.

* Understand current practices.

* Have a clear understanding of how your organization approaches and tracks progress towards each excellence principle.

* Identify items to enhance the excellence framework

Key Points

* The site visit is NOT an audit or inspection.

* FDA and company will collaborate and be in a learning mode to refine the framework.
Example deep dive: Tell Us How You Approach....

- In design and development activities?
- In verification and validation activities?
- In clinical evaluation activities?
- For software updates and iterations?
- In post-market surveillance activities?
Questions and Discussion
Next Steps

• Site Visit Logistics
• Exchange of Information Prior to and Following Site Visits
• Public Meeting
  – Goals and Objectives
  – Roles and Expectations