# Developing a Software Precertification Program:
## *A Working Model*

v1.0 - January 2019

# 1 Building the Program with Continuous Public Input

As part of the Software Precertification Program development process, FDA has been providing opportunities to the public to provide input on the program elements by publishing incremental versions of the working model of the program. FDA is using this transparent and open approach to provide continuous notice and solicitation of public input, by means of an open public docket, throughout the program development. The public docket is available at https://www.regulations.gov/comment?D=FDA-2017-N-4301-0001.

The FDA intends to continue reviewing the public docket approximately every two weeks, and to refine this program by incorporating, as appropriate, comments in future versions of the working model. We encourage the public to provide feedback early and often. For this version of the Working Model, FDA reviewed comments posted to the docket through October 31, 2018. A high-level summary of the comments received and FDA's response to those comments are provided in Section 9 Appendix.

This Working Model describes an innovative approach for software precertification that may require additional statutory authority to implement fully. For now, FDA intends to implement the pilot program using its current authorities. Along with this version of the Working Model, FDA is issuing two companion documents: (1) a Test Plan that describes how FDA intends to iterate and confirm that the framework proposed in this Working Model provides a reasonable assurance of safety and effectiveness for software as a medical device products and (2) the Regulatory Framework for conducting the pilot program within current authorities.

FDA will continue to build and refine this working model by considering public comments, incorporating comments received, as appropriate, and regularly seeking additional public input throughout the development of this program.

*Software Precertification Program: Working Model – Version 1.0 – January 2019*

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2

# Contents

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# 2 Release Notes

**20190107 v1.0**

- Section 3: Introduction: added description of the Total Product Lifecycle approach
- Section 4: Excellence Appraisal
    o Revisions to descriptions for Levels of Pre-Cert
    o Clarified intent for FDA to be primarily responsible for all Excellence Appraisals during the 2019 testing of the program, while considering how the future program may include accreditation of third parties to conduct Excellence Appraisals
- Section 5: Review Pathway Determination
    o Revisions to Software as a Medical Device Product-Level Elements
- Section 6: Streamlined Premarket Review Process
    o Proposed list of review elements for a streamlined review
    o Provided description of the proposed review elements
    o Updated review process to apply to all submission types
- Section 7: Real-World Performance
    o Updated description of process for developing a real-world performance analysis plan
    o New examples of real-world performance analytic types and sources
    o New examples illustrating how the types of real-world performance analytics collected and the duration of collection may vary depending on the purpose for use


**20180619 v0.2**

- Introduction revised to include the vision for the program
- Scope of precertification program restated to clarify who is eligible for precertification and which review pathways are the focus for development for 2019
- Outline of Program Components includes description of component interdependencies
- Section 4: Excellence Appraisal
    o Further refinement of objectives and goals
    o New figure describing a conceptual framework for Excellence Appraisal
    o New proposed elements and organizational practice domains for the demonstration of excellence for precertification
    o Updated description of proposed appraisal process
    o New examples of activities/processes and Key Performance Indicators for two example elements
    o Revisions to descriptions for Levels of Pre-Cert
- Section 5: Review Pathway Determination
    o Further refinement of objectives and goals
    o Further details for leveraging IMDRF framework
    o New identification of product level elements
- Section 6: Streamlined Premarket Review Process
    o Clarification of expectations for products entering a streamlined review process

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- o New proposed option for an iterative, early engagement review process
  - o New proposal for possible review elements
- Section 7: Real-World Performance
  - o New description of benefits for monitoring product-level real-world performance
  - o Refinement of terminology/definitions: focus on types of analytics rather than data
  - o New elements of real-world performance analytics for post-launch product monitoring

20180426 v0.1

- First version of working model

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5

# 3 Introduction

The Software Precertification (Pre-Cert) Program is envisioned as a voluntary pathway that embodies a regulatory model more tailored than the current regulatory paradigm to assess the safety and effectiveness of software technologies without inhibiting patient access to these technologies. The program goal is to provide more streamlined and efficient regulatory oversight of software-based medical devices from manufacturers who have demonstrated a robust culture of quality and organizational excellence (CQOE) and are committed to monitoring real-world performance.

Software is increasingly used in healthcare to treat and diagnose conditions and diseases, aid clinical decision making, and manage patient care. The ability to download these software programs onto connected mobile platforms allows them to be used in the hospital and in the home, by clinicians and patients. Historically, healthcare has been slow to implement technology tools that have transformed other areas of commerce and daily life. One factor that has been cited, among many, is the regulation that accompanies medical products. But momentum toward a digital future in healthcare is advancing. FDA oversees most software, including mobile apps, that are intended to treat, diagnose, cure, mitigate, or prevent disease or other conditions as medical devices under the Federal Food, Drug, and Cosmetic Act (FD&C Act). These software-based technologies are what FDA and other regulators call "Software as a Medical Device" (SaMD).

FDA's traditional approach for the regulation of hardware-based medical devices is not well-suited for the faster, iterative design and development, and type of validation used for software device functions, including SaMD. Software products offer unique opportunities, such as addressing malfunctions quickly and efficiently to reduce adverse events, understanding and capturing patient performance outside of the clinical setting, and enabling patient engagement. Unlike manufacturers of hardware devices who modify their products every few months to years, developers of software modify their products in response to real-world performance and user feedback every few weeks to months. Evaluating software code alone may not provide a full understanding of the safety and effectiveness of a SaMD product, in part because the impact on patients is often indirect. As a result, the application of FDA's longstanding regulatory framework to software can impede access to new and improved software-based medical products. An agile regulatory paradigm is necessary to accommodate the faster rate of development and potential for innovation in software-based products. It is important for public health to address these distinctive aspects of digital health technology – its clinical promise, unique user interface, ability to facilitate patient engagement with the developer, and compressed commercial cycle of new product introductions – while ensuring that existing standards of safety and effectiveness are met or exceeded.

To address these challenges, in July 2017 FDA announced the Software Pre-Cert Pilot Program to develop a new regulatory paradigm that would focus first on the assessment of organizations that perform high-quality software design, testing, and monitoring. This proposed approach is based on demonstration of a culture of quality and organizational excellence (CQOE) and a commitment to monitoring product performance. Because SaMD products can be adapted to respond to glitches, adverse events, and other safety concerns quickly, FDA is working to establish a regulatory framework that would allow efficient responses to software issues, and thus continue to ensure that consumers have access to safe and effective products. The

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*Software Precertification Program: Working Model – Version 1.0 – January 2019*

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6

Software Pre-Cert Program is envisioned to, among other things, evaluate a firm's capability to respond to real-world performance, and FDA intends to work with precertified firms to quickly and effectively address software issues.

## 3.1  Software Precertification Program Goal

The goal of the program is to have tailored, pragmatic, and least burdensome regulatory oversight that assesses organizations (large and small) to establish ***trust*** that they have a culture of quality and organizational excellence such that they can develop high quality SaMD products, leverages ***transparency*** of organizational excellence and product performance across the entire lifecycle of SaMD, uses a tailored streamlined premarket review, and leverages unique postmarket opportunities available in software to ***verify*** the continued safety, effectiveness, and performance of SaMD in the real world.

The Software Pre-Cert Program is intended to build stakeholder confidence that participating organizations have demonstrated capabilities to build, test, monitor, and proactively maintain and improve the safety, efficacy, performance, and security of their medical device software products, so that they meet or exceed existing FDA standards of safety and effectiveness.

## 3.2  Software Precertification Program Vision

The program aims to design a new approach for software products: a Precertification Program for the assessment of organizations that perform high-quality software design and testing. Under this program, software developers would be assessed (by FDA or by an FDA-accredited third party) for the rigor of their practices in software design, testing, clinical assessment, and real-world performance monitoring, along with other appropriate capabilities. A successful assessment would permit the organization to qualify for a more streamlined premarket review while better leveraging postmarket data collection on the device's safety and effectiveness. This new, organization-based approach enhances the ability to assure the safety and effectiveness of software products by using the precertification framework in addition to aspects of the Agency's traditional reliance on individual product-based oversight. This program is intended to extend beyond consideration of organizations' traditional Quality Management Systems, place emphasis on cybersecurity practices, and incorporate recognition of excellence in other aspects, such as clinical responsibility. The software products from precertified companies must continue to meet the same statutory standards as software products that have followed the traditional path to market. The Precertification Program is simply a pathway or method to access and evaluate necessary information at different points in the product's lifecycle, to establish a reasonable assurance of safety and effectiveness (see Figure 1) for the product. This approach is intended to provide patient access to critical evolutions of software technology, and to enable more efficient and streamlined oversight without compromising safety and effectiveness of medical device software products.

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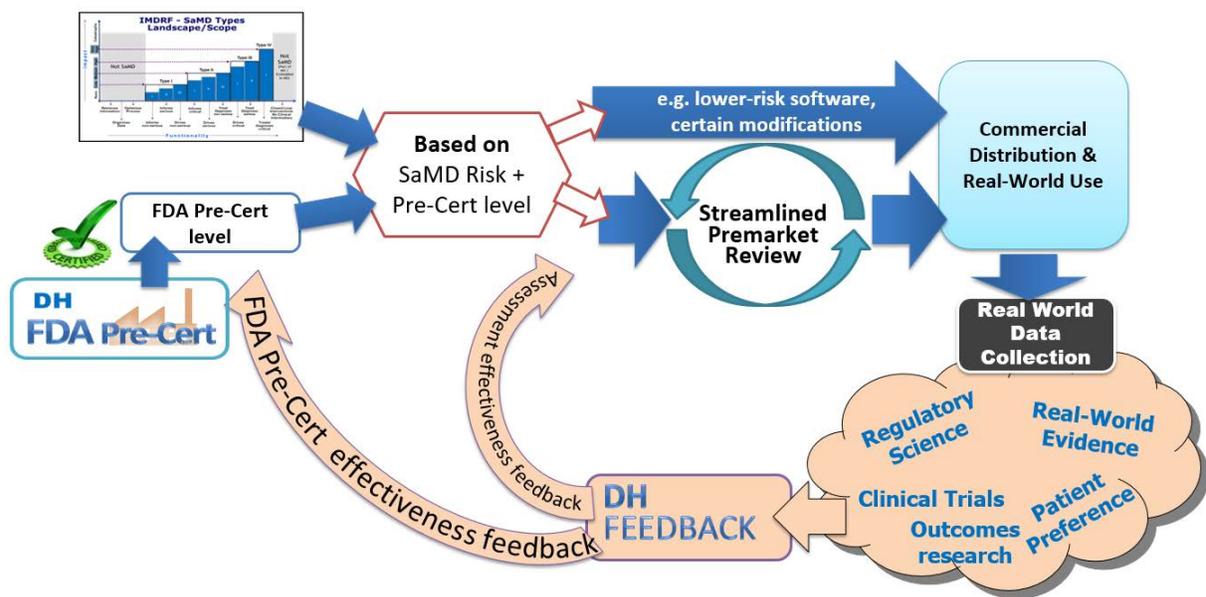*Software Precertification Program: Working Model – Version 1.0 – January 2019*

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7

**Figure 1. A reimagined approach for the regulation of software**

There are many innovators that are ready to solve healthcare challenges and are willing to bring unique skills, approaches, and solutions to solve patient needs. We believe that providing a clear framework and expectations would empower these innovators to bring solutions to patients and users. This process should enable patients and healthcare providers to have high confidence in precertified companies and the devices they produce because precertified organizations leverage real-world performance to continuously monitor and improve upon the safety and effectiveness of marketed SaMD products. The vision for the program is to be available for organizations of any size that are currently developing medical devices or have the potential to deliver products that are medical devices. By establishing clear organizational excellence expectations and clear regulatory expectations, and leveraging real-world performance, this program intends to create a regulatory environment that would enable patients and healthcare providers to have timely access to technologies that are built by excellent organizations.

FDA recognizes that the underlying principles of the Excellence Appraisal need to be consistently interpreted and applied across industry. However, we currently believe that there should be flexibility in the specific mechanisms by which excellence can be demonstrated. This means we would like to provide an organization the flexibility to show how its processes and own measures of performance track to the program's specified elements, performance measures, and ultimately, the Excellence Principles.

FDA anticipates many benefits for various stakeholders. We envision that this program would align the device review process with the software development process, enabling faster patient access to technologies. The program would also establish a consistent Excellence Appraisal process, so that manufacturers know what to expect when they are appraised. FDA also recognizes the need for transparency so that end users of the products from precertified companies can understand the premarket review and postmarket monitoring conducted for

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these products. We anticipate that the evidence and insights gleaned from the precertification process, including a commitment to robust postmarket oversight, would support a streamlined regulatory review paradigm. Table 1 below shows anticipated benefits for various stakeholders.

| Table 1. Example of Anticipated Program Benefits | End user | Business | FDA | Payor | Investor |
|---|---|---|---|---|---|
| | Patients, Providers, Caregivers | SaMD Developer | Agency Reviewer | Insurance Provider | Venture Capitalist |
| Enhanced confidence in organizations developing SaMD products | + | | + | + | + |
| Improved quality/safety/proactivity to address known and emerging risks | + | + | + | + | |
| Timely availability of solutions to patients | + | + | + | + | + |
| Enhanced regulatory simplicity and experience | | + | + | + | + |
| Business simplicity - faster/timely market access | + | + | + | | + |

## 3.3  Software Precertification Pilot Program Scope

Organizations that are developing or planning to develop a software that could be subject to FDA oversight are included within the scope of the Software Pre-Cert Pilot Program.

Ultimately, the product types that may benefit from precertification might include all software that meets the definition of a device in section 201(h)[1] of the FD&C Act including SaMD, software in a medical device (SiMD), and other software that could be considered accessories[2] to hardware medical devices. However, in developing Version 1.0 of the program, the current focus is to

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[1] As stated in section 201(h) of the FD&C Act, the term "device" does not include software functions excluded pursuant to section 520(o) of the FD&C Act, as amended by the 21st Century Cures Act.
[2] An accessory is a finished device that is intended to support, supplement, and/or augment the performance of one or more parent devices. See Medical Device Accessories – Describing Accessories and Classification Pathways; Guidance for Industry and FDA Staff, available at https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM429672.pdf.
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establish processes for SaMD technologies, which may include software functions that use artificial intelligence and machine learning algorithms.

Non-device software functions are not subject to regulation and are not within the scope of the Software Pre-Cert Pilot Program. In particular, software functions intended (1) for administrative support of a health care facility, (2) for maintaining or encouraging a healthy lifestyle, (3) to serve as certain types of electronic patient records, (4) for transferring, storing, converting formats, or displaying data without interpreting, or analyzing clinical laboratory test or other device data, results, and findings, or (5) to provide certain limited clinical decision support are not medical devices[3] and are not subject to FDA regulation.

Current policies for the review of software device functions continue to apply. For device software functions for which FDA has expressed an intent not to enforce compliance to applicable requirements, those policies continue to apply for software products developed by organizations participating in the Pilot Program. Submission of product-specific program components described in this Working Model, including Review Determination, Streamlined Review, and Real-World Performance monitoring, would not be expected for device software functions for devices that are 510(k)-exempt.

See boxed definition statement and Figure 2 for a description of SaMD. See Section 10 Appendix for further clarification on what is considered SaMD. The program scope has been limited to SaMD for Version 1.0 in order to allow FDA to gain experience in the precertification process. As FDA gains insights from implementation of Version 1.0, we hope to expand the program to be able to leverage a software manufacturer's precertification status to the review of all medical device software products.

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"Software as a Medical Device" (SaMD) is defined as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.[4]

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[3] Section 520(o)(1) of the FD&C Act (21 U.S.C. 360j(o)(1)(A)-(E)) as added by Section 3060(a) of the 21st Century Cures Act (December 13, 2016)

[4] http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-samd-key-definitions-140901.docx

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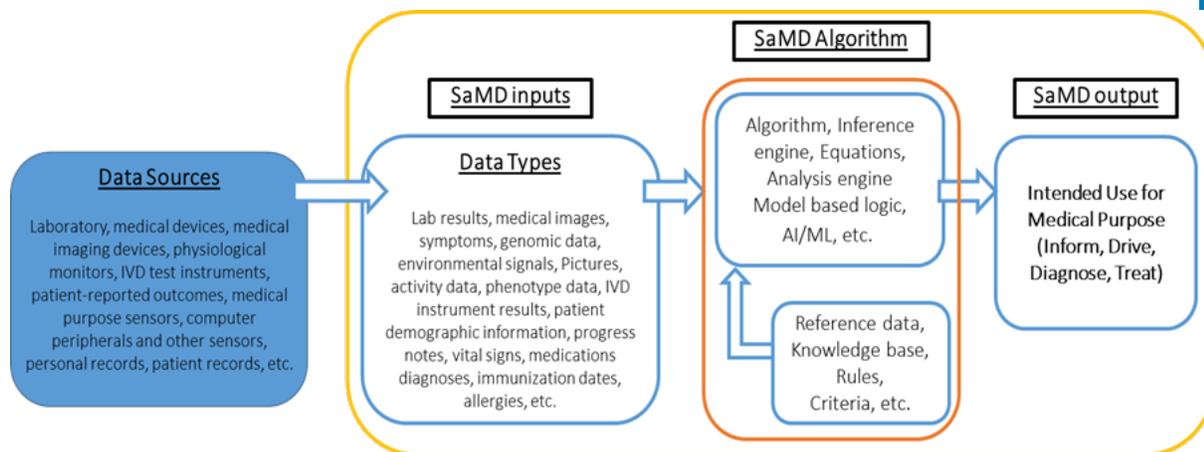
**Figure 2. Description of SaMD, including possible data sources from which inputs are derived and that may be used for one or more medical purposes.**

## 3.4 Software Precertification Program Overview

The program concept is based upon precertification of software manufacturers who have demonstrated a culture of quality and organizational excellence and would leverage postmarket data from all appropriate sources. FDA would evaluate organizational excellence based on five culture of quality and organizational excellence (CQOE) principles (hereafter referred to as "Excellence Principles"):

- **Product Quality** – Demonstration of excellence in the development, testing, and maintenance necessary to deliver SaMD products at the highest level of quality.

- **Patient Safety** – Demonstration of excellence in providing a safe patient experience and emphasizing patient safety as a critical factor in all decision-making processes.

- **Clinical Responsibility** – Demonstration of excellence in responsibly conducting clinical evaluation and ensuring that patient-centric issues, including labeling and human factors, are appropriately addressed.

- **Cybersecurity Responsibility** – Demonstration of excellence in protecting cybersecurity and proactively addressing cybersecurity issues through active engagement with stakeholders and peers.

- **Proactive Culture** – Demonstration of excellence in a proactive approach to surveillance, assessment of user needs, and continuous learning.

Leveraging the data gleaned from the precertification process, FDA would seek to adopt a risk-based, streamlined regulatory approach to SaMD review to either replace the need for a premarket submission or, for higher risk products, to allow for streamlined premarket review that maximizes efficiency and engagement. The premarket review pathway determination would apply the least burdensome principles of balancing premarket-postmarket information needs by leveraging real-world performance data. Similar to FDA's current regulatory system under which

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not all devices require premarket review (e.g., 510(k)-exempt devices), this program envisions exemptions from premarket review for lower risk SaMD products or more efficient review of higher risk SaMD products that are developed, delivered, and maintained by precertified organizations.

As established by demonstration of excellence in the Proactive Culture excellence principle, precertified organizations would have a robust mechanism to collect, monitor, and analyze ongoing organizational performance and real-world performance of the products they deliver. FDA also intends to bolster postmarket monitoring by more effectively leveraging real-world data from device registries and other electronic health information sources. The collection of real-world performance data on precertified organizations' SaMD products is anticipated to enable improvements to the Software Pre-Cert Program itself.

## 3.5  Total Product Lifecyle

The goal and vision of the Software Pre-Cert Program can be achieved by applying a Total Product Lifecycle (TPLC) approach to the regulation of software products. This TPLC approach would allow for the evaluation of organizations and their SaMD products throughout the lifecycle of the organization and products, so that patients, caregivers, and other users have assurance of the safety of those products. A key tenet of this program and one of the five Excellence Principles is patient safety; during the Excellence Appraisal, organizations are evaluated on their commitment and ability to provide a safe patient experience and their prioritization of patient safety as a critical factor in all their decision-making processes. The TPLC approach further provides for continued monitoring and evaluation of a product's safety, so that if any patient safety issues arise, they can be quickly identified and remedied.

To deliver the goals of the program as described above, we have divided the program into four key program components, depicted in Figure 3. These components are interdependent and are intended to be part of a comprehensive Software Pre-Cert Program, essentially a TPLC approach for the regulation of software products, depicted in Figure 4.

1. Demonstrate a culture of quality and organizational excellence through an **Excellence Appraisal.**

2. Determine the SaMD's required review through **Review Determination**

3. Conduct a **Streamlined Review**

4. Verify a SaMD's continued safety, effectiveness and performance and the organization's commitment to culture of quality through post-market **Real-World Performance**.
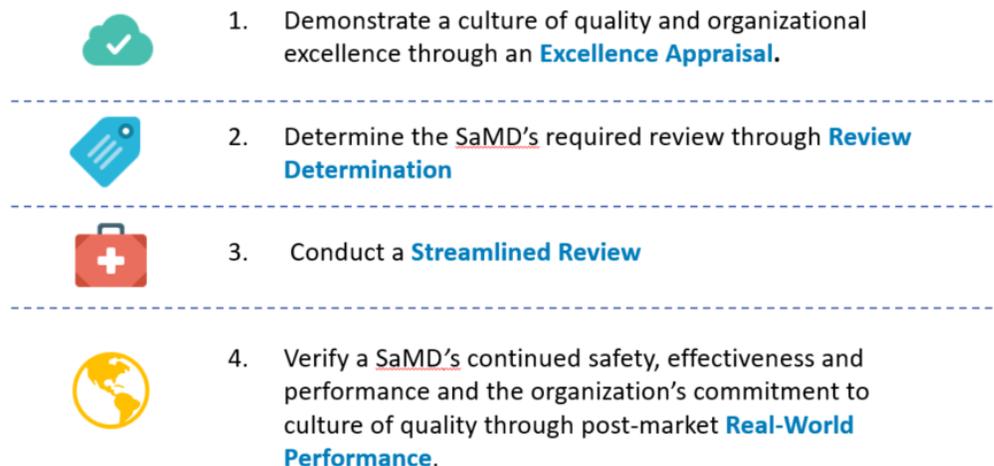
**Figure 3. Software Pre-Cert Program Components**

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This TPLC approach enables the evaluation and monitoring of a software product from its premarket development to postmarket performance, along with continued demonstration of the organization's excellence. The Excellence Appraisal evaluates an organization's capability for developing, testing, and managing high-quality software throughout a product's lifecycle, which provides confidence in the products made and marketed by the organization. The FDA believes organizations committed to the Excellence Principles can show, through their existing processes and activities, a demonstration of the Excellence Principles for the purposes of precertification. FDA intends to leverage relevant existing standards and certifications from accredited bodies as acceptable evidence to demonstrate CQOE. This is consistent with the Agency's goal, where possible, to support a least burdensome approach to the Excellence Appraisal of an organization and to avoid unnecessary duplication of efforts. (See Section 11 Appendix for a list of standards, accreditation certifications, and evaluations that may be considered to demonstrate the Excellence Principles during an appraisal.)

When fully developed, this program would provide the parameters to allow precertified organizations to assess if their products may be eligible for streamlined review or if their precertification status and review pathway determination may replace the need for a traditional premarket submission. Review pathway determination depends not only on the risk of the medical device software product, but also on the results of the Excellence Appraisal for an organization. The information evaluated during the Excellence Appraisal and Review Determination components can be leveraged to support a marketing authorization for a software product. The review of a precertified organization's software product would rely on the Excellence Appraisal and a commitment to real-world performance monitoring to proactively manage and continually assure product safety and effectiveness. The real-world performance monitoring enables verification of the SaMD's continued safety, effectiveness, and performance, and verification of the organization's ongoing commitment to the Excellence Principles. Excellent organizations may generate and analyze post-market (post-launch) data analytics to understand how their products are being used, to identify opportunities for improvement, and to respond quickly and proactively to emerging signals. The real-world performance (RWP) component of the Software Pre-Cert Program is designed to leverage these signals of proactively managed products to verify ongoing excellence following precertification, identify emerging safety and cybersecurity risks, provide critical feedback to the other components of the Program, and support the appropriate use of postmarket data in clinical evidence generation.

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*Software Precertification Program: Working Model – Version 1.0 – January 2019*

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13
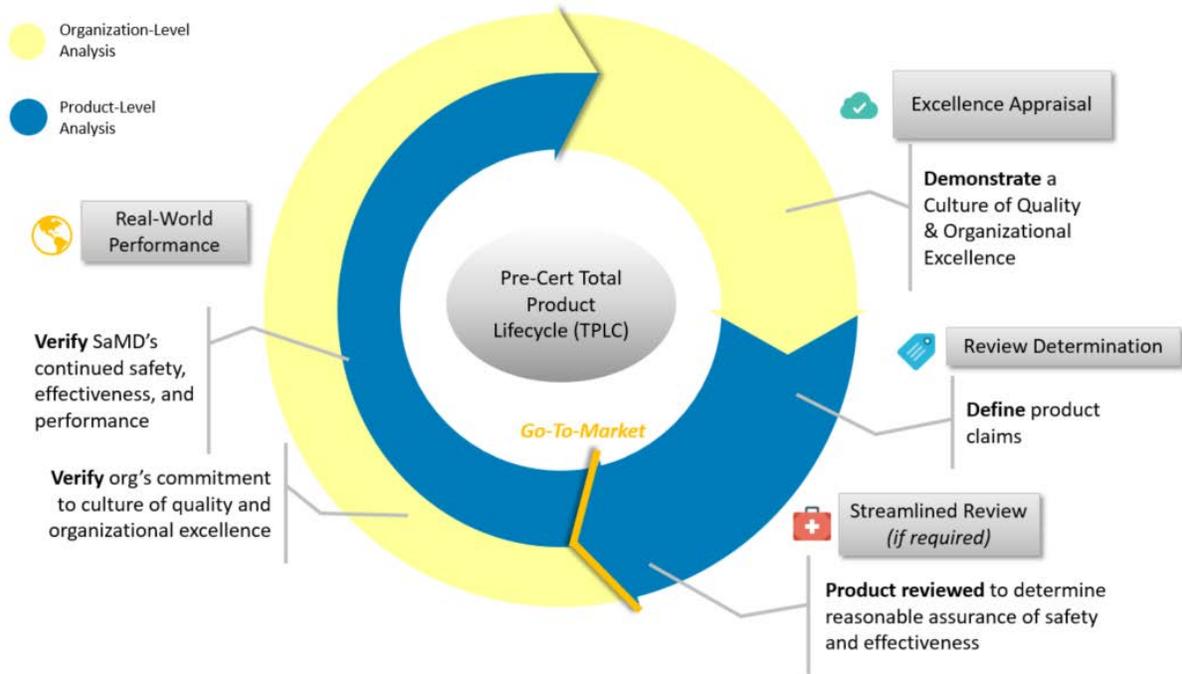
**Figure 4. Total Product Lifecycle Approach of the Software Pre-Cert Program**

The FDA proposes that certain elements traditionally reviewed in a premarket submission for a SaMD product can be evaluated at the organization level during the Excellence Appraisal and at the product level during Review Pathway Determination and Streamlined Review. Furthermore, Real-world Performance plans may be leveraged to verify a SaMD's continued safety, effectiveness, and performance. Figure 5 provides a depiction of different points in the lifecycle of a software product when certain review elements could be evaluated. FDA intends to test the details of the evaluation of premarket review elements throughout a SaMD's lifecycle during the 2019 testing of this approach. As these details are finalized, FDA intends to share them in future public updates.



**Figure 5. Evaluation of Premarket Submission Elements throughout a Total Product Lifecycle.**

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## 3.6   Maintenance of Precertification

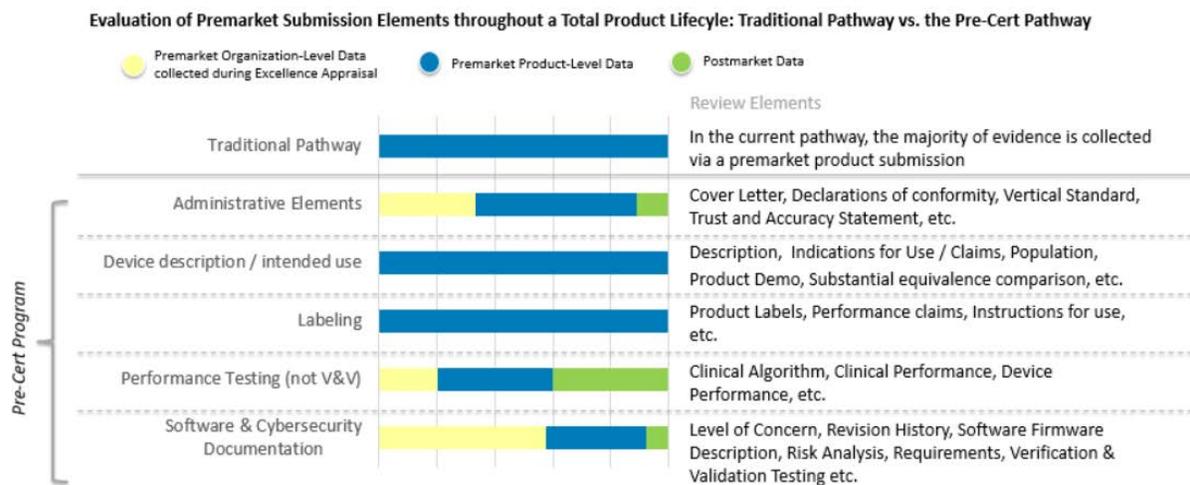The Excellence Appraisal conducted for an organization is part of a TPLC approach. As depicted in Figure 4, the organization level processes would be relied on to demonstrate excellence during the appraisal and would be continually monitored throughout the lifecycle of the organization to verify the organization's continued commitment to the Excellence Principles. For example, the initial Excellence Appraisal may identify performance metrics that are indicative of the organization's processes and business objectives, and the organization would commit to sharing those metrics with FDA through a real-world performance plan. Real-world performance data would be used to demonstrate responsiveness and effectiveness of the organizational systems. Several factors may trigger the need for an additional Excellence Appraisal, in addition to other requirements under the FD&C Act or its implementing regulations. The following list focuses only on the triggers for an additional Excellence Appraisal; this does not mean that other requirements do not apply. Examples of such triggers may include:

- Significant recurring patient and product issues;
- Significant restructuring of the organization that impacts the leadership, team, and unit activities;
- Merger or acquisition that impacts the evaluated quality system and processes;
- Continuous improvement efforts conducted by the organization that may lead to a change in performance capability (in this scenario, the changes may be addressed through a reduced Excellence Appraisal or FDA's review of documented changes);
- Performance in new activities or incorporation of a new clinical domain that was not part of the original assessment (in this scenario, the changes may be addressed through an abbreviated Excellence Appraisal or FDA's review of documented changes); or
- Continued recurrence of a safety signal observed in real-world performance monitoring.

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# 4 Excellence Appraisal and Precertification

Organizations that produce safer and more effective device software products not only "do the right things," but they also "do the things right" based on evidence that informs better decision-making. While governance and processes may differ, these organizations tend to follow a common set of goals, objectives, and approaches across the product lifecycle. FDA believes organizations committed to these principles can show, through their existing processes and activities, a demonstration of the Excellence Principles for the purposes of precertification.

The Excellence Appraisal incorporates the following development principles:

- Designed for organizations of all sizes
- Allows organizations to demonstrate excellence based on outcomes achieved by their unique processes, operations, and capabilities
- Applies least burdensome approach by observing organizations' current processes
- Recognizes organizations following existing standards (e.g., Quality System Regulations, ISO 13485, ISO 12207, ISO 62304, ISO 14971, ISO 9001)[5] and outcomes achieved by following those processes

The principal objective of the Excellence Appraisal and precertification component of the pilot program is to develop and refine the process of precertification, identify the elements necessary for the Excellence Appraisal process, and explore best practices for ongoing monitoring of organization excellence, including:

- Pre-Cert Application: identifying the characteristics of participating organizations and the application process for requesting appraisal for precertification.

- Appraisal: refining reference "domains" and "elements" necessary for the process of collecting/observing an organization's information for Pre-Cert status determination.

- Pre-Cert Status Determination: identifying the method and process of aggregating and analyzing appraisal results to Excellence Principles to determine Pre-Cert level.

- Maintenance and Monitoring of Pre-Cert Status: identifying the processes and mechanisms for an organization to monitor and maintain Pre-Cert status, be transparent with all stakeholders, and engage with FDA.

Figure 6 shows a conceptual framework for Excellence Appraisal that begins to identify key elements necessary for the appraisal processes and the Pre-Cert determination.

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[5] Quality System Regulations at 21 CFR 820, ISO 13485:2016(en) Medical devices – Quality management systems – Requirements for regulatory purposes; ISO/IEC/IEEE 12207:2017(en) Systems and software engineering — Software life cycle processes; IEC 62304:2006(en) Medical device software — Software life cycle processes; ISO 14971:2007(en) Medical devices — Application of risk management to medical devices; ISO 9001:2015  Quality management systems – Requirements

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*Software Precertification Program: Working Model – Version 1.0 – January 2019*

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16
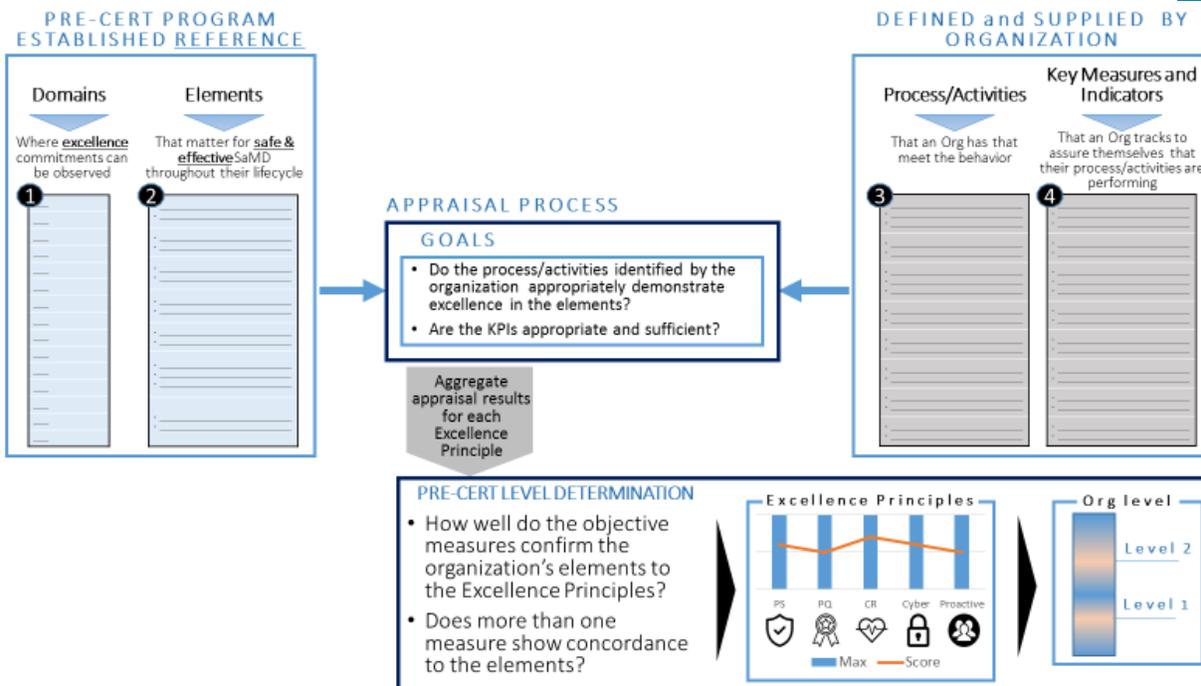
**Figure 6. Conceptual Framework for Excellence Appraisal**

## 4.1 Eligibility

Any organization that intends to develop or market software that meets the definition of device in section 201(h) of the FD&C Act in the United States would be considered in-scope for the Software Pre-Cert Program. This could include organizations that are developing SaMD and organizations that are planning to develop SaMD. FDA recognizes the potential for significant variability in the culture and internal processes of different business units within a single organization, particularly for large organizations that are multinational or include multiple business units.

As part of determining eligibility, the proposed program would allow companies to identify the boundaries of the organization themselves to determine the business unit or center of excellence that should be considered for precertification. The boundaries of a "business unit" should be clearly determined by the company itself prior to participating in the precertification process.

> **Testing of Excellence Appraisal in 2019**
>
> During the 2019 testing of the Software Pre-Cert Program Version 1.0, the FDA intends to conduct Excellence Appraisals with Pilot Participants who volunteer to participate in this testing.
>
> The FDA will determine what information about the boundaries of the organization, as well as the organization's portfolio of software products, is necessary to be a part of a company's application to participate. FDA will continue to develop the details of other information that should be included in an application for an appraisal and subsequent precertification.

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*Software Precertification Program: Working Model – Version 1.0 – January 2019*

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## 4.2 Excellence Appraisal Elements

The appraisal process seeks to understand how the organization's processes and measures are used effectively in turn to demonstrate the organization's excellence in the five Excellence Principles (Product Quality, Patient Safety, Clinical Responsibility, Cybersecurity Responsibility, Proactive Culture). FDA understands that software development methodologies, processes, and practices differ between and within organizations. In recognition of these differences, the Pre-Cert Program outlines discrete **elements** that have been identified as leading to safer and more effective SaMD. The elements are grouped into **domains** taken from the [IMDRF N23: Software as a Medical Device (SaMD): Application of Quality Management System](). The appraisal process is envisioned to assess whether an organization has demonstrated excellence in product development that can be leveraged to provide reasonable assurance of safety and effectiveness of the organization's SaMD products. The elements and domains ultimately map to the Excellence Principles; however, during the appraisal process, an organization seeking precertification is expected to demonstrate how its specific processes are aligned and objectively managed for the identified elements. A full list of elements and domains, mapped to Excellence Principles they support, can be found in Section 12 Appendix.

1. **Leadership and Organizational Support** – Elements related to the organization's leadership establishing the strategic direction, responsibility, authority, and communication to assure the safe and effective performance of the SaMD.

2. **Transparency** – Elements related to the organization's open sharing of relevant information with all stakeholders to build confidence in the organization and its products.

3. **People** – Elements related to providing appropriate resources as needed for ensuring the effectiveness across all lifecycle processes and activities in meeting user requirements.

4. **Infrastructure and Work Environment** – Elements related to the availability of infrastructure such as equipment, information, communication networks, tools, and the physical facility throughout SaMD lifecycle processes.

5. **Risk Management: A Patient Safety Focus** – Elements related to monitoring and managing risks along multiple dimensions such as user-based, application-based, device-based, use environment-based, and security-based across all lifecycle processes.

6. **Configuration Management and Change Control** – Elements related to identifying and defining the software configuration and controlling the release and change of the software throughout all lifecycle processes.

7. **Measurement, Analysis, and Continuous Improvement of Processes and Products** – Elements related to managing and improving product realization and use through real-world performance monitoring.

8. **Managing Outsourced Processes, Activities, and Products** – Elements related to understanding, maintaining control, and managing the effect of outsourced activities, processes or products.

9. **Requirements Management** – Elements related to clear, and often repeated user interaction to understand and clearly articulate user needs throughout all lifecycle processes.

FDA will continue to build and refine this working model by considering public comments, incorporating comments received, as appropriate, and regularly seeking additional public input throughout the development of this program.

10. **Design and Development** – Elements related to ensuring safe, effective, and secure SaMD based on user and other performance requirements during all lifecycle phases at key milestones and good development practices incorporating appropriate review activities such as code review, peer review, and self-review.

11. **Verification and Validation** – Elements related to understanding the criticality and impact to patient safety by providing assurance of conformity to requirements and reasonable confidence that the software meets its intended use/user needs and operational requirements.

12. **Deployment and Maintenance** – Elements related to activities such as delivery, installation, setup, and configuration of software including documentation and user training materials that identify any limitation of the algorithm, provenance of data used, assumptions made, etc. that should be considered during deployment. Additionally, modification of previously deployed software while preserving the integrity of the software by not introducing new safety, effectiveness, performance, and security hazards.

## 4.3  Appraisal Process

Although the appraisal method is not fully developed, we generally intend to evaluate organizational elements based on objective, observable evidence. Each organization would determine which processes/activities and Key Performance Indicators (KPIs) best meet these elements for purposes of meeting regulatory requirements. We recognize that means of demonstrating **excellence in product development elements** can vary across types and sizes of organizations. In addition to having KPIs in place, excellent organizations will typically assign action/threshold levels and target time frames to help measure performance along the way.

The FDA's current thinking is that organizations would provide this evidence as a part of the application or appraisal process, which may be followed up by site visits, interviews, or other methods. The program envisions that ultimately using automation or tapping into an organization's metric systems could reduce appraisal burden, increase confidence in organizations, and enhance the capability to respond quickly and improve products without reducing confidence in or the reliability of the program.

As a part of the appraisal process, organizations would describe how their practices and activities fulfill each element and how they measure their output, as well as provide their measurements or KPIs, targets, thresholds, and trends.

Development and tracking of KPIs can help an organization monitor, improve, and demonstrate performance, as well as inform key organizational decisions (such as product release readiness). KPIs can be at an organizational-level, group-level, and/or project- or product-level. As part of the objectives of the Excellence Appraisal (or re-appraisal) for precertification, it is important to assess organizational KPIs as well as post-market product performance. KPIs identified as part of the premarket Excellence Appraisal of the organization would drive the postmarket, product-specific evaluation based on real-world performance data.

**Excellence Appraisal Scope**

The scope of the Excellence Appraisal includes an evaluation of the processes, activities, systems, tools, and culture of an organization to determine capability and performance of the organization seeking the assessment. The appraisal is not intended to serve as an audit or to primarily collect evidence of compliance or non-compliance.

FDA will continue to build and refine this working model by considering public comments, incorporating comments received, as appropriate, and regularly seeking additional public input throughout the development of this program.

During an Excellence Appraisal, the appraisal team would engage with the organization to define the organizational structure and the processes, as well as the products that have been or are in development. The appraisal team would identify the processes that are critical to the core of the Excellence Appraisal, including how real-world evidence is collected, identify the products that provide evidence of how these processes were implemented – and by extension – are representative of the expected safety/efficacy of the SaMD. The appraisal team would engage with the staff – both clinical and technical – who are performing the work, responsible for the processes, and on the project or product development teams. The Excellence Appraisal team would review and collect information and output of the organization and its processes as evidence that the organization has the ability to demonstrate reasonable assurance of safety and effectiveness for the devices the company produces or intends to produce. The information reviewed and collected during the Excellence Appraisal would be available during the review of a SaMD product (see Section 6 Streamlined Premarket Review Process).

The appraisal team would also review the business objectives and performance indicators, as well as the robustness and relevance of the measures the organization uses, to monitor progress and sustained excellence.

The Excellence Appraisal is expected to range from 2 to 5 days, but the timing may be dependent on the following example factors:

- Organization size

- Complexity of the processes the organization uses

- Number of product(s)/project(s) sampled for review

## 4.4   Key Performance Indicators

The FDA recognizes that a "one size fits all approach" to collection of key performance indicators (KPIs) may not work in the diverse health software ecosystem but will ensure that all companies satisfy regulatory requirements. The FDA intends to work with precertified companies to identify the unique key performance indicators and underlying performance data to be collected by each organization. The FDA intends to collect KPI summary reports periodically (for example, quarterly) that describe the relevant results, highlight and explain any outliers or anomalies in the data, and summarize any actions taken or planned to address those outliers or anomalies. The scope of the KPI collection is intended to be confined to the boundaries described by the organization when requesting an Excellence Appraisal and to their regulated products. The FDA does not intend to make individual organizations' KPI reports or results available publicly, to the extent consistent with the Freedom of Information Act (FOIA), 5 U.S.C. § 552.

The following table includes examples of activities/processes and KPIs related to two elements of the Excellence Appraisal:

| Table 2. Examples of activities/processes and KPIs and metrics related to two elements | |
|---|---|
| **Domain** | Measurement, Analysis, and Improvement of Processes and Products |
| **Element** | Analyzing and providing the learning collected from real-world data back to development teams throughout all lifecycle processes. |
| **Example activities/processes** | **KPIs / Metrics** |

*Software Precertification Program: Working Model – Version 1.0 – January 2019*

The organization starts the learning and improvement process throughout the development lifecycle through established retrospectives and post-mortems. This learning is captured in a centralized system and is available and searchable by design and development teams for future products and feature releases.

Analysis is performed of the customer data and feature suggestions. The firm also performs competitive benchmarking, research, and usability studies. The data is analyzed, trended, and prioritized and made available through product analysis dashboards that provide fast visualization to the development teams. This may also include defects and product issues identified and prioritized for addressing.

The organization uses two indicators to measure performance of integrating the learning collected from real-world data back to development teams throughout all lifecycle processes:
− Time-to-market of changes to existing software, and
− Ratio of positive vs. negative sentiment after new feature(s) are introduced.

These KPIs align with the business objective to enhance adoption of the software.

The organization assesses performance and tracks progress of the KPI by analyzing:
   − Number of critical defects
   − Number of complaints
   − Reduced rate of customer support contacts
   − User engagement metrics
   − User retention metrics
   − Customer survey results

The KPIs are reviewed periodically and are expected to sustain or show positive trends. Drops in the KPIs are analyzed for potential improvements, feature releases, or new product introductions.

| Domain | Configuration Management and Change Control |
|---|---|
| Element | Source control by establishing mechanisms for initiating, evaluating and controlling changes to software during all lifecycle processes and after deployment. |
| **Example activities/processes** | **KPIs / Metrics** |

| Example activities/processes | KPIs / Metrics |
|---|---|
| The organization has a well-defined system architecture showing system and sub-system configurations. There is an established process for assessing the impact to other software sub-systems for configuration changes in any part of the system. The firm shows traceability from configuration items (or components) to development and has a process established for "tagging" each component of a software system to identify it throughout the product lifecycle. | The organization measures the number of returning bugs associated with configuration management issues as an indicator of the quality of the processes for updating the software.<br><br>This KPI aligns with the business quality objectives for product release.<br><br>The organization assesses performance and tracks progress of the KPI by analyzing: |

FDA will continue to build and refine this working model by considering public comments, incorporating comments received, as appropriate, and regularly seeking additional public input throughout the development of this program.

| Changes in the software are reviewed by a cross functional team consisting of clinical, regulatory, engineering, marketing, and production staff. A clinical review of the software change is performed for impact to clinical functionality or performance and the clinical data supporting the change is re-evaluated. The product risk analysis is continuously reviewed and updated throughout each change. | − Tag coverage (i.e. components are all synced or traceable to a master release number) <br> − Traceability audit results (i.e. # of unlinked PRs or user stories) <br> − # P/F regression tests post-release <br> − # risks <br> − Risk analysis update frequency <br> − # design reviews <br> − # of critical bug reports submitted by customers <br><br> The KPIs are reviewed during release cycles and are expected to trend down. No changes or increases in the numbers are indicators that errors are being introduced in updates or their release system and process may need review for improvement. |
|---|---|

By aggregating and analyzing collected information, we can understand *how* organizations build safe and effective SaMD, how they *know* the devices are safe and effective in the real world, and how they *improve* safety and effectiveness, as well as efficiency and time to market. As the program continues forward, our goal is to develop a library of activities, processes, and KPIs that high performing organizations use. In addition, we anticipate gaining greater insight into measures that can indicate higher performing organizations. The FDA believes that driving a focus on performance would encourage the industry to strive for excellence in the manufacture of software device products.

> **Testing of Excellence Appraisal in 2019**
>
> **Ongoing data collection:**
>
> During the 2019 testing of the Software Pre-Cert Program Version 1.0, the FDA anticipates collecting real-world information on the effectiveness and ease of appraisal. Through development of tools, techniques, and processes, we anticipate the appraisal elements would be further refined with the goal of providing increased precision, accuracy, and confidence in the appraisal methods and demonstration of excellence in product development.

## 4.5  Precertification Levels

The goal of establishing levels of precertification is to maintain the same standards of safety and effectiveness of products marketed today for software manufactured by precertified companies. The levels of precertification are intended to provide, to both FDA and the users, confidence in an organization's ability in developing, maintaining, and marketing safe and effective SaMD. Organizations seeking precertification will have different levels of maturity. Some organizations may have no or limited experience in delivering medical devices, but they have the culture,

FDA will continue to build and refine this working model by considering public comments, incorporating comments received, as appropriate, and regularly seeking additional public input throughout the development of this program.

*Software Precertification Program: Working Model – Version 1.0 – January 2019*

processes, and systems to produce high quality products and the capacity to identify and fill gaps and other demonstrable characteristics that support the potential to create safe and effective SaMD.

Our current thinking reflects the belief that an organization of any size without a medical device or SaMD currently on the market should have the opportunity to deliver products for medical purposes as a precertified organization. We believe organizations that have objectively demonstrated excellence in product development elements in all five Excellence Principles and have successfully marketed and maintained products can achieve Level 2 Pre-Cert (as described below) and provide reasonable assurance that it can:

- Understand the clinical use and patient environment, disease or condition complexities;
- Identify and rapidly address unanticipated postmarket issues in the SaMD; and
- Apply postmarket lessons to iteratively improve the SaMD throughout the lifecycle processes.

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**Testing of Excellence Appraisal in 2019**

**Levels of Precertification:**

The FDA has proposed two levels of precertification based on an organization's excellence. FDA expects that the Excellence Appraisal would be able to identify the performance of various types of organizational structures and normalize that performance using the Excellence Principles. The FDA intends to leverage learning from the upcoming 2019 pilot to develop the process and considerations for the establishment of Precertification Levels. As described in the Software Pre-Cert Program Test Plan document accompanying this Working Model, FDA does not intend to establish precertified companies, nor levels of precertification, during the testing in 2019. Therefore, the precertification levels described in this section are intended only for exploration and consideration for a future Software Pre-Cert Program.

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**Level 1 Pre-Cert** – This level of certification is designed to allow organizations to develop and market certain lower risk software without review while requiring a streamlined review for other types of software. The FDA envisions this level would be awarded to an organization that has objectively demonstrated excellence in product development in all five Excellence Principles, with a limited track record in  developing, delivering and maintaining products. This level of certification may benefit an organization with limited or no  experience in delivering software products, but with established organizational elements and strategies in  place that indicate they have or can acquire the capability to deliver and maintain high-quality lower-risk SaMD that are safe and effective.

**Level 2 Pre-Cert** – This level of certification is designed to allow organizations to develop and market certain lower and moderate risk software without review while requiring a streamlined review for other types of software. The FDA envisions this level would be awarded to an organization that has  objectively demonstrated excellence in product development in all five Excellence Principles, with a proven track record in developing, delivering and maintaining products. This level of certification may benefit an organization with extensive experience in delivering software products to suggest a level of assurance in the development of safe and effective lower and moderate risk SaMD.

FDA will continue to build and refine this working model by considering public comments, incorporating comments received, as appropriate, and regularly seeking additional public input throughout the development of this program.

Specific types of SaMD that would require streamlined review or not for the two Pre-Cert levels are described below under "Component 2: Review Pathway Determination."

## 4.6 Third Party Appraisers

The FDA's vision for the future of the Software Pre-Cert Program includes the identification and accreditation of third parties with the capacity and expertise to conduct an Excellence Appraisal and who would perform the Excellence Appraisals for organizations seeking precertification. The appraisal information collected by third parties would be used as information in FDA's regulatory decision making, similar to a conformity assessment of an FDA recognized consensus standard.

The FDA is working to build the Excellence Appraisal Program so that third parties would be able to consistently assess a broad spectrum of organizations using equivalent rigor and completeness as assessments conducted by the FDA. The accreditation of third-party appraisers for this program would include a process to monitor the quality of services provided by the third-party appraisers. The FDA may seek input and/or assistance from third parties on the process of conducting appraisals.

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**Testing of Excellence Appraisal in 2019**

The FDA will be primarily responsible for all Excellence Appraisals during the 2019 testing of the program.

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**Testing of Excellence Appraisal in 2019**

**Objectives:**

- Evaluate whether the appraisal provides assurance that the organizational processes and activities are persistent and can be evaluated for levels of excellence performance across varying organizational structures.
- Evaluate whether the appraisal can determine the clinical responsibility of the varying organizational structures, and across varying track records of software products.
- Evaluate whether the varying organizational structures can meet the baseline criteria established for participation in the streamlined review.
- Evaluate whether the domains and elements appropriately demonstrate the organizational performance against the Excellence Principles to assure safe/effective SaMD.
- Evaluate whether the appraisal process identifies the metrics or indicators used by the organization to monitor and sustain their processes and organizational effectiveness.
- Evaluate the time, resources, and scoping process for the Excellence Appraisal of varying organizational structures.

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FDA will continue to build and refine this working model by considering public comments, incorporating comments received, as appropriate, and regularly seeking additional public input throughout the development of this program.

*Software Precertification Program: Working Model – Version 1.0 – January 2019*

# 5  Review Pathway Determination

The principal objective for establishing the Review Pathway Determination component of the Software Pre-Cert Program is to develop a risk-based framework so precertified organizations developing SaMD can determine the premarket review pathway for their products. This process will include:

- Identifying elements, methods, and process for precertified organizations to use in determining review pathway based on risk of the product (e.g., by a flow chart or a decision tree).
- Developing a structured method for precertified organizations to inform the public, end users, and FDA about key elements of the SaMD, including a robust description.

> **Testing of Review Determination in 2019**
>
> In 2019, the information proposed for this component of the Software Pre-Cert Program would be provided during an optional Pre-Submission meeting or as part of the premarket submission.

## 5.1  Risk Categorization

The premarket review for a precertified organization's SaMD product would be informed by the organization's precertification status, precertification level, and the SaMD's risk category. The FDA envisions leveraging the risk category framework for SaMD developed by the International Medical Device Regulators Forum (IMDRF)[6] to inform the risk category. (See Table 3 below.)

The unmodified IMDRF framework describes the spectrum of SaMD functions, some of which may not meet the definition of a device in 201(h) of the FD&C Act and others that may meet the definition of a device but for which FDA has expressed its intent not to enforce compliance with applicable requirements. For purposes of the Software Pre-Cert Program, the application of the risk category framework would remain consistent with the current definition of device under section 201(h) of the FD&C Act and FDA's current enforcement policies.

The IMDRF framework establishes types of SaMD products based on the state of the healthcare condition and the significance of the information provided by the products (Table 3[7]).

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[6] https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM524904.pdf.

[7] The table was first introduced by IMDRF in http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-140918-samd-framework-risk-categorization-141013.pdf.

FDA will continue to build and refine this working model by considering public comments, incorporating comments received, as appropriate, and regularly seeking additional public input throughout the development of this program.

*Software Precertification Program: Working Model – Version 1.0 – January 2019*

25

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Table 3. IMDRF type (I to IV) of SaMD products by state of healthcare condition and significance of information provided by the products to healthcare decision.[8]

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

Software manufacturers would be able to use the IMDRF "SaMD Definition Statement" as defined in "Software as a Medical Device": Possible Framework for Risk Categorization and Corresponding Considerations IMDRF N12 document[9] as a guide to determine where a SaMD falls in the IMDRF risk categorization table.

## 5.2   Product-level elements of a SaMD

The FDA proposes to leverage the IMDRF proposed SaMD Definition Statement to develop a structured format for program participants to identify the IMDRF type (based on the significance of information provided by the SaMD to the healthcare decision, the state of the healthcare situation or condition, and the core functionality of the SaMD). Because transparency is one of the key goals of the program, we expect all program participants to be transparent in providing information on their SaMD(s).

The FDA proposes the following list of product-level elements that precertified organizations would provide on their SaMD:

1. Significance of the information provided by the SaMD to the healthcare decision (as described in Section 5.3);
2. State of the healthcare situation or condition (as described in Section 5.3);
3. Core functionality of the SaMD (as described in Section 5.3);
4. Device description,[10] which may include a general description of the software device including the following: explanation of how the software works; significant security, technical, and safety risks; information regarding supporting platforms, components, and compatibility; instructions and limitations for use; inputs used; and customer support;
5. SaMD performance, which may include a general description of the software performance characteristics, such as the analytical or clinical performance of the SaMD

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[8] Some functions in Table 3 may not meet the definition of a device or may meet the definition of a device but are functions for which FDA does not intend to enforce compliance with applicable requirements of the FD&C Act.

[9] http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-140918-samd-framework-risk-categorization-141013.pdf, p. 12. This framework was adopted in FDA guidance/IMDRF N41 document Software as a Medical Device (SaMD): Clinical Evaluation.

[10] Adapted from Refuse to Accept Policy for 510(k)s Guidance for Industry and Food and Drug Administration Staff available at https://www.fda.gov/RegulatoryInformation/Guidances/UCM315014.

FDA will continue to build and refine this working model by considering public comments, incorporating comments received, as appropriate, and regularly seeking additional public input throughout the development of this program.

in the intended healthcare situation or condition, as well as information regarding the SaMD privacy and security policies.

These key elements are necessary to determine the risk category of the SaMD and, therefore, the premarket review pathway for the SaMD to be introduced to market. These elements also provide information on the SaMD intended use, context of use, and performance of the SaMD.

In a future state of the Software Pre-Cert Program, the SaMD product-level elements would be submitted when the precertified organization is ready to 1) market their SaMD if review is not required or 2) submit their SaMD for Streamlined Review if review is required based on the manufacturer-determined risk category. The Review Determination team would review the information provided to confirm the risk category and that the information submitted is complete. In order to avoid duplicative submission of the same elements, the elements submitted during the Review Determination stage would be retained and documented so that FDA can reference them during the review of a subsequent marketing submission. In a future state of the Software Pre-Cert Program, FDA intends to post the SaMD product-level elements on the FDA website following completion of review pathway determination (when no additional review is required) or following clearance or approval of the SaMD (when a marketing submission is required). If product-level information is incomplete or requires changes following a Streamlined Review, manufacturers would revise SaMD product-level elements during an interactive discussion with FDA (via a Pre-Submission, for example), prior to public posting. At this time, FDA intends to post the SaMD product-level elements on its website, and excellence appraised pilot participants would follow standard procedures for medical device registration and listing.[11]

## 5.3   Determining SaMD Risk

As described by the IMDRF, to understand the risk of a SaMD, the SaMD Definition Statement should include a clear and strong statement about the intended medical purpose of the SaMD. This would include the FDA definition of intended use, as defined by 21 CFR 807.92, which is described as a statement of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is intended. The statement would be written using the following terminology, as defined by the IMDRF[12]:

-- The "**significance of the information provided by the SaMD to the healthcare decision,**" which identifies the intended medical purpose of the SaMD. The statement should explain how the SaMD meets the definition of a medical device in section 201(h) of the FD&C Act.[13] The significance of the information provided by the SaMD and other information on the SaMD product need not be provided for functions that do not meet the definition of a device or that

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https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm134495.htm.

[12] Further clarification on the IMDRF terminology, including the significance of information provided by the SaMD to the healthcare decision (treat/diagnose, drive clinical management, and inform clinical management) and healthcare situation or condition (critical, serious, non-serious), can be interpreted for all SaMD, and therefore extends beyond the scope of the Pre-Cert Program. This clarification will be provided in a separate document.

[13] Section 201(h) of the FD&C Act defines the term "device," which is distinct from the IMDRF key definitions Final document "medical purposes" definition.

FDA will continue to build and refine this working model by considering public comments, incorporating comments received, as appropriate, and regularly seeking additional public input throughout the development of this program.

may meet the definition of a device but for which FDA does not intend to enforce compliance with applicable requirements of the FD&C Act. **This statement could be structured in the following terms as defined in section 5.1 of the IMDRF N12 Framework document:**

| Significance of Information |
| --- |
| • To treat or to diagnose:<br>   - To provide therapy to a human body.<br>   - To diagnose/screen/detect a disease or condition.<br>• To drive clinical management:<br>   - To aid in treatment by providing enhanced support to safe and effective use of medicinal products or a medical device.<br>   - To aid in making a definitive diagnosis.<br>   - To triage or identify early signs of a disease or conditions.<br>• To inform clinical management:<br>   - To inform of options.<br>   - To provide clinical information by aggregating relevant information. |

-- The "**state of the healthcare situation or condition**" that the SaMD is intended for, includes the intended user, intended disease or condition, and intended population. The IMDRF risk framework allows for a systematic way to identify the context of the intended medical purpose of the SaMD. Information on the SaMD product need not be provided for functions that do not meet the definition of a device or that may meet the definition of a device but for which FDA does not intend to enforce compliance with applicable requirements of the FD&C Act. **This statement would be structured in the following terms as defined in section 5.2 of the IMDRF N12 Framework document:**

| | Critical | Serious | Non-Serious |
| --- | --- | --- | --- |
| **The type of disease or condition is:** | o Life-threatening state of health, including incurable states;<br>o Requires major therapeutic interventions;<br>o Sometimes time critical, depending on the progression of the disease or condition that could affect the user's ability to reflect on the output information. | o Moderate in progression, often curable;<br>o Does not require major therapeutic interventions;<br>o Intervention is normally not expected to be time critical in order to avoid death, long-term disability or other serious deterioration of health, whereby providing the user an ability to detect erroneous recommendations. | o Slow with predictable progression of disease state (may include minor chronic illnesses or states);<br>o May not be curable; can be managed effectively;<br>o Requires only minor therapeutic interventions;<br>o Interventions are normally non-invasive in nature, providing the user the ability to detect erroneous recommendations. |
| **Intended target population is:** | Fragile with respect to the disease or condition (e.g., pediatrics, high risk population, etc.). | NOT fragile with respect to the disease or condition. | Individuals who may not always be patients. |
| **Intended to be used by:** | Specialized trained users. | Either specialized trained users or lay users. | Either specialized trained users or lay users. |

FDA will continue to build and refine this working model by considering public comments, incorporating comments received, as appropriate, and regularly seeking additional public input throughout the development of this program.

**-- Description of the SaMD's core functionality**[14]**,** which identifies the critical features/functions 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. This description should include only the critical features. This could include specific functionality to maintain performance, safety profile, and/or other attributes.

The table below describes a potential future model for a premarket review pathway for SaMD from precertified companies, depending on (1) the IMDRF risk category of the SaMD and (2) the level of precertification of the organization. This table describes a proposal for when the precertification of organizations and commitment to leverage real-world performance might allow for no premarket review ("No Review" in Table 4 below) or streamlined premarket review ("SR" in Table 4 below), according to the IMDRF type of the SaMD and the Pre-Cert Level of the organization (L1, Level 1; L2, Level 2).[15]

| Table 4. Proposed Level of Review for Level 1 and Level 2 Precertified Organizations' SaMD in Future Pre-Cert Program | | | | |
|---|---|---|---|---|
| IMDRF Risk Categorization | | Level of Review for Level 1 and Level 2 Precertified Organizations' SaMD | | |
| Type | Description | Initial product | Major changes | Minor changes |
| Type IV | Critical x diagnose/treat | SR | SR | No Review |
| Type III | Critical x drive | SR | L1 – SR L2 – No Review | No Review |
| Type III | Serious x diagnose/treat | SR | L1 – SR L2 – No Review | No Review |
| Type II | Serious x drive | L1 – SR L2 – No Review | L1 – SR L2 – No Review | No Review |
| Type II | Non-serious x diagnose/treat | L1 – SR L2 – No Review | No Review | No Review |
| Type II | Critical x inform | L1 – SR L2 – No Review | No Review | No Review |
| Type I | Non-serious x drive | No Review | No Review | No Review |
| Type I | Serious x inform | No Review | No Review | No Review |
| Type I | Non-serious x inform | No Review | No Review | No Review |

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[14] These could include specific functionality that is critical to maintain performance and safety profile, attributes identified by risk management process undertaken by the manufacturer of SaMD.

[15] As described in section 4 above, Level 1 Pre-Cert would be awarded to an organization that has objectively demonstrated **excellence in product development** in all five Excellence Principles, with a limited track record in developing, delivering and maintaining products. This level of certification may benefit an organization with limited or no experience in delivering software products, but with established organizational elements and strategies in place that indicate they have or can acquire the capability to deliver and maintain high-quality lower-risk SaMD that are safe and effective. Level 2 Pre-Cert would be awarded to an organization that has objectively demonstrated **excellence in product development** in all five Excellence Principles, with a proven track record in developing, delivering and maintaining products. This level of certification may benefit an organization with extensive experience in delivering software

FDA will continue to build and refine this working model by considering public comments, incorporating comments received, as appropriate, and regularly seeking additional public input throughout the development of this program.

**Testing of Review Determination in 2019**

**Objectives:**

- Develop and evaluate a decision tree or support tool for determining if precertified organizations' SaMD products are regulated and, if so, their applicable risk categorization.
- Evaluate proposed risk category framework delineation levels for premarket submission for precertified organizations as input to the proposed level of review for SaMD in a future Software Pre-Cert Program.
- Develop and evaluate a framework for how major/minor software changes of SaMD will be reviewed in the Software Pre-Cert Program, beginning with the framework outlined in the guidance Deciding When to Submit a 510(k) for a Software Change to an Existing Device.

products to suggest a level of assurance in the development of safe and effective lower and moderate risk SaMD.

FDA will continue to build and refine this working model by considering public comments, incorporating comments received, as appropriate, and regularly seeking additional public input throughout the development of this program.

# 6 Streamlined Premarket Review Process

It is expected that software products that are considered for Streamlined Review are from organizations that have successfully gone through Excellence Appraisal, and thus these organizations would have demonstrated excellence in developing, testing, maintaining, and improving software products. The streamlined premarket review process would be available to precertified organizations who have demonstrated excellence in and shown a capacity for and a commitment to real-world performance analytics. Using this information and the processes outlined under the review determination component of this working model (see section 5), precertified organizations that determine their SaMD product meets the requirement for being reviewed by FDA would begin a streamlined premarket review process.

The principal objectives of establishing the streamlined premarket review process component of the Software Pre-Cert Program are to identify the elements necessary for a premarket review and to develop a premarket review process that provides reasonable assurance of safety and effectiveness of a software product from a precertified organization. This includes what information would be reviewed, how modifications affect marketing authorization, and how to leverage existing SaMD standards (for example, refer to Appendix section 11).

The FDA envisions reviewing the risk management for the device's intended use and the SaMD's clinical evaluation results (per the FDA guidance/IMDRF N41 document Software as a Medical Device (SaMD): Clinical Evaluation), as appropriate. The FDA intends to conduct an interactive review supported by automated analysis, where appropriate, and aspires to provide a decision on the marketing of the precertified organization's SaMD product within a shorter timeline than traditional premarket review processes.

> **Testing of Streamlined Review in 2019**
>
> During the 2019 testing of proposed Software Pre-Cert Program Version 1.0, if FDA does not authorize the marketing of the product, the organization and FDA would complete an after-action review to determine gaps in the evidence supporting the submission and determine a plan for future submission. The FDA expects to implement a process where repeated unsuccessful streamlined reviews of a precertified organization's SaMD trigger a reassessment of the organization's precertification determination. FDA would review the basis of the precertification to address any systemic issues within both the organization and the precertification program.

At a high level, we envision the Streamlined Review process would work as follows:

1. Understanding the product: FDA would use the information received during a Review Determination Pre-Submission, if submitted by the organization, to facilitate a better understanding of the product. FDA would work interactively with the program participant to understand the details of the software functions. FDA is considering options for how the organization could describe the SaMD and its intended use, such as an interactive demonstration or submission of a wireframe of the SaMD, while the Agency simultaneously meets its obligations to maintain an administrative record.

FDA will continue to build and refine this working model by considering public comments, incorporating comments received, as appropriate, and regularly seeking additional public input throughout the development of this program.

2. Premarket review: FDA envisions interactive review of supporting information, which could include evaluating the software's analytical performance, clinical performance, and appropriate safety measures. FDA is considering various options for conducting the review of the supporting information, for example, through screen sharing, access to the development environment, and testing logs—using freeform audit of test results.

3. Marketing authorization: FDA would make a premarket decision, document a decision summary, retain the information and records on which the decision was based, and communicate the decision to the organization.

## 6.1  Elements necessary for assuring safety and effectiveness in premarket review

As described in Section 3.5 above, FDA proposes that certain elements traditionally reviewed in a premarket submission for a SaMD product can be evaluated at the organization level during the Excellence Appraisal and at the product level during Review Determination. The following table includes the elements that would be reviewed during a Streamlined Review in order to provide a reasonable assurance of safety and effectiveness at the point of market entry.

| Table 5. Streamlined Review Elements |
|---|
| **Administrative Elements** |
| Cover letter |
| Financial Certification and Disclosure Form |
| Truthful and Accuracy Statement |
| **Product-Specific Elements** |
| Clinical algorithm |
| Clinical Data Analysis and Interpretation |
| Cybersecurity product-specific information including threat model |
| Declaration of Conformity and Summary Reports for Vertical Standards |
| Hazard Analysis (product-specific) |
| Instructions for use |
| Labeling review |
| Regulatory Pathway Specific Items (e.g., 510(k) substantial equivalence comparison) |
| Requirements (product-specific) |
| Revision history |
| SaMD product demo |
| Software architecture |
| Validation (product performance) |
| **Elements Leveraged from other components** |
| Excellence Appraisal Assessment |
| Review Determination information (Indications for Use, Device Description, etc.) |
| Real-world Performance Plan |

Many of the traditional elements included in a regulatory submission for software serve as surrogates for a well-defined, repeatable, and predictable software development process. These elements would not need to be assessed at the time of the review of a premarket submission from a precertified company, because the software development process would be extensively

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*Software Precertification Program: Working Model – Version 1.0 – January 2019*

evaluated during the Excellence Appraisal. Therefore, the review process can focus only on those elements that are related to the specifics of the product and not on those elements that would otherwise provide insight into the development process, which would already have been evaluated during the Excellence Appraisal. In addition, the information submitted during Review Determination, including the SaMD Definition Statement that describes the intended medical purpose and the device description, supports the development of the Indications for Use and the Device Description. This information would be reviewed in parallel with the additional evidence provided in the Streamlined Review documentation.

In addition to those elements that are leveraged from the Excellence Appraisal and Review Determination, there are different submission elements of a traditional premarket submission that capture the same information. For example, User Stories may capture requirements. Therefore, the User Stories element is not expected to be submitted as part of a Streamlined Review Pre-Cert package, because the necessary information would already be captured by the Requirements element.

Furthermore, while most of the Streamlined Review elements are the same across all categories of the IMDRF, the depth of review changes with the risk of the product under review. The following list describes each of the elements that would be included in a Streamlined Review Pre-Cert package and, for certain elements, the list describes how the depth of review changes depending on the risk for that item:

- Clinical Algorithm (including mechanism of action, design, development): This element provides adequate information on any clinical algorithms including mechanism of action.
- Clinical Performance: The Clinical Performance of the device is product-specific and primarily reviewed during Streamlined Review for all risk levels. This would include the clinical data analysis and interpretation demonstrate the adequate clinical performance of the device.
- Cybersecurity: Cybersecurity is a Total Product Lifecycle activity. FDA evaluates the ability of the company to assess security, manage updates, perform postmarket security assessments of products, and proactively update products during the Excellence Appraisal and from Real-World Performance data. Streamlined Review would evaluate product-specific elements of cybersecurity to include how identified threats and mitigations impact the safety of the device.
- Hazard Analysis: Product-specific risks, hazards, and subsequent mitigations are critical for understanding safety and effectiveness in the context of the intended use of the device and would be part of a Streamlined Review. The overall risk management plan and process can be leveraged from the Excellence Appraisal process.
- Instructions for Use/Labeling: This element includes instructions or other material (electronic or otherwise) that is intended to help the user understand the device and how to use it.
- Regulatory Pathway Specific Items: The Streamlined Review information would include, for example: a Substantial Equivalence (SE) comparison for 510(k) submissions to assess substantial equivalence to the identified predicate; an explanation of how special controls identified for a regulation are met; or a Risk/Benefit Analysis and proposed special controls for a De Novo application. Note that this is not a complete list of such items.
- Requirements (including user interface/user stories/workflow): Product-specific requirements provide insight into the intended use of the device and would be reviewed

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*Software Precertification Program: Working Model – Version 1.0 – January 2019*

FDA.gov

33

in Streamlined Review. The methods by which the requirements are gathered and the ability to develop appropriate requirements is evaluated in the Excellence Appraisal.

- Revision History: The revision history is device specific in that it helps the reviewer understand product-specific changes during the design process that can impact the safety and effectiveness of the device. This element would not be included for lower risk products that undergo streamlined review as this can be demonstrated adequately (for lower risk products) through the software development processes evaluated during the Excellence Appraisal.

- Software Architecture: This element refers to information that provides a detailed depiction of functional units and software modules and may include state diagrams as well as flow charts.

- Validation (Performance Claims/Device Performance): Validation of the clinical algorithm is of primary importance and would be fully described and would include both protocols for testing and results demonstrating performance. For lower risk products, summary information for the validation information would be acceptable.

## 6.2   Interactive Streamlined Review Process for  Premarket Review

Based on feedback received, FDA has considered how to streamline 510(k) submissions, De Novo Requests, and PMA applications for the Software Pre-Cert Program. While each of these regulatory pathways has their own requirements, processes, procedures, and nuances, there are significant commonalities on how FDA approaches product-specific review.

There are common review elements among 510(k) submissions, De Novo Requests, and PMA applications. When using a reduced set of elements described in section 6.1, the Streamlined Review process is focused on what the subject device is and on its intended use. While there are unique elements of Streamlined Review for each of these processes, we find that the processes converge conceptually. For this reason, we present a generic regulatory pathway in Figure 7 that depicts the generic process FDA would propose to follow in the Pre-Cert program, regardless of the regulatory pathway.
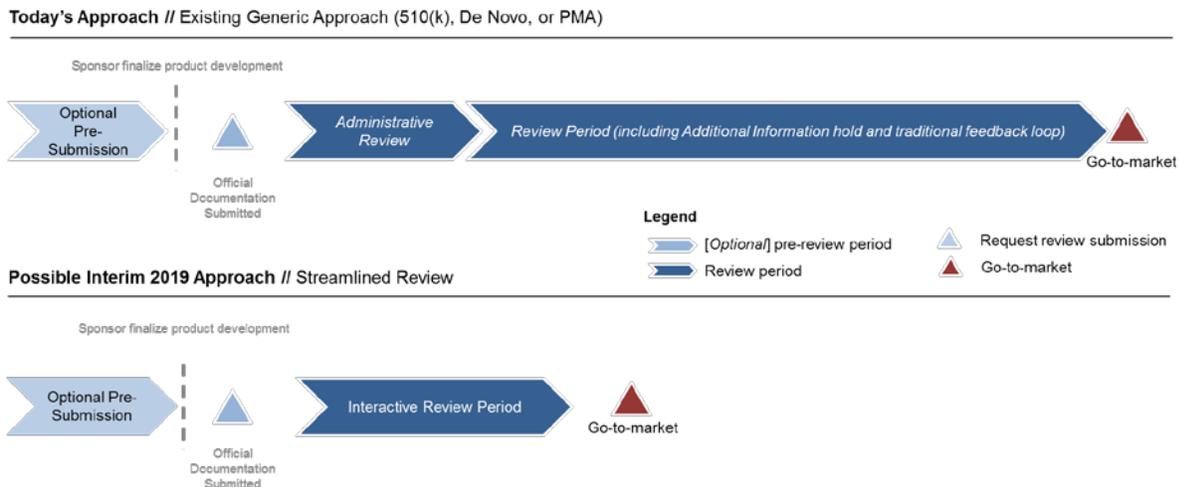


**Figure 7. Conceptual framework for conducting a generic interactive Streamlined Review of a SaMD from a pre-certified organization.**

FDA will continue to build and refine this working model by considering public comments, incorporating comments received, as appropriate, and regularly seeking additional public input throughout the development of this program.

The FDA developed the common reduced set of elements listed in Table 5 to streamline the review process by collectively removing administrative reviews and leveraging demonstrated excellence from the Excellence Appraisal, product-specific information from the Review Pathway Determination, and Real-world Performance plans. Additionally, FDA has considered feedback from sponsors regarding pros and cons of the Pre-Submission process, including that sponsors may find the interactions valuable but often subject to time and process constraints. While FDA envisions iterations of the regulatory pathways for the Pre-Cert program, we believe the concepts of Streamlined Review result in a similar approach for all pathways. Based on the content reduction described in section 6.1, FDA is developing a Streamlined Review process that a) eliminates duplicative information, b) is interactive, and c) where possible, is automated.

A) Eliminate Duplication. The mapping analysis described in Section 3.5 revealed that several review elements would be accounted for across the Pre-Cert Program. Duplicative information is presented in many parts of the traditional documentation. For example, for a SaMD product, the software/firmware description typically included in the software documentation is duplicative of the product description, because the device itself is software. In another example, we considered information across precertification processes. Many of the elements typically found in a device description for a device are the same information that is part of Review Determination. Thus, we will carry that information over from the Review Determination into Streamlined Review with minimal duplication, if the information is submitted as part of the optional Review Determination Pre-Submission and remains unchanged. We aim to eliminate repetitive information as one means of reducing burden and making the review process more efficient.

B) Interactive. Promoting the use of an interactive review process may contribute to a more efficient review. In particular, enhanced early interaction may benefit and improve the review process because it would expose potential challenges early in the process, so that both parties can proactively plan interactions that move towards the goal of a complete and transparent premarket clearance.

C) Automation. Where possible, automation would be used to streamline the review process and to perform administrative functions. For example, FDA is considering suggestions to develop templates that help the sponsor to determine if the submission is complete before it is submitted to FDA. This automation should shift the focus of the review process to a technical review of the product rather than an administrative review of the package.

In total, the measures discussed in this section along with the content reduction in section 6.1 are expected to result in reductions in review timelines. We anticipate that the amount and complexity of clinical data will ultimately be the driver for the duration of the review.

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*Software Precertification Program: Working Model – Version 1.0 – January 2019*

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35

**Testing of Streamlined Review in 2019**

**Objectives:**

- Determine the company's and FDA's responsibilities for interactive review as part of the Streamlined Review process.
- Determine the most efficient method for conducting a product demo and determine how to capture that information in the review.
- Develop a robust training program for FDA reviewers to make FDA Pre-Cert review as efficient and user-friendly as possible.
- Continue to refine our approach to find a balance between internal resources, timely review, and reasonable assurance of safety and effectiveness.

FDA will continue to build and refine this working model by considering public comments, incorporating comments received, as appropriate, and regularly seeking additional public input throughout the development of this program.

*Software Precertification Program: Working Model – Version 1.0 – January 2019*

FDA.gov

36

# 7   Real-World Performance

We believe that excellent organizations not only focus on quality while developing SaMD products, but they also grow and evolve based on lessons learned from real-world usage of their products after they launch. While specific RWP data elements and analytic methodologies may differ across organizations and product categories, excellent organizations consistently collect and analyze post-launch data from diverse sources to inform their operations and decision making, from quality control to product development for new market segments. We envision that precertified organizations would select specific data elements within the proposed framework based on the intended use, functionality, and risk classification of the SaMD product. *FDA believes organizations can show excellence toward continuous improvement through proactive monitoring of RWP data related to their SaMD products.*

During the Excellence Appraisal, all organizations would demonstrate the capability to collect and analyze post-launch RWP data, whether by instrumenting their SaMD products to generate needed data, or by leveraging alternative data sources. Therefore, FDA expects that these organizations will consistently collect and analyze post-launch data related to the safety, effectiveness, and performance of the products they manufacture in order to inform their decision-making related to product or process improvements.

Excellent organizations may generate and analyze post-launch data to understand how their products are being used, to identify opportunities for improvement, and to respond quickly and proactively to emerging signals. The real-world performance (RWP) component of the Software Pre-Cert Program is designed to use these readily available data analytics to verify ongoing excellence following precertification, identify emerging safety and cybersecurity risks, provide critical feedback to the other components of the Program, and support the appropriate use of postmarket data in clinical evidence generation. Given the importance of these functions, the Agency anticipates that all precertified organizations introducing a product to market through the precertification pathway would be expected to actively monitor RWP data and allow FDA access to analytics on data elements relevant to organizational excellence and product-level safety and effectiveness. However, this RWP Analytics (RWPA) framework would not apply to SaMD products cleared by FDA prior to precertification of the organization.

## 7.1   RWPA Framework

For the purposes of this document, RWPA are defined as systematic computational analyses of data relevant to the safety, effectiveness, and performance of a SaMD product in real-world settings marketed by a precertified organization. FDA anticipates that not only data from appropriately instrumented SaMD products may be generated, collected, and analyzed efficiently, but also real-world data from device registries, well-structured data commons, and other electronic health information sources, including patient registries and the National Evaluation System for health Technology (NEST) currently under development.

The FDA considers RWPA to encompass at least three types of analyses, as defined below. Additional detail can be found in Section 13, Appendix G: Real-World Performance Data Elements for Post-Launch Product Monitoring.

- **Real-World Health Analytics (RWHA)** *are defined as analyses of real-world clinical outputs and outcomes related to the intended use of the SaMD product.*

FDA will continue to build and refine this working model by considering public comments, incorporating comments received, as appropriate, and regularly seeking additional public input throughout the development of this program.

RWHA can inform changes to the intended use of a SaMD product, support expanded functionalities and use in broader target populations, and identify emerging safety issues in postmarket use.[16] While all medical device manufacturers are required to report clinical adverse events related to their products,[17] excellent organizations would leverage the ability of appropriately designed SaMD products to collect and analyze clinical safety data, in order to identify and address issues in a more timely manner. For lower-risk products, RWHA may be collected from sources including user complaints, search analytics, and product-level monitoring of human factors measures, such as use errors. Depending on the claim, FDA anticipates that precertified organizations with higher-risk products may proactively seek out external sources of safety and effectiveness data through activities, such as participation in registries, partnerships with healthcare systems, or utilization of data commons or other structured postmarket data collection efforts.

For example, a precertified organization markets a moderate risk computer-aided detection SaMD product, which is designed to capture both the SaMD output and the final read by the radiologist. False-positive rates, defined as instances in which the SaMD detects disease but the radiologist disagrees with the finding, are monitored over time as an example of RWHA. When the SaMD manufacturer identifies a negative trend in average false-positive rates, the manufacturer investigates, determines that a software defect is leading to erroneous detection of disease, and issues a software update after receiving FDA marketing authorization, if appropriate. FDA notes in the periodic submission of RWHA that the negative trend line has been corrected, which supports maintenance of precertification for the manufacturer.

- **User Experience Analytics (UXA)** *are defined as analyses of user experience outputs related to the real-world use of a SaMD product.*

UXA monitoring facilitates timely identification and correction of user issues and enables improvements to the utilization and effectiveness of the software. Depending upon the intended use of the software, UXA may be collected from a variety of sources. Products instrumented to collect UXA may passively monitor measures including use patterns, download rates, and user retention. For metrics related to product satisfaction or user complaints, organizations may use proactive mechanisms of soliciting or incentivizing user feedback. To ensure that feedback is representative of the full range of users, excellent organizations would also actively seek UXA from diverse sources, which may include social media platforms, search analytics, or other third-party online networks.

For example, a precertified manufacturer introduces a low-risk SaMD product directly to market. The SaMD is intended to improve health outcomes by generating tailored recommendations to help a patient manage a chronic disease in an outpatient setting. After noting a spike in user drop rates that exceeds target thresholds, the manufacturer initiates a discussion with FDA about whether these drop rates are likely to impact the

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[16] See FDA's guidance Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices for FDA's current thinking on use of real world evidence (RWE), including when an IDE or other requirements may apply.
[17] 21 CFR Part 803
FDA will continue to build and refine this working model by considering public comments, incorporating comments received, as appropriate, and regularly seeking additional public input throughout the development of this program.

effectiveness of the SaMD product. Upon reviewing the UXA, most patients spent a relatively long time answering the same question before dropping out. The manufacturer decides to implement a design change in the user interface to improve user retention rates.

- **Product Performance Analytics (PPA)** *are defined as analyses of outputs and outcomes demonstrating the real-world accuracy, reliability, and security of a SaMD product.*

PPA monitoring enables excellent organizations to address software bugs and security vulnerabilities through timely patches and product updates. FDA expects that excellent organizations would instrument SaMD products to track product performance measures related to the reliability and availability of the device. As described for UXA, proactive surveillance may be needed to identify product defects and track time to resolution.

For connected SaMD products, FDA anticipates that precertified organizations will demonstrate ongoing commitment in cybersecurity responsibility by monitoring and addressing security vulnerabilities and threats. FDA's recommendations for cybersecurity risk management, including participation in Information Sharing and Analysis Organizations, are included in the guidance document Postmarket Management of Cybersecurity in Medical Devices.

For example, after a SaMD product is marketed, a security researcher notifies the precertified organization of an open communication port. The organization's analysis demonstrates that other design features of the SaMD can mitigate risk of patient harm and the residual risk of patient harm is thus considered "acceptable". Therefore, closing the open communication port would be considered a cybersecurity routine update or patch. The manufacturer expedites the release of a validated patch to close the communication port, pushes the patch remotely, and provides adequate communication to end-users. A full variant analysis is performed to find other instances of open ports, after which requirements are modified, developers are trained, and test cases are added to prevent future instances of the issue. This type of timely, feedback-orientated, and proactive security behavior supports maintenance of precertification for the manufacturer.

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*Software Precertification Program: Working Model – Version 1.0 – January 2019*
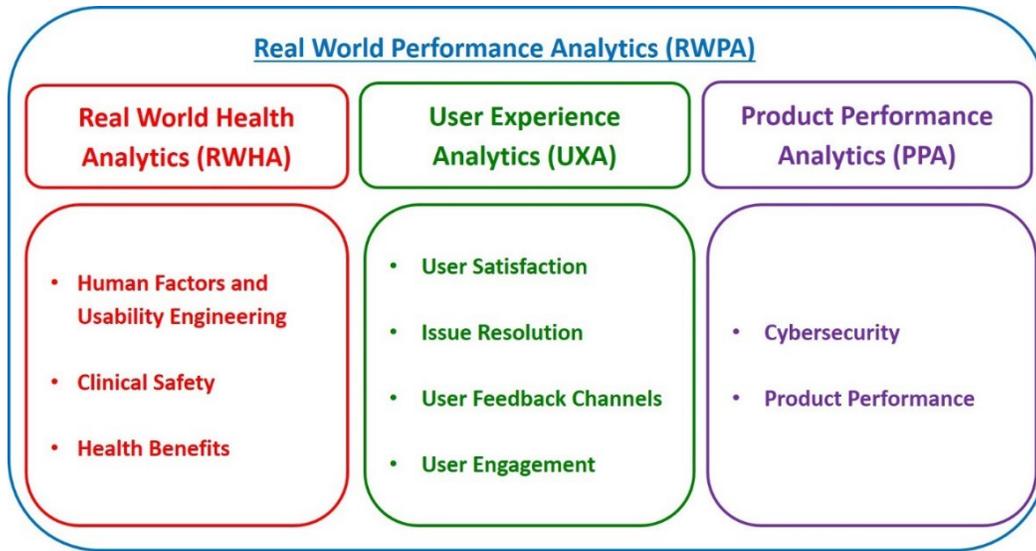
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39

**Figure 8. RWPA Post-Launch Product Monitoring Domains**

Figure 8 illustrates the domains and subdomains of RWPA under Pre-Cert 1.0. FDA anticipates that precertified organizations would identify specific data analytics aligned to each of these domains and subdomains of the proposed RWPA framework based on the intended use, functionality, and risk category of the SaMD product. While appropriate analytics will vary by product type, FDA expects that the organizations would select those analytics that drive their internal decision-making by exhibiting meaningful variation and actionable thresholds.

Where a RWPA domain is not relevant to a specific SaMD product, a precertified organization may provide a justification for not collecting data associated with that domain. For example, an organization manufacturing a SaMD diagnostic device not associated with a clinical outcome claim might appropriately justify not collecting data associated with downstream health benefits.

## 7.2 RWPA Collection Plan

The RWPA framework for post-launch product monitoring is intended to provide robust evidence supporting the determination of safety and effectiveness of a particular SaMD product from a precertified organization, while retaining sufficient flexibility to accommodate the full range of organizations capable of demonstrating excellence in digital health. To that end, FDA envisions engaging in an iterative process to refine the types of data elements most relevant to SaMD real-world performance monitoring, to streamline the monitoring process following a least burdensome approach, and to increasingly automate the process of developing a product-specific RWPA plan.

FDA anticipates that Pilot Participants will develop a RWPA plan in advance of introducing a product to market. FDA intends to focus its post-launch product monitoring efforts on trends and summary analytics, rather than on raw data.[18] For all products, a RWPA plan should include:

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[18] Existing requirements, including adverse event reporting and other reporting requirements, under the FD&C Act and its implementing regulations continue to apply.

FDA will continue to build and refine this working model by considering public comments, incorporating comments received, as appropriate, and regularly seeking additional public input throughout the development of this program.

- Proposed RWP data elements to be collected;
- Intended frequency of data collection;
- Intended data structure and format; and
- Commit and stretch goals for each proposed data element.

For purposes of further optimizing the RWPA framework, FDA intends to review submitted RWPA plans and to work with individual Pilot Participants to refine needed data elements in the 2019 test phase. Following an interactive FDA review and mutual agreement that the proposed RWPA plan is adequate for monitoring safety and effectiveness of the SaMD product, Pilot Participants will collect and analyze RWP data elements through the processes and methodologies defined by the organizations and share the selected RWPA with the FDA as agreed. RWHA may be used to reduce the extent of uncertainty postmarket, by establishing a special control for RWP monitoring when granting a De Novo Request for a SaMD product.

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**Testing of Real-World Performance in 2019: RWPA collection plan**

In 2019, the RWPA plan would be submitted as part of the De Novo or 510(k) submission, as appropriate for the product type, or discussed during a voluntary Review Determination Pre-Submission meeting.

Based on experience from 2019, FDA aims to provide additional guidance to precertified organizations on appropriate types of analytics for verification of their ongoing commitments to excellence. While FDA does not intend to further tailor the data domains in the RWPA framework based on organizational precertification tiers, product risk categories, or product premarket review requirements at this time, the Agency plans to refine the RWPA framework based on experience accumulated in 2019.

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## 7.3   RWPA Monitoring

As described below, the purpose for which RWPA is being monitored and analyzed influences the type of data to be collected and the duration of data collection. Precertified organizations would use best practices of monitoring and analyzing product-specific data to demonstrate their ongoing commitments to organizational excellence, and to identify and address any safety or security issues in a timely manner.

- *Verification of ongoing excellence.*
  Verification that precertified organizations are identifying, tracking, analyzing, and responding to measures related to the safety and effectiveness of SaMD products postmarket enables FDA to have continued confidence in the excellence of the organization. Such confidence, in turn, will ensure maintenance of precertification and may support extension of the interval between Excellence Appraisals.

  Robust reporting and increased transparency in postmarket data collection on the part of precertified organizations may also enable FDA to explore opportunities to optimize existing postmarket obligations for precertified organizations, including reporting and inspection requirements.

  For example, a SaMD manufacturer would undergo an Excellence Appraisal and would be precertified. For the release of the first product, which is intended to drive

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*Software Precertification Program: Working Model – Version 1.0 – January 2019*

FDA.gov

41

treatment for a non-serious condition, the precertified organization would work closely with the FDA to develop a RWPA plan during the Review Determination process. Selected RWPA tracking real-world health analytics, user experience analytics, and product performance analytics could be submitted to FDA on a periodic basis. Given evidence that the organization continues to address safety and security issues in a timely and user-centered manner, FDA might be able to reduce the frequency of RWPA reporting in subsequent years.

- *Early identification and remediation of safety and security vulnerabilities.*
  Ongoing monitoring of product-specific RWPA enables organizations to respond rapidly to emerging issues, including safety and security vulnerabilities. Regular access to RWPA would increase FDA familiarity with the types of data being collected and any potential signals being monitored by precertified organizations. The Agency believes that this increased familiarity would facilitate collaborative engagement between FDA and precertified organizations when products require modifications or updates. Collaborative engagement aimed at rapidly addressing any postmarket safety or security concerns, in turn, may reduce the need for compliance actions and streamline review of any required product modifications.

  While access to RWPA would allow FDA to work with individual manufacturers to maintain product quality and ensure patient safety, it additionally might enable FDA to identify potential or emerging issues across product classes and to notify manufacturers before product quality is affected.

  For example, there may be a precertified organization that is manufacturing a SaMD product that analyzes a signal from a third-party wearable sensor, which is not considered a medical device. Through RWPA, the organization may identify an increase in user complaints regarding product performance and trace the root cause to a change in the sensor sampling rate, which has negatively impacted the signal quality of inputs to the SaMD algorithm. The precertified manufacturer would adjust the algorithm to maintain its cleared performance characteristics, and FDA would be able to notify manufacturers of other SaMD products relying on that third-party sensor that additional hardware testing may be needed to ensure adequate signal detection.

In addition to the purposes of RWPA collection described above, structured collection of RWPA may also serve, where appropriate, to streamline clinical evidence generation and support continuous learning and improvement of SaMD products.

- *Addressing premarket uncertainty.*
  In certain circumstances, the review team may determine that postmarket data should be utilized as a special control. RWPA used for this purpose will be collected over a defined time period and should be structured in collaboration with the review team to ensure that the evidence generated is appropriate, reliable, and scientifically valid.

  For example, following precertification, an organization intends to submit a De Novo request for a moderate risk SaMD product intended for use in a small patient population. FDA may determine based on the facts and circumstances that greater

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*Software Precertification Program: Working Model – Version 1.0 – January 2019*

FDA.gov

42

uncertainty, as reflected in a lower confidence level for the clinical study, is appropriate for the device, provided that there is certain postmarket data collection and other special controls. A RWPA plan could be developed that would meet requirements for verifying ongoing excellence but would also be used to collect the requisite postmarket data over a two-year time period to address the greater uncertainty.

- *Generation of adequate clinical evidence to support label expansion.* Manufacturers may introduce a SaMD product to market with limited functionality at first, intending to expand its functionalities and associated claims over time. FDA anticipates that continuous collection and analysis of RWPA would support precertified manufacturers in understanding postmarket performance and in improving the product over time. Where postmarket RWPA provide evidence of superior real-world performance as compared to premarket data, FDA would work with the precertified manufacturer to modify claims and labeling to reflect actual performance characteristics. Real-world performance data may identify issues that the manufacturer must address, as appropriate.

  For example, a precertified organization may introduce a SaMD product to market based on a review of clinical evidence for its target population. Over time, RWPA may demonstrate improved performance for a subset of the target population. A RWPA plan would be developed to collect additional safety and effectiveness data from the subset of the patient population, and results may be used to support a change in claims for use in the patient subpopulation.

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**Testing of Real-World Performance in 2019**

**Objectives:**

- Test processes and methodologies for data sharing and interpretation of analytics. Pilot Participants would provide FDA with access to RWPA, usage data, and software version information on a periodic basis (e.g., quarterly).
- Refine the RWPA framework and provide additional clarity to industry on the attributes of RWP metrics that have high concordance with ongoing excellence.
- Test the sensitivity of RWPA in detecting postmarket signals, as well as the alignment between RWPA signals and traditional postmarket reporting.
- FDA expects that the 2019 testing and validation of the Pre-Cert framework would enable expanded uses of RWPA in future versions of the Program.

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*Software Precertification Program: Working Model – Version 1.0 – January 2019*

FDA.gov

43

# 8  Next Steps and Public Engagement

FDA is publishing this version 1.0 of the working model of the Software Pre-Cert Program to gather public input as we continue to develop this program. FDA will continue to consider and evaluate comments received, incorporate comments into the model as appropriate, and seek additional public input throughout the development of this program. Along with this version of the Working Model, FDA is issuing two companion documents: (1) a Test Plan that describes how FDA intends to iterate and confirm that the framework proposed in this Working Model provides a reasonable assurance of safety and effectiveness for SaMD products and (2) the Regulatory Framework for conducting the pilot program within current authorities.

FDA intends to consider stakeholder comments by reviewing the public docket approximately every two weeks, and to incorporate comments, as appropriate, in future versions of the working model. We encourage the public to provide feedback early and often.

FDA is seeking public feedback on this version of the working model **by March 8, 2019**, at https://www.regulations.gov/comment?D=FDA-2017-N-4301-0001. This feedback will be incorporated into future versions of the program model, which will also be disseminated for public input.

FDA will continue to build and refine this working model by considering public comments, incorporating comments received, as appropriate, and regularly seeking additional public input throughout the development of this program.

*Software Precertification Program: Working Model – Version 1.0 – January 2019*

FDA.gov

44

# 9  Appendix – FDA Response to Comments Received

The following table provides a high-level summary of comments received in the public docket and FDA's responses to those comments.

| Summary of Comment(s) Received | FDA Response |
|---|---|
| Commenters discussed the assessment criteria for the Excellence Appraisal, including specific comments addressing the domains and elements introduced in v0.2 of this Working Model. Stakeholders' comments include stressing the need for prioritizing elements specific to patient safety and clinical responsibility, emphasizing the importance for the underlying principles of the Excellence Appraisal to be consistently interpreted and applied across participants, and supporting the program's intent to base the appraisal process on objective, observable evidence. | During 2019 testing, FDA intends to explore how to prioritize the patient safety and clinical responsibility elements during the Excellence Appraisal. FDA further intends to consistently apply the Excellence Principles for all participants in the Software Pre-Cert Program. |
| Commenters provided recommendations for which standards and certifications could be considered as objective evidence for a subset of the elements. | FDA incorporated these recommendations into potential standards and certifications that may be considered to demonstrate the Excellence Principles during an appraisal. See Section 10. |
| Commenters provided recommendations for appraisal of organizations using artificial intelligence/machine learning technology. | FDA is considering how organizations that produce software using artificial intelligence or machine learning algorithms may be assessed during an Excellence Appraisal. FDA intends to incorporate the recommendations received as part of the 2019 testing, as needed. |
| Commenters provided recommendations for metrics and KPIs. | FDA intends to develop a library for metrics and KPIs and will incorporate recommendations as appropriate. |
| Commenters raised questions related to the maintenance of a precertification status over time. | The precertification program is not intended to be an indefinite designation for an organization. The program will require organizations to commit to and share with the agency key performance metrics that are part of the precertification maintenance. FDA outlined in Section 3.6 organizational change "triggers" that will require increased oversight or potential reassessment as part of the precertification maintenance. |
| Commenters supported use of the IMDRF Risk Category framework for the risk classification of SaMD products. Commenters raised concerns that the | FDA intends to continue exploring the use of the IMDRF framework as a risk-based approach to review SaMD products included in the Pre-Cert Program. FDA intends to develop methods to assist manufacturers in using the |

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*Software Precertification Program: Working Model – Version 1.0 – January 2019*

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|---|---|
| IMDRF Risk Category framework is too complex. Commenters noted the need for the IMDRF Risk Category framework to align to the U.S. FDA device classification system. | IMDRF framework and aligning it with FDA jurisdiction and terminology. |
| Commenters raised the need for a regulatory toolkit or framework to navigate existing FDA policy in the context of the Pre-Cert Program. | FDA intends to develop a decision tree or support tool for organizations to determine: <br>• whether a SaMD software function meets the definition of device in section 201(h) of the FD&C Act; <br>• whether a SaMD software function is a function for which FDA has expressed an intent not to enforce compliance to applicable requirements; and <br>• its applicable risk categorization for Pre-Cert. This extends beyond the scope of the Pre-Cert Program, and FDA will provide its current thinking in a separate document. |
| Commenters requested clarification on the IMDRF risk category framework terminology. Commenters also questioned how the intended user of the SaMD would affect the risk categorization. Commenters also requested example SaMD definition statements with mapped risk categories. | FDA recognizes the need for further clarity on the IMDRF risk category framework and its application to SaMD products evaluated by FDA. FDA's current thinking on interpreting the IMDRF terminology and risk categories and applying those interpretations to the regulation of software extends beyond the scope of the Pre-Cert Program because it applies to the regulation of such SaMD from companies not participating in the Pre-Cert Program. FDA intends to provide its current thinking on this topic in a separate document. |
| Comments requested clarification on the SaMD product-level elements, and goals to ensure that this process is least burdensome. | FDA considered these comments and clarified the proposed content and procedures for SaMD product-level elements submission to support 1) Review Pathway Determination and 2) precertified organizations' commitment to transparency to users. FDA will apply least burdensome principles to Streamlined Review for review of the SaMD, as appropriate. |
| Commenters requested clarification on registration and listing, and if this would be required in addition to the product-level elements submission. | At this time, manufacturers should adhere to standard registration and listing requirements. |
| Commenters suggested how to address SaMD modifications of products marketed by precertified organizations. | FDA is continuing to develop how precertified organizations' SaMD products may be modified and intends to incorporate suggestions received, as appropriate, in the next version of the working model. FDA will utilize the current software modifications guidance for SaMD modifications in the 2019 pilot. |

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*Software Precertification Program: Working Model – Version 1.0 – January 2019*

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|---|---|
| Commenters felt that a staged approval process would only be confusing and should be avoided it at all possible. | FDA is not considering utilizing a staged approval approach for Streamlined Review of a Pre-Cert package. |
| Commenters suggested that the review elements submitted for streamlined review should be non-redundant. | FDA agrees and has worked to eliminate redundant information from the Streamlined Review process and seeks to further reduce duplicative information provided as part of the streamlined review package. |
| Commenters felt that streamlined review should be a truly interactive process, supported by modern communication technology and scheduling to minimize misunderstandings and communication delays. | FDA supports the idea of Streamlined Review being a highly interactive process, possibly including product demonstration and interactive review with the sponsor. We envision modern tools for teleconference could facilitate live interaction during the review process. |
| Commenters suggest that there should be a designated facilitator from digital health group for precertified companies to facilitate the review process between the review staff and the manufacturer. | FDA is considering this option. |
| Commenters requested clarity on the rationale and potential benefits for product-level monitoring in a real-world environment. | FDA believes that monitoring product-level performance of SaMD products will increase the ability of precertified organizations to use collected RWP data to support product claim modifications, changes in intended use, or expansions of product functionality. Furthermore, it will enable increased public confidence in the Pre-Cert program and in the SaMD products manufactured by precertified organizations and will increase FDA's ability to support industry in taking proactive actions to address emerging safety or cybersecurity issues. |
| Commenters requested additional detail about the types of data analytics that would be shared with FDA for real-world performance monitoring. | FDA has provided details of types of data analytics that could be shared with FDA in Section 13 Appendix – Real-World Performance Analytics for Product Monitoring. |
| Commenters requested clarity on how data analytics that are shared with FDA would be used. | FDA intends for the data analytics shared with FDA to be used for continuous improvement and refinement of the Pre-Cert program, to benchmark and develop standards for emerging technologies, to support corrective action to emerging safety or cybersecurity issues affecting multiple products, and to enable transparency around SaMD product performance. |
| Commenters suggested refinements in terminology and example KPIs. | FDA adopted changes in terminology where appropriate (e.g., effectiveness, human factors and usability engineering). FDA also removed KPIs that comments identified as not representative of a wide range of SaMD products, in addition to removing those that commenters found difficult to interpret. FDA acknowledges that particular KPIs may address more than one domain. |

FDA will continue to build and refine this working model by considering public comments, incorporating comments received, as appropriate, and regularly seeking additional public input throughout the development of this program.

*Software Precertification Program: Working Model – Version 1.0 – January 2019*

# 10 Appendix – Clarification of IMDRF Definition of Software as a Medical Device (SaMD)

The International Medical Device Regulators Forum's (IMDRF) defines "software as a medical device (SaMD)" as: *software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.*

This definition is further clarified through the following notes that accompanied the definition of SaMD. In order to further explain these notes we are providing the following clarifications:

- *SaMD is a medical device and includes in-vitro diagnostic (IVD) medical devices.*
  - o For purposes of the Software Pre-Cert Program, the application of the risk category framework would remain consistent with the current definition of device under section 201(h) of the FD&C Act and FDA's current enforcement policies. The unmodified IMDRF framework describes the spectrum of SaMD functions, some of which may not meet the definition of a device in 201(h) of the FD&C Act and others that may meet the definition of a device but for which FDA has expressed its intent not to enforce compliance with applicable requirements of the FD&C Act.
  - o Non-device software functions are not subject to regulation and are not within the scope of the Software Pre-Cert Program, including software functions intended (1) for administrative support of a health care facility, (2) for maintaining or encouraging a healthy lifestyle, (3) to serve as certain types of electronic patient records, (4) for transferring, storing, converting formats, or displaying clinical laboratory tests or other device data and results, without interpreting or analyzing clinical laboratory tests or other device data, results, and findings s, or (5) to provide certain types of limited clinical decision support.  Software functions described in final guidance documents that may meet the definition of a device but for which FDA does not intend to enforce compliance with applicable requirements of the FD&C Act are not within the scope of the Software Pre-Cert Program.

- *SaMD is capable of running on general purpose (non-medical purpose) computing platforms.*
  - o This means that a SaMD is capable of running on any computing platform that has a microprocessor or microcontroller, which can live in many types of products, i.e., a computing platform is location-agnostic and platform-agnostic. A myriad of smart electronic products, which may be hardware medical devices or other general purpose software/hardware, including glucose meters, smart phones, MRI machines, laptops, infusion pumps, smart watches, and ECG machines all have a computing platform that executes software.
  - o A computing platform (that may or may not be part of a medical device) typically includes microprocessor or microcontroller with peripherals, intended solely for executing instruction and software logic or calculations described through a programming language. Peripherals provide input to the microprocessor and deliver output from the microprocessor. Example inputs may include a mouse, keys, touchscreen, gyroscope, accelerometer and GPS, whereas example outputs may include display, speaker, light and vibration actuators.

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*Software Precertification Program: Working Model – Version 1.0 – January 2019*

- *"without being part of" means software not necessary for a hardware medical device to achieve its intended medical purpose.*
  - This statement refers to software (typically known as "embedded software") that is included in a hardware medical device or an IVD test instrument. Such software is primarily relied upon (necessary) for achieving the "intended use" of the hardware medical device or the IVD instrument. Such software is not considered a SaMD. Alternatively, such software when executed on another general-purpose computing platform would not achieve the same intended use.

- *Software does not meet the definition of SaMD if its intended purpose is to drive a hardware medical device.*
  - This statement refers to software whose function is to control or drive another medical device. Autonomous, closed-loop medical devices, i.e., those that do not require clinicians to make an interpretation from signal-gathering to decision-state, are not considered SaMD.

- *SaMD may be used in combination (e.g., as a module) with other products including medical devices.*
  - This statement indicates that a SaMD may be used as a module in a larger system interconnected or bundled with other software modules that may or may not be medical devices.

- *SaMD may be interfaced with other medical devices, including hardware medical devices and other SaMD software, as well as general purpose software.*
  - In this statement "interfaced" refers to the notion that input to a SaMD can come from many sources.
  - SaMD is software that acts on data for a medical purpose and that data that SaMD may use as input can come from a variety of medical and non-medical products. Medical devices such as ECG machines, MRI, and in vitro diagnostics, collect many types of data that may be used as input into a SaMD. Non-medical products, such as general wellness devices and general-purpose sensors may also collect data that could be used as input into a SaMD. The SaMD algorithm acts on that data for a specific medical purpose, which may be to inform, drive, diagnose, or treat a healthcare situation or condition. Further clarification on the data quality and collection principles for non-medical sensors used as inputs into SaMD is under development.

- *Mobile apps that meet the definition above are considered SaMD.*
  - The intent of this statement is that SaMD can also be mobile apps, as FDA defined such mobile apps as "mobile medical apps." This could include mobile apps that perform patient-specific analysis, provide patient-specific diagnosis, or recommend treatments, for example.

FDA will continue to build and refine this working model by considering public comments, incorporating comments received, as appropriate, and regularly seeking additional public input throughout the development of this program.

*Software Precertification Program: Working Model – Version 1.0 – January 2019*

# 11 Appendix – Possible Standards and Certifications for Demonstration of Excellence

FDA intends to leverage relevant existing standards and certifications from accredited bodies as acceptable evidence to demonstrate CQOE where possible to support a least burdensome approach to the Excellence Appraisal of an organization and to avoid unnecessary complexity. This Appendix includes an example list of standards, accreditation certifications, evaluations, etc., including recommendations made by the public to the docket, that the FDA intends to evaluate to determine whether they can be used to demonstrate the Excellence Principles during an appraisal. However, FDA does not intend to include a specific standard or certification as a requirement of the Excellence Appraisal or Precertification Program.

- National Institute of Standards and Technology's (NIST) Framework for Improving Critical Infrastructure Cybersecurity (Cybersecurity Framework) certification
- ISO Certifications
    - ISO 9001, Quality Management System
    - ISO 14971, Medical devices – Application of risk management to medical devices
    - ISO 13485, Medical devices – Quality management systems – Requirements for regulatory purposes
    - ISO 62304:2006, Medical device software – Software lifecycle processes
    - ISO 90003 Software Engineering – Guidelines for the application of ISO 9001:2000 to computer software
    - ISO/TC 210, Quality management and corresponding general aspects for medical devices
    - ISO/IEC 15414:2006, Information technology – Open distributed processing – Reference model – Enterprise language
    - ISO/IEC 25010, Software engineering – Software product quality requirements and evaluation (SQuaRE) – Data quality model
    - ISO 62366:2008, Medical devices – Application of usability engineering to medical devices
- ISB 0129 Clinical risk management implementation
- Department of Defense (DoD) certifications
- Office of the National Coordinator (ONC) certification
- Accredited third-party certification of Software Development Life Cycle (SDLC)
- Covered entity under Health Insurance Portability and Accountability Act (HIPAA)
- Medical Device Single Audit Program (MDSAP)
- Case for Quality Medical Device Discovery Appraisal Program (MDDAP)

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*Software Precertification Program: Working Model – Version 1.0 – January 2019*

# 12 Appendix – Proposed Organizational Elements to Demonstrate Excellence Principles

FDA intends to evaluate organizational elements based on objective and observable evidence. Although the appraisal method is under development, we expect organizations would provide this evidence as part of the appraisal process, which may include site visits, interviews, or other methods. FDA hopes to implement automation for the acceptance and review of an organization's demonstration of their elements in future iterations to reduce appraisal burden, increase transparency, and enhance the capability to respond quickly and improve products without reducing public confidence in the program.

| Organizational Domains | Elements | Excellence Principle(s) | | | | |
|---|---|---|---|---|---|---|
| | | PS | PQ | ClinR | CybR | PC |
| PS: Product Safety; PQ: Product Quality; ClinR: Clinical Responsibility; CybR: Cybersecurity Responsibility; PC: Proactive Culture | | | | | | |
| Leadership, and Organizational Support | Providing clear accountability and responsibility to address product issues, user issues, constraints, and conflicting priorities throughout the product lifecycle. | X | X | X | X | X |
| | Empowering staff to act regarding the decisions or issues impacting users, products, or patient safety. | X | X | X | X | X |
| | Providing the resources and focus to assure important infrastructure and processes to assure patient safety are sustained and improved. | X | X | X | X | X |
| Transparency | Developing and maintaining systems or dashboards where all levels of the organization can rapidly see and understand how they are performing among metrics relevant to the organization. | X | X | X | X | X |
| | Making defects, deviations, safety issues transparent to internal and external stakeholders, as appropriate. | | X | | | X |
| | Security and quality issues are communicated with internal and external stakeholders sufficiently to catalyze corrective and preventive action. | X | X | X | X | X |
| | Buyers and users understand design assumptions about expected operational conditions/environment to use devices safely, securely, and effectively. | | | | X | |

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| Organizational Domains | Elements | Excellence Principle(s) | | | | |
|---|---|---|---|---|---|---|
| | | PS | PQ | ClinR | CybR | PC |
| PS: Product Safety; PQ: Product Quality; ClinR: Clinical Responsibility; CybR: Cybersecurity Responsibility; PC: Proactive Culture | | | | | | |
| | Buyers and users (patients/physicians) understand expected or minimum support lifetimes and levels. | | | | X | |
| People | Developing and maintaining access to highly skilled employees with relevant/applicable clinical knowledge | X | X | X | X | X |
| | Involving appropriate cross functional subject matter expertise including, engineering, clinical expertise, and user advocates, with frequent engagement and communication in product decisions and potential safety events. | X | X | X | X | |
| | Continuous development of employees through robust knowledge management, employee development options, coaching, training, and succession planning. This includes keeping updated with the latest clinical developments and patient safety priorities. | X | X | X | X | X |
| | Developing and maintaining clear and objective employee performance metrics, rewards, and recognitions aligning behaviors to the business goals, values, and rapidly responding to patient safety issues. | X | X | X | X | X |
| Infrastructure and Work Environment | Customer engagement and providing multiple avenues for outreach, feedback, and learning. | | X | | X | X |
| | Implementing the tools, automation, and test environments in development that establish a centralized and visible process. | X | | | | |
| | Develop and maintain a robust notification and communication framework. | X | X | X | X | X |
| | Communicate and preserve the relevant results of the activities, processes and expectations related to the SaMD lifecycle processes. | | X | X | | |
| | Developing and maintaining processes and mechanisms for rapid learning from successes, failures, and near-misses. | X | X | X | X | X |

FDA will continue to build and refine this working model by considering public comments, incorporating comments received, as appropriate, and regularly seeking additional public input throughout the development of this program.

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| Organizational Domains | Elements | Excellence Principle(s) | | | | |
|---|---|---|---|---|---|---|
| | | **PS** | **PQ** | **ClinR** | **CybR** | **PC** |
| PS: Product Safety; PQ: Product Quality; ClinR: Clinical Responsibility; CybR: Cybersecurity Responsibility; PC: Proactive Culture | | | | | | |
| Risk Management: A Patient Safety Focused Process | Regularly questioning how software works by understanding, identifying, and proactively anticipating potential issues and factors that can influence what can go wrong with the software. | X | X | X | X | X |
| | Favor rigorously tested software components (i.e. well-vetted cryptographic libraries vs roll your own) or identify risks and mitigations. | X | X | | X | X |
| | Identifying, receiving, and handling vulnerability reports from third parties directly (coordinated vulnerability disclosure) or from public sources, such as vulnerability databases. | | | | X | |
| | Accounting for support lifecycles of hardware and software components and dependencies. (i.e. If the SaMD is expected to be used longer than the operating system is supported, how will you continue to address things like security vulnerabilities?). | | | | X | |
| Configuration Management and Change Control | Source control by establishing mechanisms for initiating, evaluating and controlling changes to software during all lifecycle processes and after deployment. | X | X | | X | |
| | Good release management with a secure update process. | X | X | | X | X |
| | The ability to rollback software in the event of an emergency. | X | X | | | |
| Measurement, Analysis, and Improvement of Processes and Products | Responsive issue escalation & resolution. | | X | X | | |
| | Actively monitoring, analyzing, rapidly addressing, and implementing resulting process improvements from user feedback and product issues including safety, cyber or data issues. | | X | | | X |
| | Analyzing and providing the learning collected from real world data back to development teams throughout all lifecycle processes. | X | | | | X |
| | Developing and maintaining process performance metrics that are clear, simple, and actionable across all staff and organizational levels with integrated improvement activities. | X | | | | X |

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*Software Precertification Program: Working Model – Version 1.0 – January 2019*

| Organizational Domains | Elements | Excellence Principle(s) | | | | |
|---|---|---|---|---|---|---|
| | | **PS** | **PQ** | **ClinR** | **CybR** | **PC** |
| PS: Product Safety; PQ: Product Quality; ClinR: Clinical Responsibility; CybR: Cybersecurity Responsibility; PC: Proactive Culture | | | | | | |
| | Supporting rigorous interrogation into sources of failure, error, and tampering, including tamper resistant, forensically sound evidence capture and publicly known mechanisms to perform or trigger investigations. | | X | X | | |
| Managing Outsourced Processes, Activities, and Products | Comprehensive risk management of third-party and open source software throughout all lifecycle process and activities. | X | | | X | |
| | Avoid third-party software components with known vulnerabilities when less vulnerable alternatives are available. | X | X | | X | X |
| | Maintain and provide traceability and assurance of third-party and open source software throughout the effective lifetime of the software. | X | X | | X | |
| Requirements Management | Understanding the clinical association between the SaMD output and a clinical condition (i.e., clinical performance) and understanding and updating the priorities, concerns, and value to intended user based on user feedback throughout all lifecycle phases. | X | X | X | | X |
| | Buyers and operators understand the impact of operational isolation (e.g. which features are fully available in standalone/no network mode). | X | X | X | X | X |
| | Carefully manage and gate remote access to all device components and dependencies. (e.g. Avoid hardcoded default credentials within the device and enforce secure identity and access management for any provider-operated components like software update distribution servers.) | X | X | X | X | X |
| Design and Development | Secure software development lifecycle, including adversarial resilience analysis and testing, reducing elective attack surface & complexity, and minimizing elective exposure throughout the software lifecycle. | X | X | X | X | X |
| | Designing software based on good quality clinical evidence from research and can reference published, peer-reviewed studies that show claimed results. | | | X | | |
| | Incorporating resilience, containment, and isolation into the design solution so that product fails safely and visibly, continue to perform as | | X | X | | |

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| Organizational Domains | Elements | Excellence Principle(s) | | | | |
|---|---|---|---|---|---|---|
| | | PS | PQ | ClinR | CybR | PC |
| PS: Product Safety; PQ: Product Quality; ClinR: Clinical Responsibility; CybR: Cybersecurity Responsibility; PC: Proactive Culture | | | | | | |
| | intended when there are failures in the operating environment, and assures the integrity of data input and storage. | | | | | |
| | Incorporating anticipated safety risks and mitigations throughout all lifecycle phases and actions taken to prevent recurrence of any unanticipated hazards. | X | X | X | | |
| | Reliably identifying and removing code errors at source. | X | X | | | X |
| | Integrating user experience/Human Factors and Good Clinical Practices Human Subject Protection into development in partnership with patients and caregivers. | X | X | X | X | X |
| | Secure, prompt, and agile update mechanism and process, with high rates of prompt update adoption and clear notification and communication to stakeholders. | X | X | X | X | X |
| | Leadership/peer/expert review throughout lifecycle phases and at key milestones. | X | | | | X |
| Verification and Validation | Staged release with active user testing. | X | | X | | |
| | Demonstrating software works for intended use / indications for use. | | X | X | | |
| | Measuring quality of the output of the software on the clinical target (intended use, indication of use). | | X | X | | |
| Deployment and Maintenance | Proactive patient and clinical outreach and education including limitations of software and FAQs addressing potential patient safety questions developed as part of release. | | X | X | | X |
| | Active control mechanisms to force/push patient safety and security updates. | X | X | | | X |
| | Support dependency updates, such as routine operating system upgrades. | X | X | | X | X |

# 13 Appendix – Real-World Performance Analytics for Product Monitoring

| Analytic Type | Domain | Value | Excellence Principle(s) | | | | | Example KPIs |
|---|---|---|---|---|---|---|---|---|
| | | | PQ | PS | ClinR | CybR | PC | |
| **PQ: Product Quality; PS: Product Safety; ClinR: Clinical Responsibility; CybR: Cybersecurity Responsibility; PC: Proactive Culture** | | | | | | | | |
| Real World Health Analytics | Human Factors and Usability Engineering | • Pre-Cert Organization: Support product claims by understanding user ability to comprehend and correctly navigate user interface <br> • All stakeholders: Demonstrate continuous improvement in usability engineering to drive health benefits and safety | X | | X | | X | User error rate |
| | Clinical Safety | • Pre-Cert Organization: Benefit from early safety signal detection across Pre-Cert organizations <br> • All stakeholders: Provide assurance that safety risks are managed and mitigated in a timely way | X | X | X | X | X | Anticipated adverse event rate/severity <br> Time to resolve anticipated adverse event <br> Unanticipated adverse event rate/severity <br> Time to resolve unanticipated adverse event |
| | Health Benefits | • Pre-Cert Organization: Support product claims and future claim modifications by understanding clinical benefits <br> • All stakeholders: Demonstrate positive impact on health outcomes | X | | X | | X | Rate of change in targeted health outcome by user demographic |

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| Analytic Type | Domain | Value | Excellence Principle(s) | | | | | Example KPIs |
|---|---|---|---|---|---|---|---|---|
| | | | PQ | PS | ClinR | CybR | PC | |
| PQ: Product Quality; PS: Product Safety; ClinR: Clinical Responsibility; CybR: Cybersecurity Responsibility; PC: Proactive Culture | | | | | | | | |
| User Experience Analytics | User Satisfaction | • Pre-Cert Organization: Provide insight into brand reputation and product performance<br>• All stakeholders: Demonstrate excellence in product quality, organizational proactivity, and product effectiveness | X | X | X | X | X | Average user ratings over time<br>Complaint rates<br>Customer survey responses |
| | Issue Resolution | • Pre-Cert Organization: Build consumer confidence in organization and SaMD product<br>• All stakeholders: Demonstrate excellence in safety and product quality | X | X | X | X | X | Time to resolution by clinical/cybersecurity risk category<br>Number of open complaints<br>Time to root cause analysis<br>Number of repeat issues/complaints<br>Customer rating of issue resolution |
| | User Feedback Channels | • Pre-Cert Organization: Identify and resolve important user issues early and timely<br>• All stakeholders: Demonstrate clinical responsibility and excellence in product quality by ensuring that user feedback is representative of the full user population | | | X | | X | Response rates by demographic<br>Response rates by feedback channel |
| | User Engagement | • Pre-Cert Organization: Optimize user experience and meet business targets for user engagement<br>• All stakeholders: Demonstrate product quality, clinical responsibility, and proactivity by understanding and continuously improving user experience | X | | X | | X | Unique users<br>User retention<br>Time in app |

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| Analytic Type | Domain | Value | Excellence Principle(s) | | | | | Example KPIs |
|---|---|---|---|---|---|---|---|---|
| | | | PQ | PS | ClinR | CybR | PC | |
| PQ: Product Quality; PS: Product Safety; ClinR: Clinical Responsibility; CybR: Cybersecurity Responsibility; PC: Proactive Culture | | | | | | | | |
| Product Performance Analytics | Cybersecurity | • Pre-Cert Organization: Build consumer confidence in organization and SaMD product<br>• All stakeholders: Protect user privacy, ensure product integrity, and maintain system availability | X | X | X | X | X | Number of breaches resulting in loss of user data<br>Number of remediated vulnerabilities/ vulnerabilities identified<br>System downtime |
| | Product Performance | • Pre-Cert Organization: Support product claims and future claim modifications<br>• All stakeholders: Demonstrate sustained analytical validity and excellence in continuous improvement in product quality | X | X | X | X | | False positive/false negative rates<br>Bug/defect rates<br>Version failure rates |

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*Software Precertification Program: Working Model – Version 1.0 – January 2019*