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February 7, 2019

SOFTWARE PRECERTIFICATION

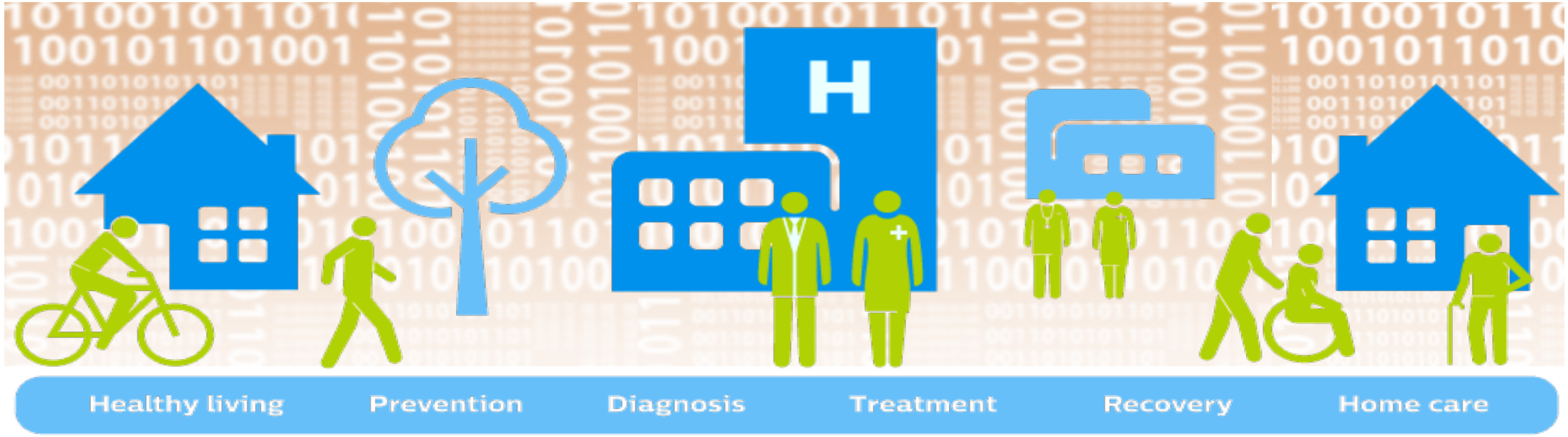
2019 TEST PHASE FOR PRE-CERT PILOT

Agenda

- Overview
  - Pre-Cert Working Model Version 1.0
  - Regulatory Framework
  - 2019 Test Plan
- 2019 Test Plan details
- Answer clarifying questions

Digitalization Across the Health Care Continuum

Digital tools are rapidly evolving. To keep pace with this promising innovation, the FDA must modernize its approach to regulation.



Digital Health Innovation Action Plan

An Integrated Approach

Refine policies & provide guidance

- Update guidances and regulations to reflect change to the device definition under the 21st Century Cures legislation

Building bench strength and expertise

- Build Digital Health Unit with right technical expertise
- Launch digital health Entrepreneurs-in-Residence program for building the new paradigm

Explore new streamlined pathway for software

- Launch an innovative Software Precertification (Pre-Cert) program to build a new approach to digital health technology, leveraging internationally harmonized principles for software regulation

FDA Software Precertification (Pre-Cert) Pilot Program

An **organization-based** regulatory approach

for

Software as a Medical Device (SaMD)

that relies on a demonstrated

Culture of Quality and Organizational Excellence

Based on 5 Excellence Principles

Patient Safety		Demonstration of a commitment to providing a **safe patient experience**, and emphasizing patient safety as a critical factor in all decision-making processes.
Product Quality		Demonstration of a commitment to the development, testing, and maintenance necessary to deliver Software as a Medical Device (SaMD) products at the **highest level of quality**.
Clinical Responsibility		Demonstration of a commitment to responsibly **conduct clinical evaluation and ensure that patient-centric issues** including labeling and human factors are appropriately addressed.
Cybersecurity Responsibility		Demonstration of a **commitment to protect cybersecurity**, and proactively address cybersecurity issues through active engagement with stakeholders and peers.
Proactive Culture		Demonstration of a commitment to a **proactive approach** to surveillance, assessment of user needs, and continuous learning.

Our Goals For a New Model

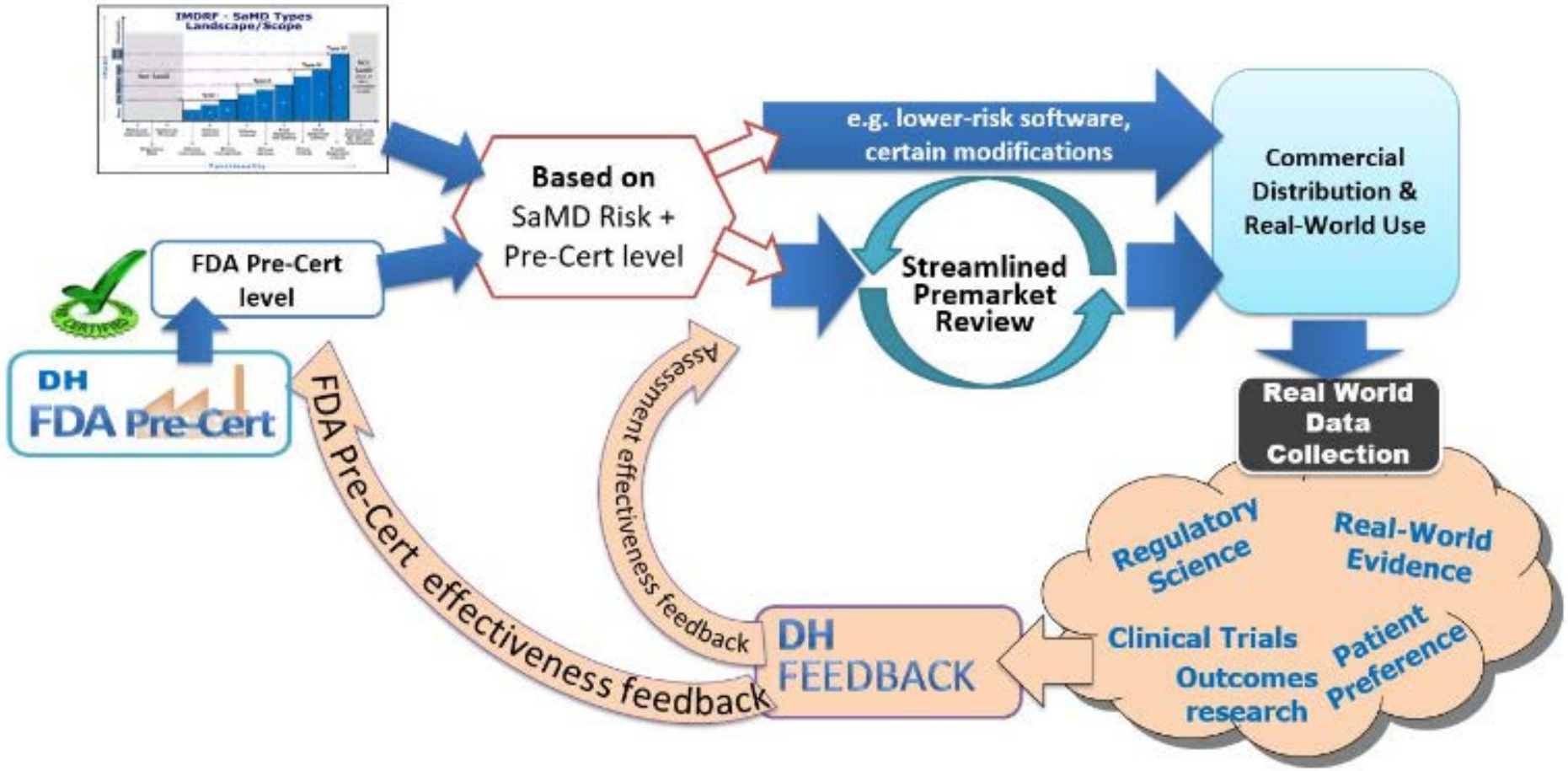
How can a pre-certification program address the evolving needs of Software as a Medical Device (SaMD) products?

Enable a tailored, pragmatic, and least burdensome regulatory oversight that

1. Assesses organizations to establish **trust** that they have a culture of quality and organizational excellence such that they can develop high quality SaMD products;
2. Leverages **transparency** of organizational excellence and product performance across the entire lifecycle of SaMD;
3. Uses a **tailored** premarket review with streamlined submission ("Streamlined Review");
4. Leverages unique postmarket opportunities available in software to **verify** the continued safety, effectiveness, and performance of SaMD in the real world.

Concept: A Reimagined Approach

An organization-based streamlined regulatory approach for Software as a Medical Device (SaMD) that relies on a demonstrated culture of quality and organizational excellence



Recent Updates and Releases

01

Pre-Cert Working Model Version 1.0 includes release notes detailing changes made from the previous version of the model and describes how the proposed key program components intersect.

02

Pre-Cert Regulatory Framework for Conducting the Pilot Program lays out how the FDA will implement the Pilot Program within its current authorities.

03

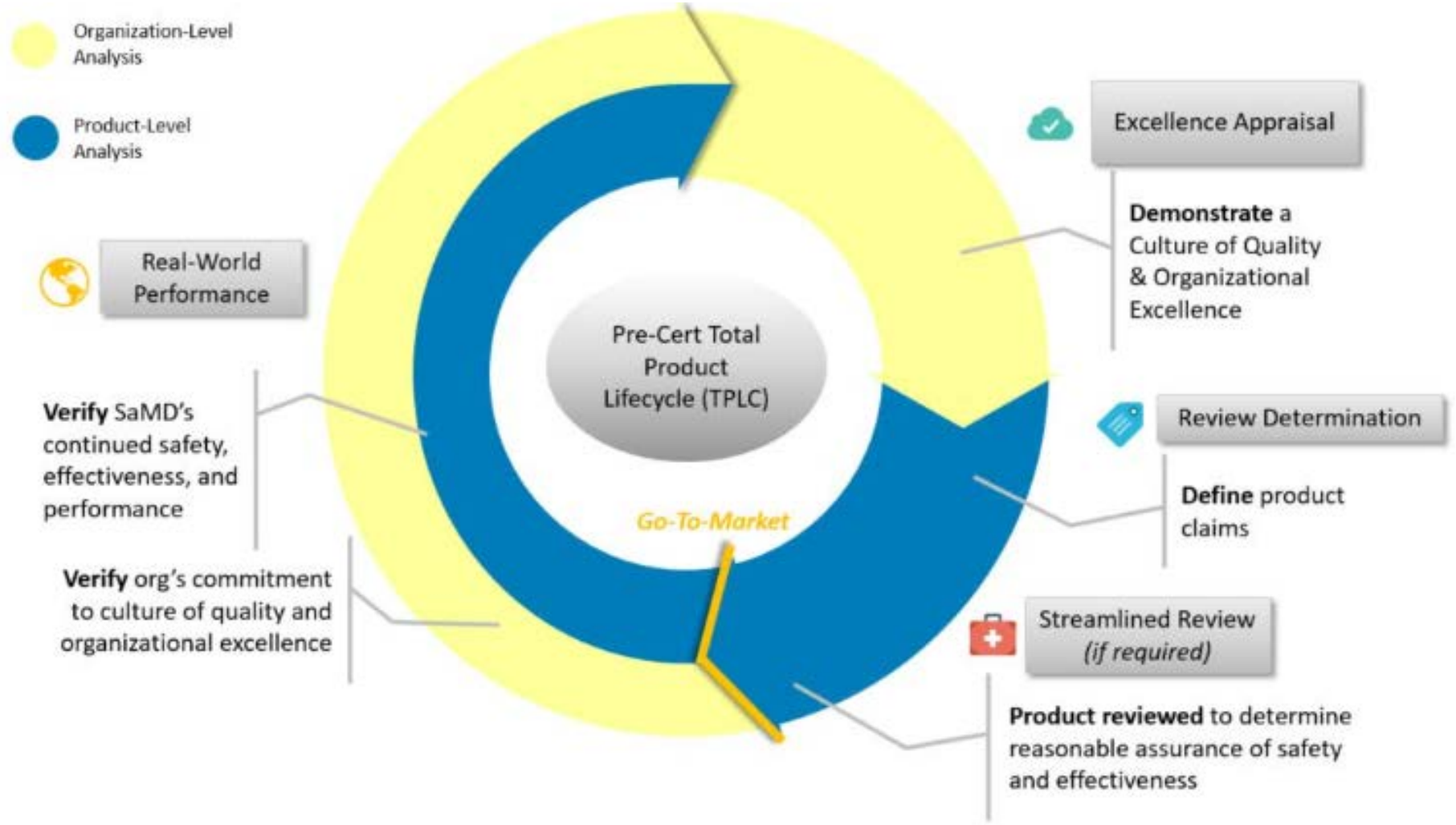
Pre-Cert 2019 Test Plan outlines how the FDA intends to iterate and confirm that the framework proposed in the Working Model provides a reasonable assurance of safety and effectiveness for software products.

Pre-Cert Update: Working Model Version 1.0

The Software Precertification Working Model version 1.0 published on Jan 7, 2019 and included the following changes:

1. A description of the **Total Product Lifecyle approach**
2. Revisions to **Excellence Appraisal** (EA) descriptions for levels of Pre-Cert and FDA's intention to conduct appraisals in 2019;
3. Revisions to SaMD product-level elements for **review determination**;
4. A proposed list and descriptions of review elements for **streamlined review**, and an updated review process to apply to all submission types;
5. An updated description of the process for developing a **Real-World Performance** analysis plan, examples of analytic types and sources, and how the types of real world performance collected and the duration of collection may vary.

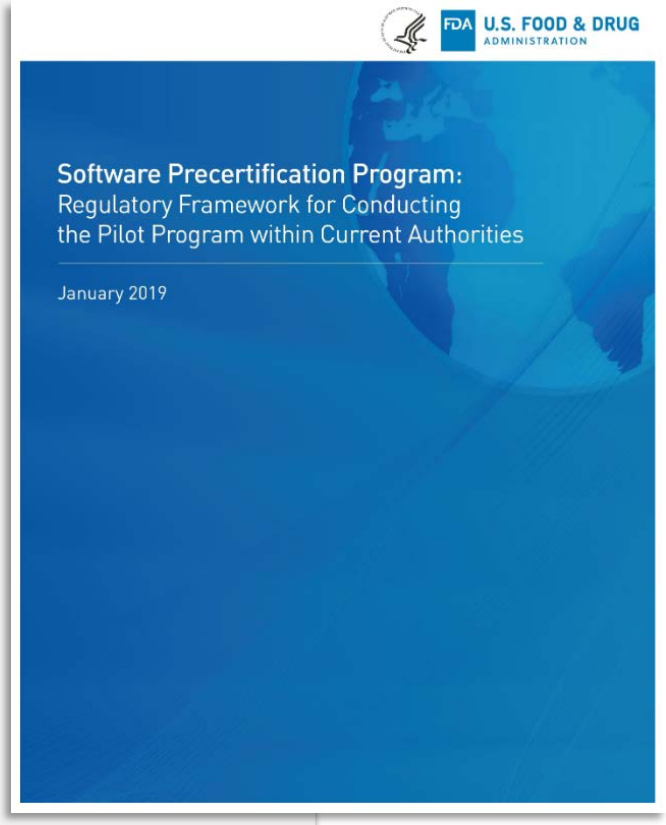
Least Burdensome
Ongoing Reasonable Assurance of Safety and Effectiveness



Regulatory Framework

The FDA intends to implement Pre-Cert Pilot Program under the De Novo Pathway so that Excellence Appraised sponsors may:

1. **Submit a "Pre-Cert De Novo"** to receive device classifications through De Novo Pathway by submitting all applicable required information to FDA at different times (that is during the Excellence Appraisal, Review Determination, and Streamlined Review);
2. **Submit a Review Determination pre-sub** to confirm a Software as a Medical Device (SaMD) sponsor is excellence appraised and is eligible for 510(k) under device classification created by Pre-Cert De Novo;
3. **Submit "Pre-Cert 510(k)"** under device classification created by Pre-Cert De Novo containing product-level information on modifications while leveraging Excellence Appraisal data to satisfy some required elements of a 510(k) submission.

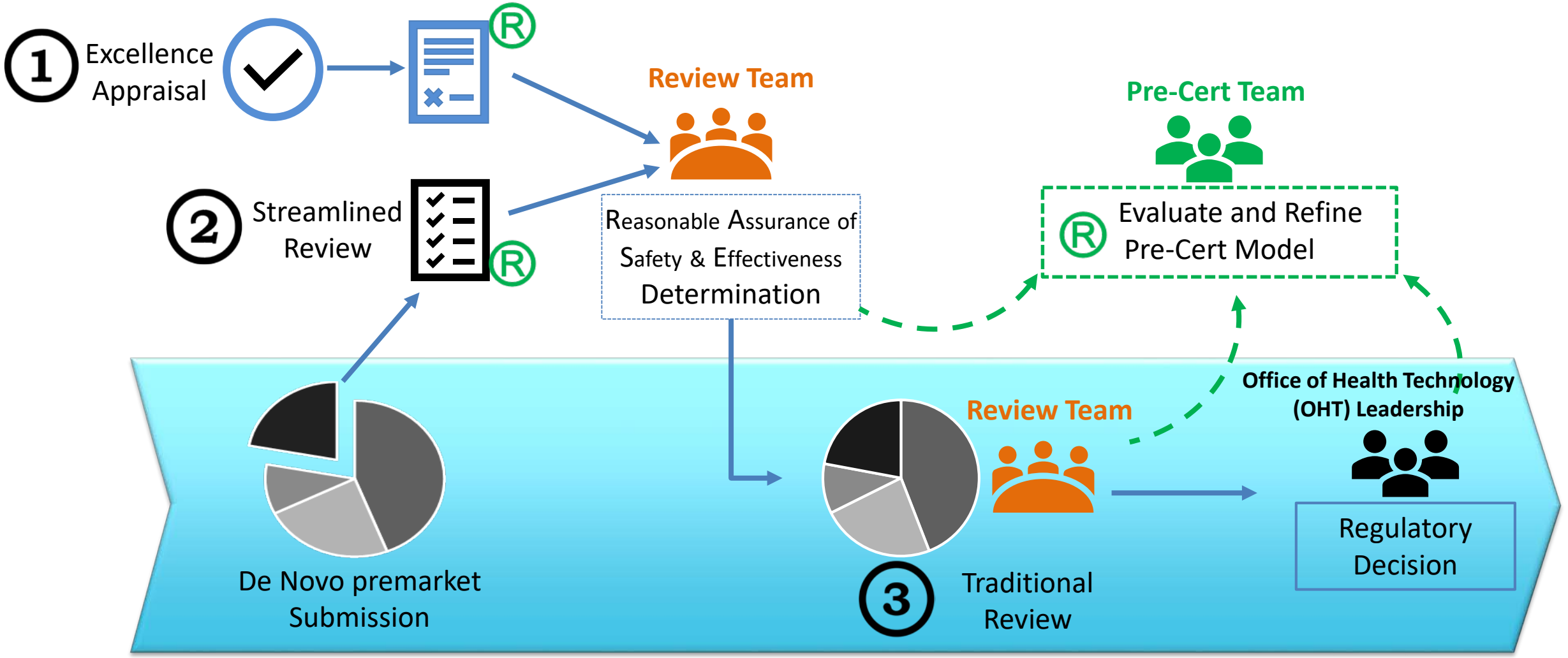


2019 Test Plan Overview

- Objective: Assess whether Excellence Appraisal (EA) + Streamlined Review (SR) together produce an equivalent basis for determining Reasonable Assurance of Safety and Effectiveness for a Software as a Medical Device (SaMD) product prior to its introduction to the market, as compared to the traditional paradigm

- Structure:
  - ❑ Sponsor submits full traditional submission
  - ❑ Streamlined Review team conducts Streamlined Review, then full review
  - ❑ Iterative refinement of Excellence Appraisal and Streamlined Review
  - ❑ Test plan to conclude when Pre-Cert framework remains stable over multiple submissions

2019 Test Approach



2019 Test Plan Details

The outcome of Excellence Appraisals (EA) will not provide "Certification."

We propose starting with De Novo under existing authority.

Pre-Cert team will work in collaboration with the FDA's review divisions during the 2019 test plan.

We are exploring ways to capture additional test cases for the program and its elements.

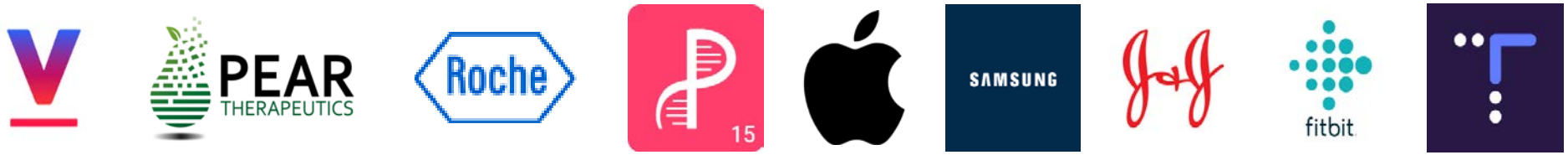
Appraisals will iterate towards a goal of an approx. Timeframe of 3-5 days/appraisal.

Submission processes and approach will be iterated to maximize learnings and efficiency.

Developing the Program with Stakeholder Input

All stakeholders

+



The FDA continues to seek input on the Pre-Cert working model from the public through the public docket by **March 8, 2019**.

Your input will help shape the next steps that we take to build the Pre-Cert program.

Resources

- **Software Precertification Pilot Program webpage**: https://www.fda.gov/MedicalDevices/DigitalHealth/DigitalHealthPreCertProgram/ucm567265.htm
- **Link to Pre-Cert Working Model:** https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/DigitalHealthPreCertProgram/UCM629276.pdf
- **Link to 2019 Test Plan:** https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/DigitalHealthPreCertProgram/UCM629277.pdf
- **Link to Regulatory Framework for Conducting the Pilot Program within Current Authorities document:** https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/DigitalHealthPreCertProgram/UCM629278.pdf
- **Link to the Open Docket:** https://www.regulations.gov/comment?D=FDA-2017-N-4301-0001

Get Updates on Pre-Cert

www.fda.gov/digitalhealth

FDAPre-CertPilot@fda.hhs.gov

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Questions?

If you have any questions about the Software Precertification Pilot Program, please contact FDAPre-CertPilot@fda.hhs.gov.

Division of Industry and Consumer Education: DICE@fda.hhs.gov

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