

Software Precertification Program Model

1. Software Precertification Program Concept and Baseline Framework.

1.1. Concept. The Software Precertification (Pre-Cert) program is envisioned to offer a voluntary pathway for a more streamlined and efficient regulatory review of software-based medical devices from manufacturers that have demonstrated a robust culture of quality and organizational excellence. The three key components of the program, depicted below, are: 1) Pre-Cert, 2) streamlined pre-market review, and 3) FDA access to post-market data collection.

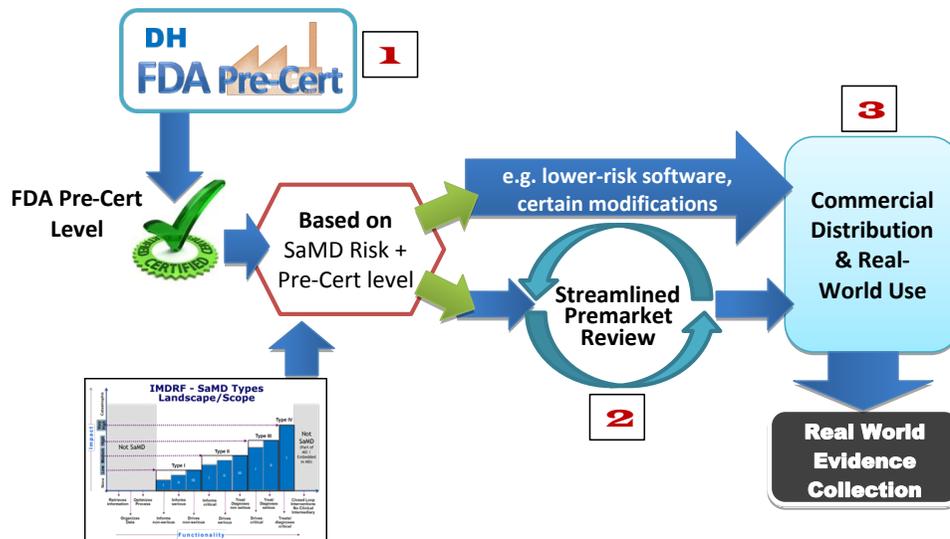


Figure 1: Software Pre-Cert Concept Model – This model illustrates three key components of the program 1) Pre-Cert, 2) streamlined pre-market review, and 3) FDA access to post-market data collection.

1.2. Baseline Framework. The International Medical Device Regulators Forum (IMDRF) has issued a series of [guidance documents](#) that outline guiding principles for regulation of Software as a Medical Device (SaMD). These principles are meant to provide an initial framework for developing jurisdiction-specific policies related to SaMD regulation. The FDA intends to leverage certain concepts from the IMDRF framework at the outset of the pilot, as described below, but such concepts may be revised throughout and following the pilot.

- SaMD will be defined initially as outlined in the IMDRF guidance documents.
- Pre-Cert Levels: The FDA anticipates more than one precertification level. We will initially assume a 2-level system. The number of levels and the qualifying criteria for

each level may evolve over the course of the pilot. For example, these levels can be imagined as follows:

- Level 1 – robust quality systems but no or little demonstrated experience in health care
 - Level 2 – robust quality systems with demonstrated experience in health care
- Pre-Cert status will be based initially on FDA evaluation of five key principles (See Appendix A for definitions of Culture of Quality and Organizational Excellence (CQOE) principles). The number of principles and the evaluation criteria may evolve over the course of the pilot.
- Patient safety
 - Product quality
 - Clinical responsibility
 - Cybersecurity responsibility
 - Proactive culture
- SaMDs will be categorized initially using the IMDRF framework below:

State of Health care situation or condition	Significance of information provided by SaMD to health care decision		
	Treat or diagnose	Drive clinical management	Inform clinical management
Critical	IV	III	II
Serious	III	II	I
Non-serious	II	I	I

Figure 2: IMDRF Software as a Medical Device Risk Categorization Framework

- The FDA will develop a draft framework for SaMD regulatory review based on the IMDRF Risk Categorization.

2. Software Pre-Cert Pilot: Roles and Responsibilities. The FDA Tactical Team for the Pre-Cert pilot will include FDA review, compliance, and policy staff, as well as a cohort of [Entrepreneurs-in-Residence](#). Pilot participants will interact with the FDA Tactical Team through a series of site visits to U.S. facilities and virtual meetings. In addition to seeking input from all stakeholders, the FDA will also solicit individual feedback on the Software Pre-Cert program framework from external stakeholders and strategic contributors (thought leaders, patient advocate groups, trade associations and others) throughout the pilot.

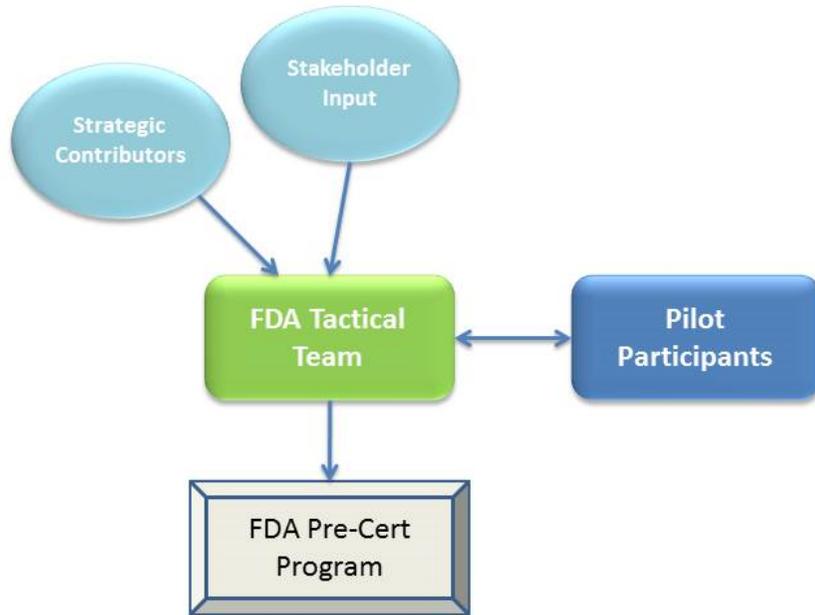


Figure 3: FDA Software Pre-Cert Pilot Program Roles and Responsibilities: Soliciting feedback from Stakeholders, Strategic Contributors, Pilot Participants, and FDA’s Tactical Team

Pilot participants and the FDA Tactical Team will develop the pilot through an iterative process of data collection and analysis. Updates on the proposed Software Pre-Cert model, including any aggregate data supporting the updates, will be shared publicly at regular intervals:

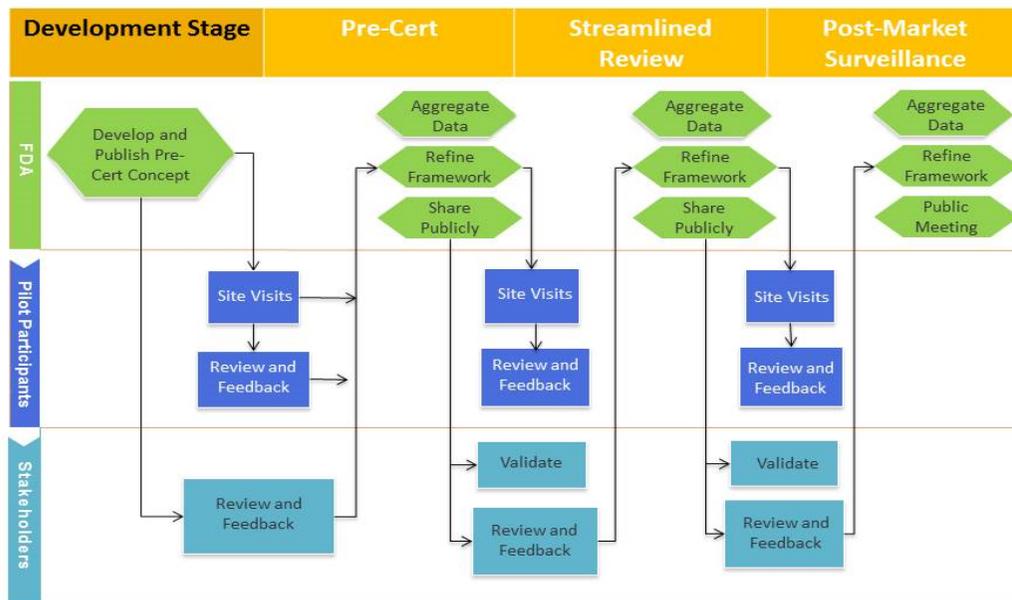


Figure 4: FDA intends to work with pilot participants to collect data and refine the program model, and periodically work with stakeholders to collect feedback.

3. Software Pre-Cert Pilot: Participant Engagement Plan.

The following represents a general framework for engagement between the FDA and individual Pilot Participants (PP) selected to participate of the Software Pre-Cert Pilot:

Activity Topic	Lead	Outcomes
Pilot Participant Selection Notification	FDA	<ul style="list-style-type: none"> • Agree on expectations • Plan for statement of understanding
Kick-Off Meeting	FDA	<ul style="list-style-type: none"> • Set frequency of engagement • Review product roadmap • Assign FDA Point of Contact (POC) for PP
CQOE Collection Plan	FDA + PP	<ul style="list-style-type: none"> • Review of PP CQOE measures • Set agenda for site visit
CQOE Collection	PP	<ul style="list-style-type: none"> • Collect CQOE measures • Establish mechanism for data sharing
Consolidate CQOE Measures	FDA + PP	<ul style="list-style-type: none"> • Aggregate and normalize CQOE measures across PP
Update CQOE / Key Performance Indicators (KPI)	FDA + PP	<ul style="list-style-type: none"> • Update Pre-Cert Framework
Determine Pre-Cert Status	FDA	<ul style="list-style-type: none"> • Establish Pre-Cert status
Prep for Public Meeting	FDA + PP	<ul style="list-style-type: none"> • Set agenda for public meeting
Product Review Plan	FDA + PP	<ul style="list-style-type: none"> • Product categorization • Set post-market data collection plan
Product Review	FDA + PP	<ul style="list-style-type: none"> • Review product prototype
Pilot Cohort Debrief	FDA + PP	<ul style="list-style-type: none"> • Aggregate lessons learned • Refine CQOE measures • Refine product review pathway

Figure 5: The Engagement Plan outlines the program’s upcoming activities and anticipated outcomes

Appendix A

CQOE Framework

1. Definitions: Excellence Principles (EP)
 - a. 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.
 - b. Product Quality: Demonstration of a commitment to development, testing, and maintenance standards necessary to deliver SaMD products at the highest level of quality.
 - c. 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.
 - d. Cybersecurity Responsibility: Demonstration of a commitment to implement appropriate measures to ensure cybersecurity, and to proactively address cybersecurity issues through active engagement with stakeholders and peers.
 - e. Proactive Culture: Demonstration of a commitment to a proactive approach to surveillance, assessment of user needs, and continuous learning.

2. Definitions: Common Validating Perspectives (CVP)
 - a. Organizational Resource Perspective: The organization can demonstrate a commitment from leadership in their behaviors and practices that support employee empowerment and that the tools, training, and infrastructure needed to achieve objectives are in place.
 - b. Customer Perspective: The organization can demonstrate that they have considered customer needs and continue to deliver customer satisfaction throughout the product lifecycle.
 - c. Learning and Growth Perspective: The organization can demonstrate incorporation of feedback in new product and service development, dedication to innovation, support and commitment to employee development.
 - d. Process Perspective: The organization can demonstrate a commitment to risk management, robust process understanding, and proactive efforts to driving efficiency, reducing defects, and minimizing process variation to optimize revenue, value, and customer experience.