



Software Precertification Program 2019 Mid-Year Update

The Software Precertification (Pre-Cert) Program is reimagining how the FDA regulates digital health devices, specifically software as a medical device (SaMD). In 2019, the [Pre-Cert Program](#) entered its test phase, with the intent to confirm that the framework proposed in the [Working Model v1.0](#) provides an equivalent reasonable assurance of safety and effectiveness for software products as our traditional review pathway.

To implement the [2019 Test Plan](#), the Agency is applying both the proposed Pre-Cert pathway (which includes Excellence Appraisal, Review Pathway Determination, Streamlined Review, and Real-World Performance) and the traditional review process to each test case, thereby enabling a comparison of review outcomes and the basis for regulatory decision-making.

The FDA is committed to keeping the process of developing the Pre-Cert Program collaborative and transparent. The following is a summary of the test activities that the FDA has conducted through May 2019, as well as an update on our progress and what we have learned.

What is the FDA Evaluating During the 2019 Pre-Cert Test Plan?

The FDA is evaluating:

1. The ability of the Pre-Cert review pathway to provide an equivalent reasonable assurance of safety and effectiveness as the traditional review pathway;
2. The value proposition of the program for the FDA, sponsors, and the broader community by seeking input on the FDA and sponsor's effort, time, and experience (interactivity, clarity, predictability, efficiency, etc.); and
3. The progress in Pre-Cert program development and maturity level.

Retrospective Testing (Completed ✓): The FDA set out to test the Excellence Appraisal and Streamlined Review components using select SaMD regulatory submissions that have been previously reviewed. The outcome of the test informs refinement of the Excellence Appraisal and the Streamlined Review components. The test was intended to determine if a premarket regulatory decision could be made based on an Excellence Appraisal summary and Streamlined Review elements.

- **What We Did:** The Pre-Cert team developed a mock Excellence Appraisal summary based on the pilot participant site visits and public comments. The team then created Streamlined Review packages by extracting elements from the original submission. Reviewers experienced with software review conducted a mock review to assess whether a regulatory decision could be made based on the Excellence Appraisal summary and the Streamlined Review elements.
- **What We Learned:** Reviewers conducting the mock review generally reported that a regulatory decision could be made using the information acquired from the mock Excellence Appraisal summary and the Streamlined Review package. The test team, including the reviewers, identified opportunities to simplify the Excellence Appraisal and Streamlined Review process for sponsors and reviewers. The test team recommended elements of the submission identified in the working model be in a structured format for submissions to be included in the

prospective testing. Results from the retrospective testing informed the development of review processes and work instructions for reviewers and FDA staff to support the Streamlined Review during the prospective testing. The test achieved its objectives in identifying the feasibility of the Streamlined Review package along with the Excellence Appraisal summary to be sufficient to conduct a premarket review of SaMD.

Prospective Testing (In Progress ): Within FDA's current authorities and utilizing traditional marketing submissions, the FDA intends to test the program components described in version 1.0 of the Working Model by using a mock Streamlined Review package for selected premarket submissions. The FDA continues to work with pilot participants and other interested stakeholders who have volunteered for the 2019 testing to conduct an Excellence Appraisal and, in some cases, to test Pre-Cert program components through the review of a De Novo request or 510(k) submission (the FDA will also conduct traditional review for all test cases). Also, the FDA plans to leverage the current Pre-Submission (Pre-Sub) process to pilot voluntary Review Pathway Determination Pre-Subs.

- **What We Are Doing:** The FDA announced the opportunity for other companies to volunteer as a test case for the prospective testing, if they are planning to submit a De Novo request or 510(k) submission for SaMD soon. The FDA has conducted several Excellence Appraisals with pilot participants. In preparation for the appraisals, participating companies discussed Excellence Appraisal plans with the FDA Pre-Cert team.



About Excellence Appraisals

Excellence Appraisals measure an organization's ongoing culture of excellence against five Excellence Principles (see Working Model v1.0). Rather than applying the traditional audit approach for evaluating adherence to company processes, the Pre-Cert model uses appraisals that are interactive, collaborative, confidential, and transparent to facilitate dialogue and evaluation of evidence. The types of activities a company may prepare for an effective appraisal include:

- *Planning and scoping discussions prior to the appraisal to communicate organizational bounds, workflow, participants, scheduling, and select representative products and processes for appraisal;*
- *Access to staff and teams engaged in the end-to-end lifecycle workflow for selected products to demonstrate the use of tools, resources, data, decisions, user input (as appropriate), processes, activities, and metrics in practice;*
- *Show evidence of the outcome(s) of the phases or steps of the workflow(s) in the form of effectiveness metric(s), e.g., metric(s) that demonstrates the processes and activities that are part of the workflow are working; and*
- *Describe how the metric(s) is used in decision making, either at the team/member level and/or as part of business/employee goals.*

What is the Format for Excellence Appraisals during the Test Plan?

Each appraisal ranged from 3 to 4 days and took place either on-site at the company or at the FDA's Headquarters. A team of FDA staff conducted appraisals, including, at a minimum, a software expert, a clinical expert, a premarket review expert, a compliance expert, and a business operation expert.

The FDA worked with the participating companies to identify boundaries of the organization seeking precertification; to discuss the company's values, goals, and objectives and how they align with Pre-Cert's Excellence Principles; to agree on the scope of software products and functional areas for the Excellence Appraisal; to identify a list of the processes, activities, and

workflows related to each of the Excellence Appraisal domains and elements; and to develop a proposal for metrics for ongoing data collection for their organization and product portfolio.

The Pre-Cert team was available for questions/collaboration with participating companies as they prepared for their Excellence Appraisal. This availability helped companies (and the FDA) align expectations and share preliminary information with the FDA staff conducting the Excellence Appraisal, which helped focus the appraisal, reduce its duration, and meet the goals of Excellence Appraisal.

During appraisals, the FDA collected feedback from companies on the domains and elements for Excellence Appraisal. Organizations discussed with the FDA what types of metrics they can provide about their organization and their products. This feedback will inform how RWP plans can be tailored according to product type, intended use, and risk category.

- **Other Activities:** To better structure the information for Review Determination, the team developed SaMD product-level elements using cleared or approved SaMD. The team sought to identify specific questions for future use by precertified organizations to provide the appropriate content and level of information needed on the SaMD product-level elements that may support Streamlined Review and transparency to the public on the sponsor's SaMD. Reviewers used the sample SaMD product-level elements to test whether they could support Streamlined Review and be used to determine the SaMD risk-category. Additional input will be sought from patient groups and the digital health community to determine if the SaMD product-level elements are understandable to SaMD users. The FDA continues to probe the practicality of identifying Real-World Performance Analytics elements using specific test cases.
- **What We Learned:** Although the Pre-Cert Working Model v1.0 estimates that the Excellence Appraisal would be completed in five business days, the process was completed in three to four business days during prospective testing. Through the Excellence Appraisals performed so far, the FDA has confirmed that the elements identified in the model can be demonstrated and provide a comprehensive view of an organization's capabilities. Applying a collaborative, capability-based approach for the appraisal creates an open and transparent evaluation that identifies organizational strengths and appropriate strategies for driving opportunities for improvement. Additionally, the FDA has learned through the process that some of the elements may need to be separated or removed to improve clarity as the program continues to develop. The SaMD product-level elements, proposed by Review Determination in the Pre-Cert Working Model v1.0, were tested with FDA reviewers who confirmed their usefulness for providing basic information on the SaMD and SaMD risk categorization.

Next Steps

The FDA will continue to test the program as outlined in the 2019 Test Plan, including testing the Pre-Cert model on new SaMD submissions. The information collected will be used to determine whether the results of the Pre-Cert pathway align with the results of the traditional pathway and satisfy FDA's regulatory requirements for safety and effectiveness.

Get Involved

Visit www.fda.gov/digitalhealth to learn more. See our recently updated [FAQs](#) for questions about the 2019 Test Plan.

Email the Pre-Cert team at FDAPre-CertPilot@fda.hhs.gov.