



Software Precertification Program: 2019 Test Plan

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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 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.

FDA describes a proposed framework for the Software Pre-Cert Program in version 1.0 of the Working Model (January 2019). In that document, FDA describes excellence principles, upon which an Excellence Appraisal would be based, to evaluate an organization that produces software products. The framework further describes that the Excellence Appraisal would be leveraged in subsequent product-specific submissions, so that those submissions could proceed with a streamlined premarket submission (referred to for purposes of this pilot program as a “Streamlined Review”). As described in the Pre-Cert Regulatory Framework document, FDA intends to utilize the De Novo classification process for the next phase of this pilot program. For SaMD De Novo Requests from excellence appraised sponsors, FDA would establish special controls that may include certain Excellence Appraisal elements or postmarket data collection requirements. In keeping with the FDA’s mission to protect and promote public health, FDA intends to perform testing of the Software Pre-Cert Program model prior to employing it as an alternative premarket pathway for Software as a Medical Device (SaMD). This document describes FDA’s 2019 plan to test the model (1) internally by conducting retrospective tests of SaMD regulatory submissions that have been previously reviewed and (2) prospectively with Pilot Participants who volunteer to participate in this testing.

The primary purpose of this Test Plan is to assess whether the Excellence Appraisal and Streamlined Review components together produce an equivalent basis for determining reasonable assurance of safety and effectiveness for a SaMD product prior to its introduction to the market, as compared to the traditional paradigm.

Scope

In 2019, the scope of the Test Plan will be limited to (1) selected SaMD with De Novo Requests, which would be used to test the concept of special controls that may include certain Excellence Appraisal elements or postmarket data collection requirements, as deemed necessary for the device type, and (2) selected SaMD 510(k) submissions, which would be tested as if they were follow-on 510(k)s for the devices classified through a “Pre-Cert De Novo Request” (see Pre-Cert Regulatory Framework document). To ensure that the entire Pre-Cert framework is appropriately evaluated, FDA intends to prioritize selection of premarket submissions that will enable evaluation and testing of all four components outlined in version 1.0 of the Working Model. Recognizing the need to test the model against a diverse set of test cases, FDA intends to focus on cases that represent a broad spectrum of software developers: small and large software development firms; companies that develop a range of products, including both low and high risk products; and companies that are not considered to be traditional medical device manufacturers but who intend to make digital health technology.

Manufacturers developing SaMD for which a De Novo or 510(k) premarket submission is currently required would submit traditional marketing submissions in 2019. Section 5 of the

Working Model proposes a future state for the Pre-Cert program (envisioning additional legislative authority) that would enable direct market entry for lower-risk products developed by precertified manufacturers.

Test Plan Approach

In implementing the Test Plan, the Agency will apply both the proposed Pre-Cert pathway (which includes Excellence Appraisal, Review Pathway Determination, Streamlined Review, and Real-World Performance plan) and the traditional review process to each test case, thereby enabling a comparison of review outcomes and the basis for decision-making. The findings from test reviews will provide input into refinement of each Pre-Cert Program component and subsequently will be used to confirm the validity of the Pre-Cert framework.

The program-level Test Plan is described in further detail below and is intended to refine each component of the Pre-Cert model by applying the framework proposed in the Working Model version 1.0 document to a series of regulatory submission test cases. Each individual component of the Pre-Cert model will additionally be subject to component-specific testing to support ongoing model iteration and confirmation.

1. Retrospective tests

Internally, the FDA will test and refine the Excellence Appraisal and Streamlined Review components using selected SaMD regulatory submissions that have been previously reviewed. In the Working Model, FDA proposes that elements which are traditionally reviewed in a product-specific premarket submission, but which are applied systematically across all SaMD products, can be evaluated at the organization level during the Excellence Appraisal. Other elements that vary by product would continue to be included in the premarket submission, as part of a Streamlined Review package.

To test this concept, FDA will extract elements that are proposed to be included in a Streamlined Review from a previously-reviewed, complete submission package for a SaMD product. The FDA will review this set of product-specific data, then determine what additional information not supplied by the Streamlined Review package would be needed to determine a reasonable assurance of safety and effectiveness for the product. FDA will then review the proposed Excellence Appraisal elements to confirm that, if an Excellence Appraisal had been conducted for the sponsor, the questions remaining for the review of the product would be satisfied by the information that would be reviewed during an Excellence Appraisal. This analysis will be used to iteratively refine the Excellence Appraisal.

2. Prospective tests

Within FDA's current authorities and utilizing traditional marketing submissions, 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. FDA will conduct Excellence Appraisals with sponsors and will provide them the option of a "Review Pathway Determination Pre-Submission (Pre-Sub)," during which FDA and the sponsors may discuss the appropriate review pathways, product-specific review determination elements (section 5 of the Working Model), and real-world performance analytics plans (section 7 of the Working Model). The sponsors would subsequently submit traditional marketing submissions (De Novo Requests or

510(k) submissions, as appropriate). These traditional submissions will include all required elements of each submission type.

Using elements extracted from the Excellence Appraisal, Review Determination Pre-Sub, and the premarket submission, CDRH staff would assemble a mock Streamlined Review package aligning with the proposed Pre-Cert Streamlined Review process (section 6 of the Working Model). Hypothesizing the Excellence Appraisal elements to be a reasonable proxy for organization-specific review elements, an independent CDRH review team would then evaluate whether it can determine sufficient information from the Excellence Appraisal elements to provide a reasonable assurance of safety and effectiveness. If the review team finds gaps in evidence or missing artifacts in the mock Streamlined Review package, the team would request unmasking of specific elements from the full submission.

An official regulatory decision would be based on the traditional regulatory submission, which would be unmasked and reviewed to validate the Excellence Appraisal assumptions. A finding that excellence at an organizational level is highly correlated to excellence in designing, developing, and testing an individual SaMD product would support the use of organizational Excellence Appraisal in generating some of the evidence required for product premarket authorization.

To assess the adequacy of the mock package contents, FDA intends to use criteria that confirm there is sufficient information to provide a reasonable assurance of safety and effectiveness. FDA would then iteratively evaluate and modify the Streamlined Review framework, as appropriate. As the Pre-Cert model continues to be refined, FDA anticipates that fewer changes to the model will be required with each iteration. FDA will consider the Pre-Cert model to be confirmed when the program framework remains static over multiple premarket submissions.

Outcome

At the conclusion of the Test Plan, FDA will have demonstrated that the totality of evidence collected through the Excellence Appraisal and Streamlined Review processes align to and satisfy the regulatory requirements for making a determination of reasonable assurance of safety and effectiveness. FDA will also capture process-related metrics and qualitative interviews to determine the degree to which the refined Pre-Cert model meets the needs of internal and external stakeholders. The validation of the Excellence Appraisal elements during this testing phase may also provide evidence to develop a framework for a future Pre-Cert model, in which lower-risk products could be introduced directly to market by firms that have successfully been excellence appraised.