U.S. FOOD & DRUG ADMINISTRATION

Welcome to today's FDA/CDRH Webinar

Thank you for your patience while we register all of today's participants.

If you have not connected to the audio portion of the webinar, please do so now:

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Conference Number: PWXW7322399

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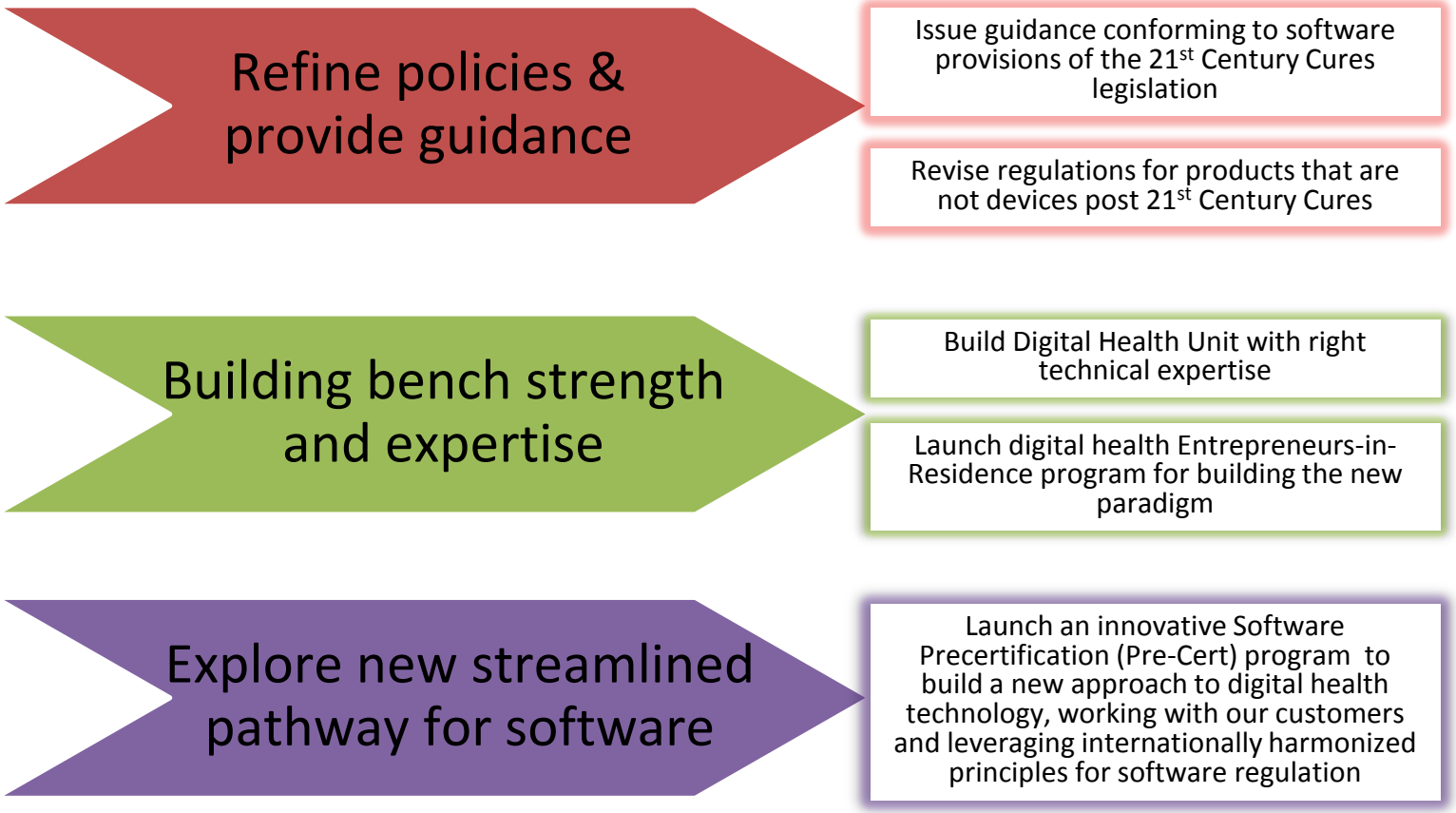
DIGITAL HEALTH: FDA ACTIVITIES

SOFTWARE PRECERTIFICATION PILOT PROGRAM – DISCUSSION OF PROPOSED FRAMEWORK

MAY 10, 2018

Digital Health Innovation Action Plan

An Integrated Approach



Digital Health Innovation Action Plan

Refine policies & provide guidance

Issue guidance conforming to software provisions of the 21st Century Cures legislation

Revise regulations for products that are not devices post 21st Century Cures

2017

Publish draft guidance: Effect of the 21st Century Cures Act on existing digital health policies.

Publish final guidance: Design considerations and premarket submission recommendations for interoperable medical devices.

Publish final guidance: Deciding when to submit a 510(k) for a software change to an existing device.

Finalize the International Medical Device Regulators Forum approach to clinically evaluating Software as a medical device (SaMD).

2017

Publish draft Clinical Decision Support Software guidance: that delineates the clinical decision support software that is no longer under FDA's jurisdiction

2018

Publish draft guidance: FDA review of products with some software functions that are devices and some functions that are not.

Withdraw and amend regulations for products that are no longer devices based on the effect of the 21st Century Cures Act on existing digital health policies.

2018

Publish draft guidance: FDA review of products with some software functions that are devices and some functions that are not.

Multiple Functionality Draft Guidance

Key Draft Policy Proposed

(A) Does the other function impact the safety or effectiveness of the device function-under review?; and

(B) Does the **impact result in increased risk or have an adverse effect** on performance?

Function:	Premarket Oversight	Postmarket Oversight
Device function under review (510(k), PMA, IDE, De Novo, or HDE)	Reviewed	General control requirements are applicable (except for IDE)
Device function that is 510(k) exempt	Not reviewed but assessed only for impact on the safety and effectiveness of the device function-under review	General control requirements are applicable
Device function for which no premarket review is sought and FDA does not intend to enforce applicable regulatory controls	Not reviewed but assessed only for impact on the safety and effectiveness of the device function-under review	General control requirements are applicable but not intended to be enforced
Non-device function	Not regulated but assessed only for impact on the safety and effectiveness of the device function-under review	Not regulated and therefore FDA requirements not applicable

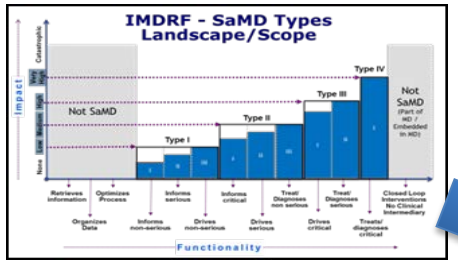
FDA Pre-Cert Program

An **organization-based** streamlined regulatory approach

for
Software as a Medical Device (SaMD)

that relies on a demonstrated
Culture of Quality and Organizational Excellence

Concept: A Reimagined Approach Using FDA Pre-Cert



Based on
SaMD Risk +
Pre-Cert level

FDA Pre-Cert level

e.g. lower-risk software, certain modifications

Streamlined Premarket Review

Commercial Distribution & Real-World Use

Real World Data Collection

Regulatory Science

Real-World Evidence

Clinical Trials

Outcomes research

Patient Preference

DH FEEDBACK

Assessment effectiveness feedback

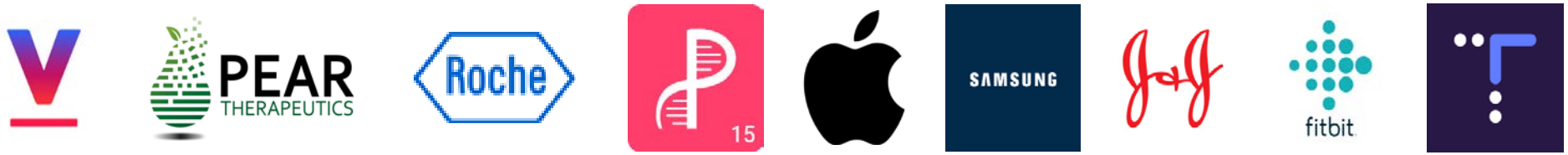
FDA Pre-Cert effectiveness feedback

DH FDA Pre-Cert

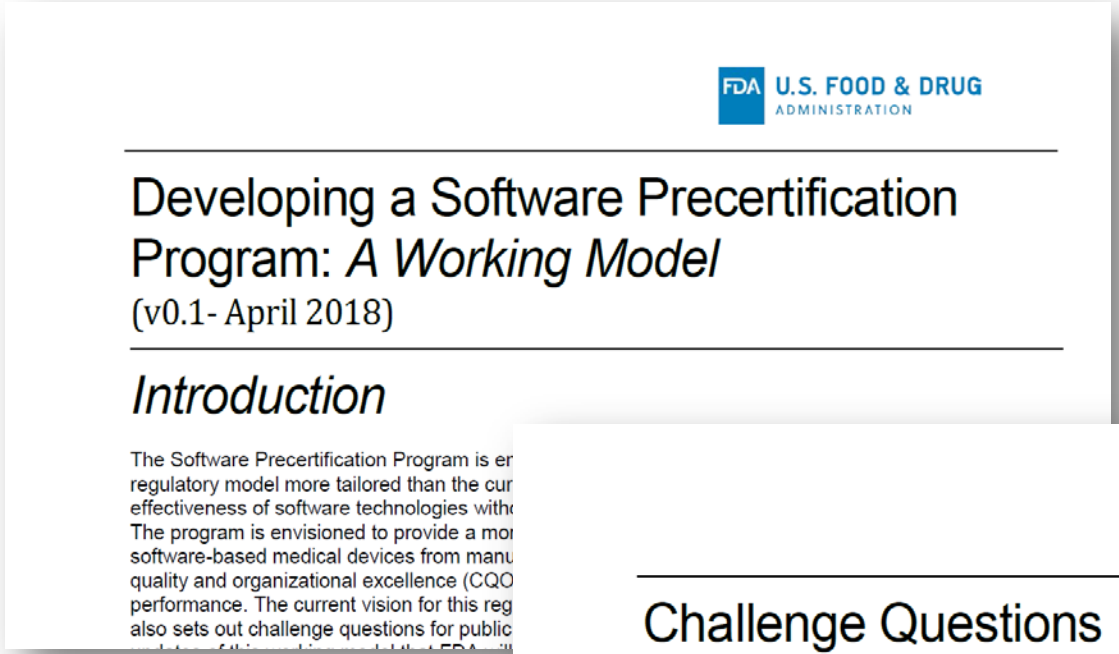
Developing the Program with Stakeholder Input

All stakeholders

+



April Program Update



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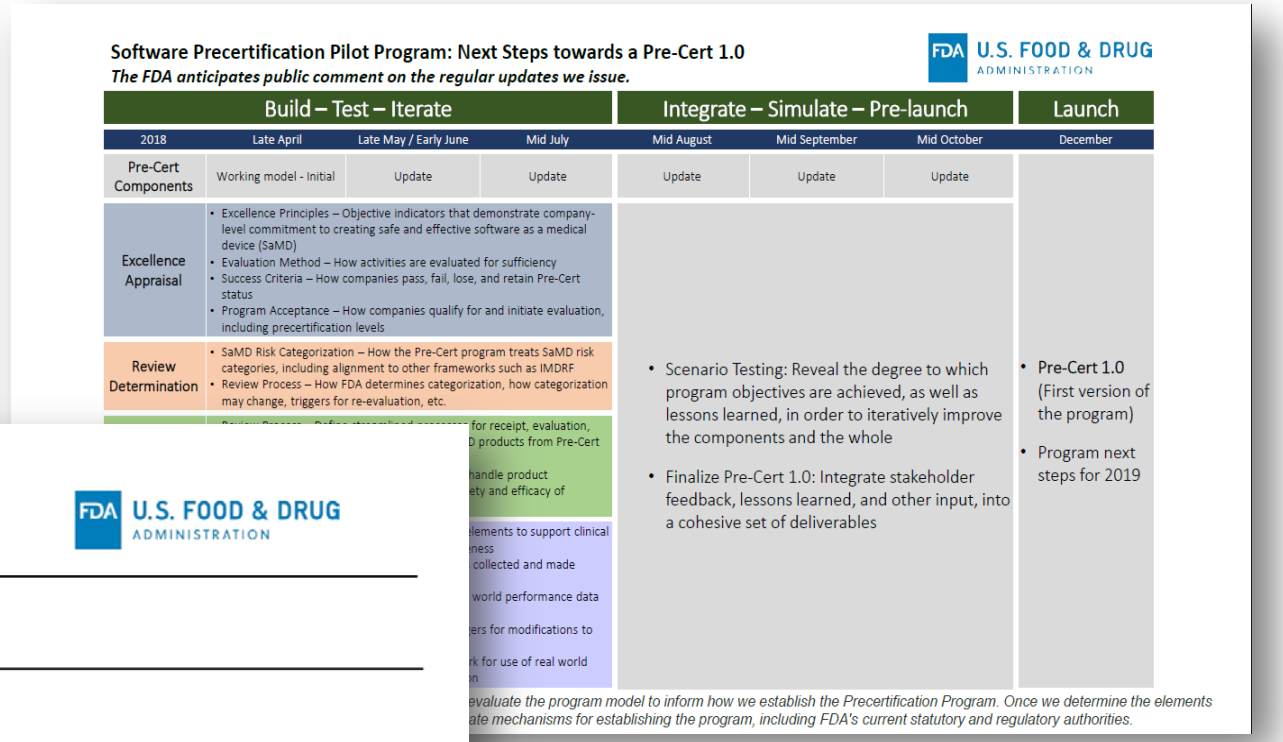
Developing a Software Precertification Program: *A Working Model*

(v0.1- April 2018)

Introduction

The Software Precertification Program is er
regulatory model more tailored than the cur
effectiveness of software technologies witho
The program is envisioned to provide a mor
software-based medical devices from manu
quality and organizational excellence (CQO
performance. The current vision for this reg
also sets out challenge questions for public



Software Precertification Pilot Program: Next Steps towards a Pre-Cert 1.0

The FDA anticipates public comment on the regular updates we issue.

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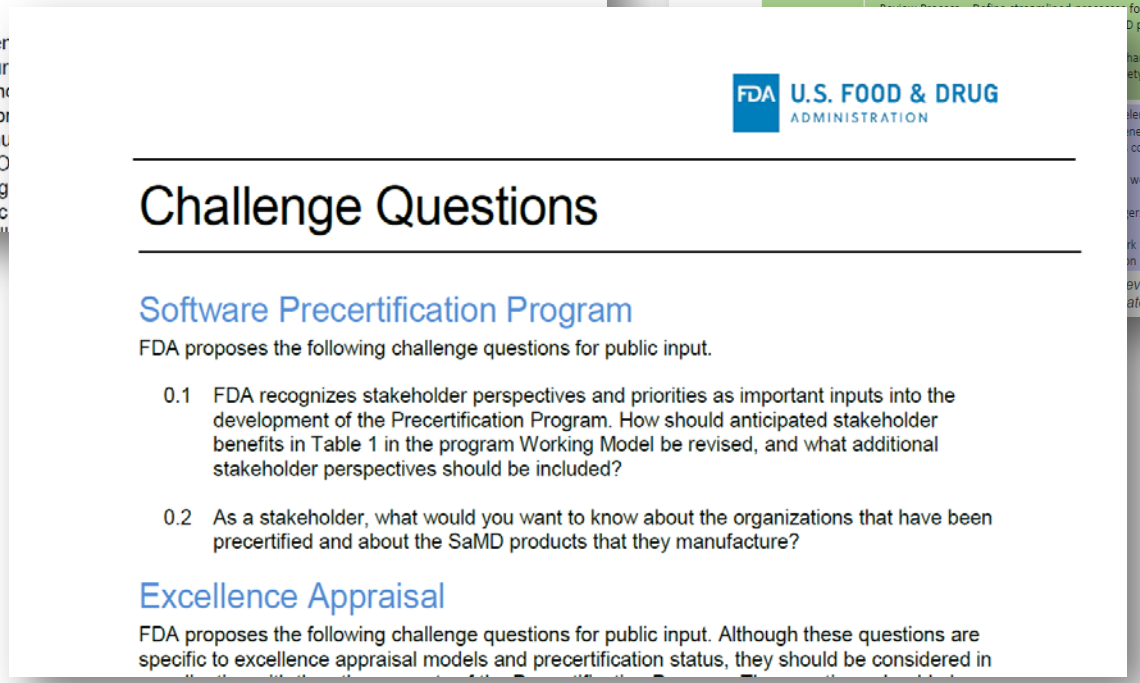
Build – Test – Iterate				Integrate – Simulate – Pre-launch			Launch
2018	Late April	Late May / Early June	Mid July	Mid August	Mid September	Mid October	December
Pre-Cert Components	Working model - Initial	Update	Update	Update	Update	Update	
Excellence Appraisal	• Excellence Principles – Objective indicators that demonstrate company-level commitment to creating safe and effective software as a medical device (SaMD) • Evaluation Method – How activities are evaluated for sufficiency • Success Criteria – How companies pass, fail, lose, and retain Pre-Cert status • Program Acceptance – How companies qualify for and initiate evaluation, including precertification levels						
Review Determination	• SaMD Risk Categorization – How the Pre-Cert program treats SaMD risk categories, including alignment to other frameworks such as IMDRF • Review Process – How FDA determines categorization, how categorization may change, triggers for re-evaluation, etc.						
	for receipt, evaluation, products from Pre-Cert			• Scenario Testing: Reveal the degree to which program objectives are achieved, as well as lessons learned, in order to iteratively improve the components and the whole • Finalize Pre-Cert 1.0: Integrate stakeholder feedback, lessons learned, and other input, into a cohesive set of deliverables			• Pre-Cert 1.0 (First version of the program) • Program next steps for 2019
	handle product ety and efficacy of						
	elements to support clinical ness collected and made						
	world performance data						
	ers for modifications to						
	k for use of real world						

evaluate the program model to inform how we establish the Precertification Program. Once we determine the elements ate mechanisms for establishing the program, including FDA's current statutory and regulatory authorities.



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Challenge Questions

Software Precertification Program

FDA proposes the following challenge questions for public input.

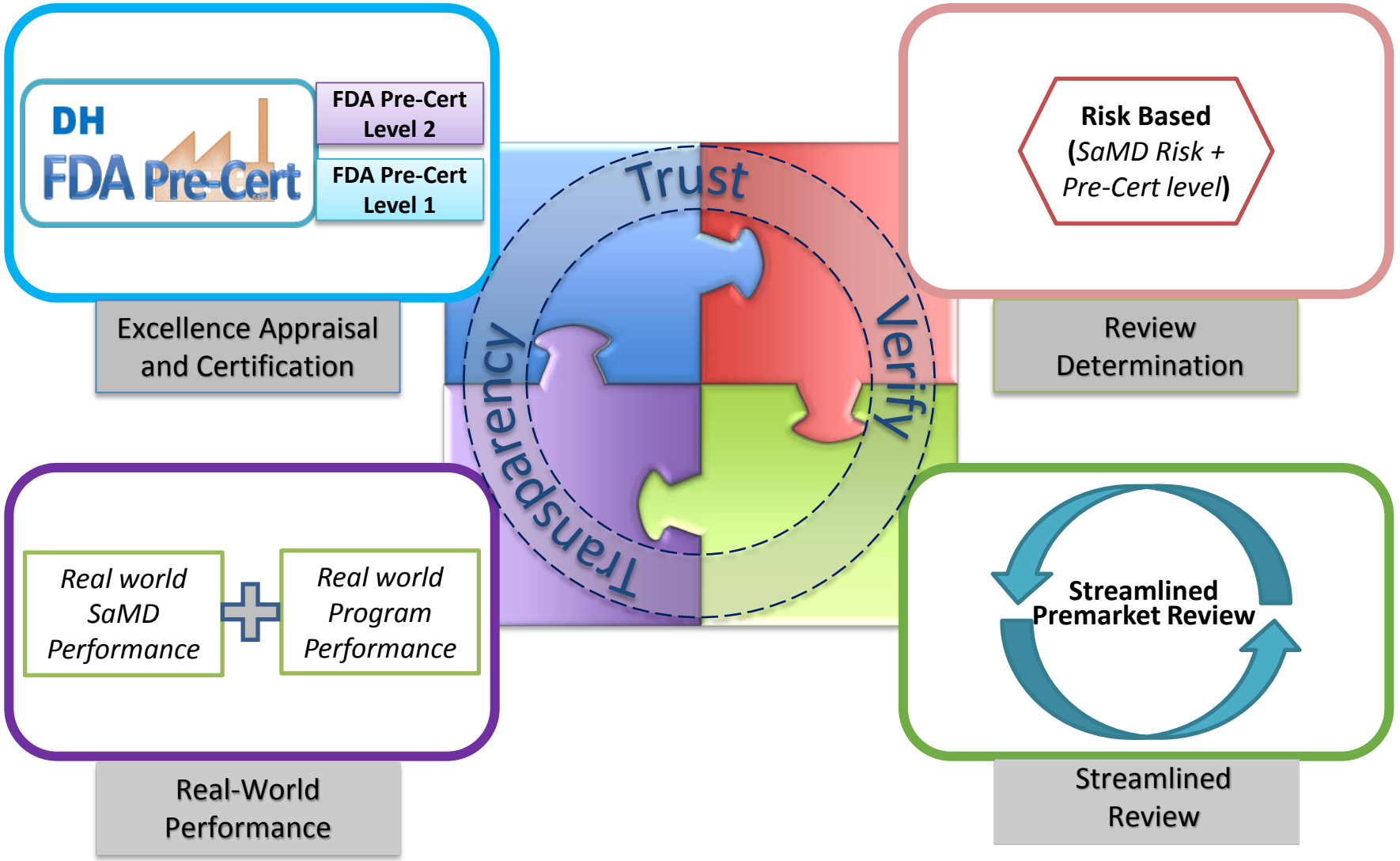
0.1 FDA recognizes stakeholder perspectives and priorities as important inputs into the development of the Precertification Program. How should anticipated stakeholder benefits in Table 1 in the program Working Model be revised, and what additional stakeholder perspectives should be included?

0.2 As a stakeholder, what would you want to know about the organizations that have been precertified and about the SaMD products that they manufacture?

Excellence Appraisal

FDA proposes the following challenge questions for public input. Although these questions are specific to excellence appraisal models and precertification status, they should be considered in

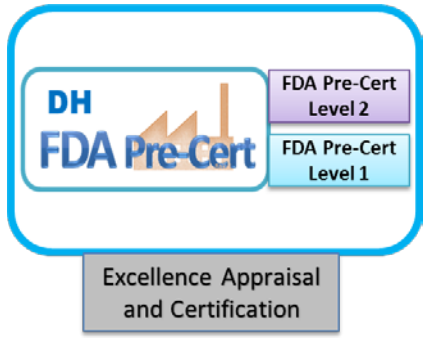
Four Key Program Components in Proposed Framework



Five Excellence Principles Proposed

Patient Safety		Demonstration of a commitment to providing a **safe patient experience**, and to emphasizing patient safety as a critical factor in all decision-making processes.
Product Quality		Demonstration of a commitment to the development, testing, and maintenance necessary to deliver SaMD products at the **highest level of quality**.
Clinical Responsibility		Demonstration of a commitment to responsibly **conduct clinical evaluation and to ensure that patient-centric issues** including labeling and human factors are appropriately addressed.
Cybersecurity Responsibility		Demonstration of a **commitment to protect cybersecurity**, and to 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.

Excellence appraisal and precertification



Scope of the component: The process for organization level precertification, including eligibility and application, evaluation against precertification criteria, and precertification status determination.

Concept in the Working Model v0.1 – April 2018

Eligibility

- Any organization that intends to develop or market a regulated SaMD in the United States.
- FDA anticipates precertification at a business unit or center of excellence level, rather than at a corporate level.

Application

Eligible organizations or business units apply.

FDA confirms eligibility and acceptability.

FDA and applicant initiate process for precertification determination.

Appraisal

- Applicant collects objective indicators related to the excellence principles.
- Collected information demonstrating capabilities and maturity made available for appraisal.

Determination

- FDA evaluates evidence and decides on approval and level of precertification.

	Pre-Cert	
	L1	L2
Demonstrates evidence of excellence in all 5 principles	✓	✓
Demonstrates evidence of capability to deliver high quality SaMD	✓	
Demonstrated track record in delivering SaMD and/or medical devices		✓

Maintenance

- Automated tracking and monitoring of adherence to excellence principles.
- Proactive response to postmarket indicators.
- Details to be developed in future version.

Challenge Question 1.1 Excellence appraisal and precertification

How might an existing excellence or maturity appraisal framework used by an organization be leveraged to demonstrate the organization's performance and success as outlined by the five excellence principles?

How should the FDA take into consideration…

- Certifications granted by external business excellence appraisal entities
- Maturity assessments made by external agencies
- Use of standards
- Accreditations
- Adoption of corporate level policies at a business unit level
- Adapting the appraisal model for start-up, new businesses
- Other…

How You Can Get Involved

#FDAPreCert

Provide ongoing input through the public docket

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Send questions about the program

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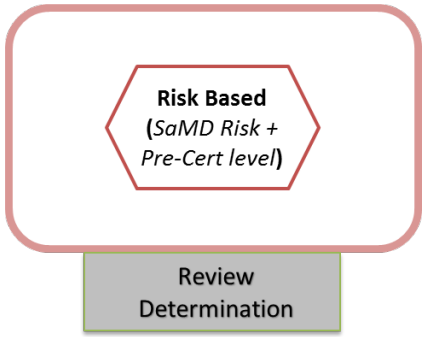
Review Determination



Scope of the component: The process and expectations for pre-certified organizations to determine when streamlined premarket review is applicable for each category of SaMD products.

Concept in the Working Model v0.1 – April 2018

1. Working to refine the SaMD International Medical Device Regulators Forum (IMDRF) Risk framework for application in the precertification program.
2. Preliminarily based on the risk category of SaMD product, determine when premarket review is necessary, including initial product availability, and major and minor product changes informed by:
   - Organization's Pre-Cert status and level (Excellence Appraisal)
   - SaMD premarket requirements (Streamlined Review)
   - SaMD postmarket requirements (Real-World Performance)

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 *(9)*	III *(7)*	II *(4)*
Serious	III *(8)*	II *(6)*	I *(2)*
Non-serious	II *(5)*	I *(3)*	I *(1)*

Challenge Question 2.2: Review Determination

We are exploring the refinement of the "IMDRF definition statement," which is intended to provide a structured way in describing intended use for SaMD.

The IMDRF framework highlights the following components:

- The significance of the information provided by the SaMD to the healthcare decision; more specifically, how the SaMD dictates treatment or diagnosis, drives clinical management, or informs clinical management;
- The state of the healthcare situation or condition that the SaMD is intended for; more specifically, a description of the health state when the SaMD is intended for use, ranging from critical to serious to non-serious; and
- A description of the SaMD core functionality; more specifically, the critical features 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.

Questions…

- Within each of the three components, are there other factors that are currently included in describing the products' intended use, and if so, what?
- Should the factors in the current components be further refined in order to provide clarity around the function and intended use of the SaMD and if so, how?

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Streamline Review

Scope of the component: The process and expectation for a precertified organization and the FDA when it is determined that a streamlined premarket review is necessary to reasonably assure safety and effectiveness of a SaMD.

Concept in the Working Model v0.1 – April 2018

Goals

- Identify information necessary to reasonably assure safety and effectiveness to be reviewed
- Identify aspects that will be relied upon during pre-certification appraisal and the organizations engagement in real world performance data monitoring of their SaMD
- Identify an interactive process of conducting the review that yields best experience for FDA reviewers and organizations participating in the program

Challenge Question 3.1 Streamline Review

Given that one goal of this program is to significantly reduce the average premarket review timeline, what would be the best way for pre-certified companies to share product review information with us? Specifically:

Questions…

- What specific elements of review could be shifted to the company-specific excellence appraisal (as opposed to the product-specific review)?
- What are the features of a SaMD product that need to be assessed during device review?
- What product-specific content would be expected to be reviewed premarket?
- What specific postmarket real world data could be collected to support the assurance of safety and effectiveness for each product if an element is not reviewed premarket?
- What updates would FDA require, and at what interval, to provide continuous assurance of safety and effectiveness?
- Should there be a phased market authorization, where some elements are reviewed premarket and other elements are gathered through real world evidence to support full market authorization? What should happen to products that receive “preliminary” market authorization but fail to provide adequate evidence in the agreed upon timeframe?

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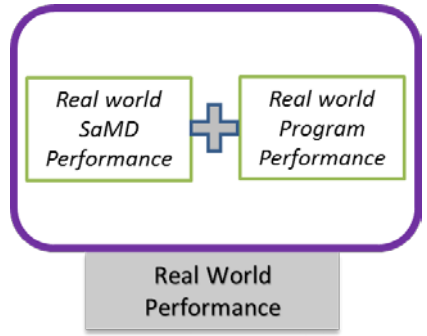
Real-World Performance



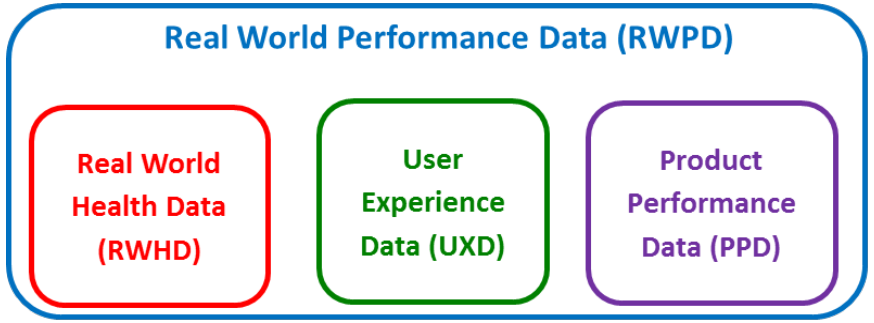
Scope of the component: The process for developing real-world performance data (RWPD) elements and analytic methodologies needed for Pre-Cert Program activities.

Concept in the Working Model v0.1 – April 2018

Program Level	**Preliminary Pre-Cert Program Feedback:** Use of aggregate organizational RWPD analysis as feedback to EA and SR components of the Pre-Cert Program
Organization Level	**Preliminary Inputs to Initial Precertification:** Use of aggregate product RWPD as inputs into initial precertification
	Preliminary Inputs to Maintenance of Precertification: Use of aggregate product-level RWPD analysis as inputs into maintenance or modification of precertification status
Product Level	**Preliminary Post-launch Product Monitoring:** Post-launch monitoring of RWPD to ensure ongoing safety and effectiveness of a SaMD product
	Preliminary Product Claim Modifications: Use of RWPD in making and modifying SaMD product claims

Challenge Question 4.4 Real-World Performance

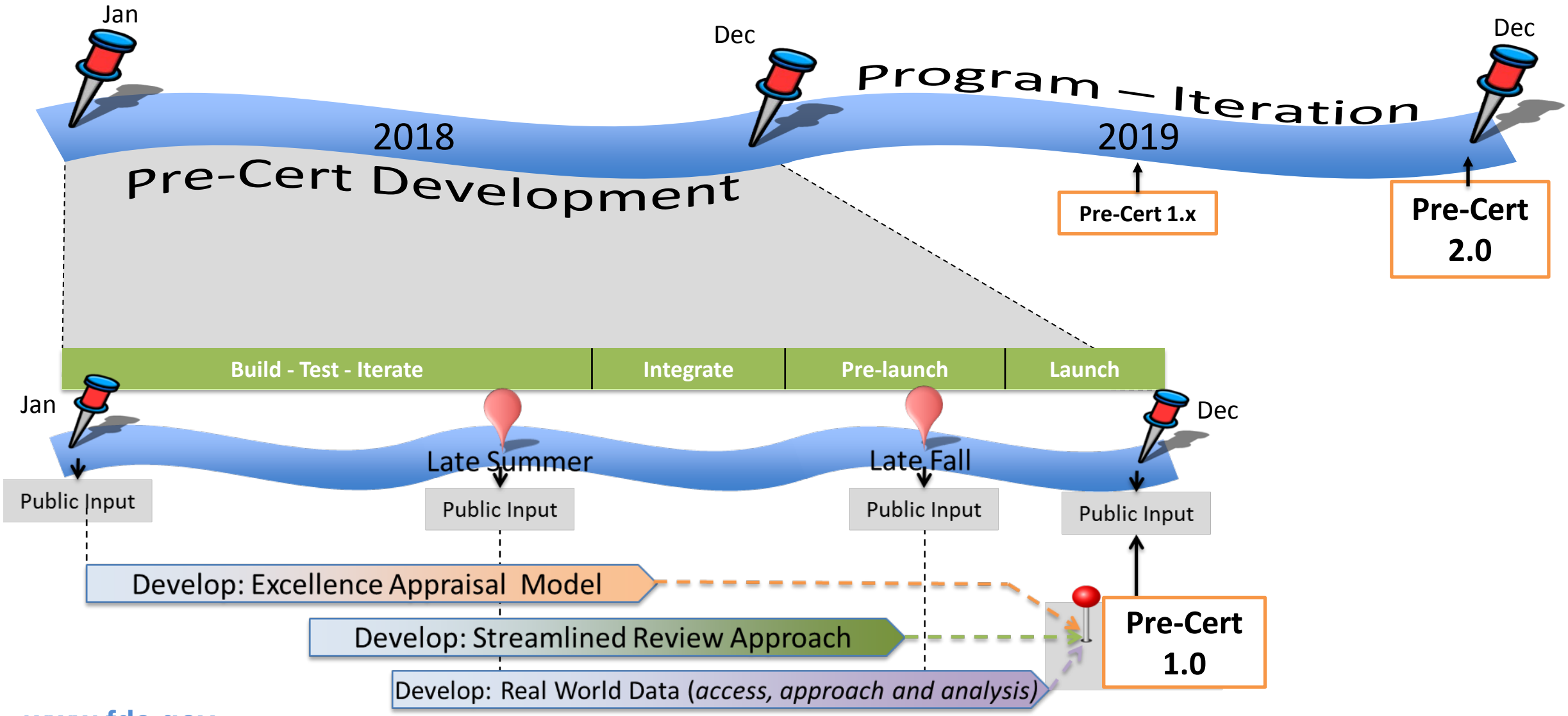
Are the definitions for data types underlying RWPD accurate and comprehensive? Do the terms used in this section need to be modified or revised?



- *Real World Performance Data*: all data relevant to the safety, effectiveness and performance of a marketed SaMD product from a precertified manufacturer
- *Real World Health Data*: outputs and outcomes related to the intended use of the SaMD product
- *User Experience Data*: outputs derived from user experiences related to the real world use of a SaMD product
- *Product Performance Data*: outputs and outcomes demonstrating the accuracy, reliability, and security of a SaMD product

Questions & Answers

Pre-Cert Program Roadmap



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