

Regulation of Digital Health Technologies

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Personalized Medicine Coalition
Policy Committee Meeting
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Digital Health

- Technologies being used to:
 - Reduce inefficiencies
 - Improve access to information
 - Better manage and track health and wellness
- Medical devices now connecting to other devices and systems or are being updated to add digital features
- FDA working to provide clarity to manufacturers to foster and enhance innovation in this space
- <https://www.fda.gov/medicaldevices/digitalhealth/>

Digital Health includes:

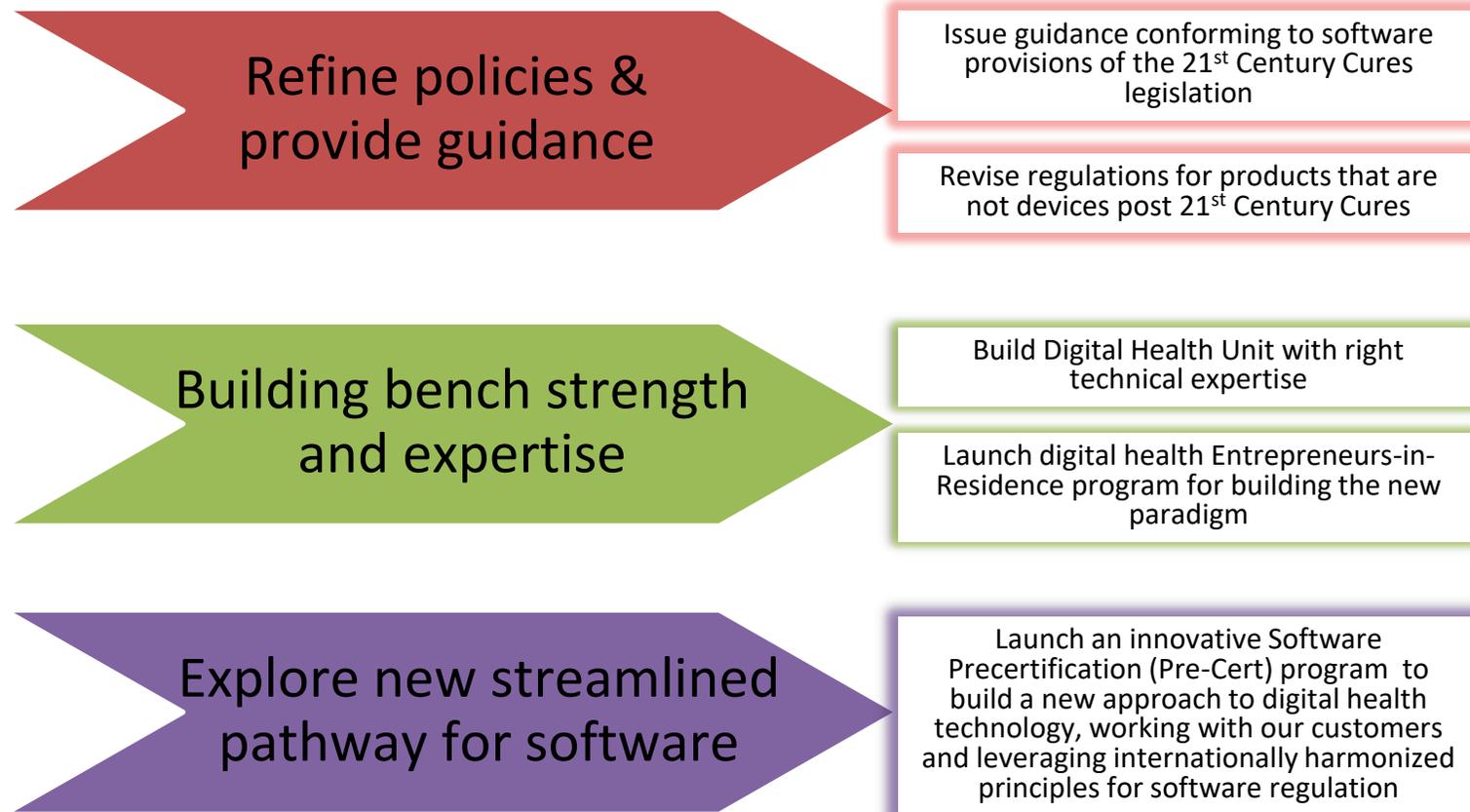
- Mobile health
- Health IT
- Wearables
- Telehealth
- Personalized medicine
- Artificial intelligence/machine learning



Digital Health Innovation Action Plan



An Integrated Approach



<https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/UCM568735.pdf>



SOFTWARE PRECERTIFICATION PROGRAM OVERVIEW

The rapidly evolving nature of digital health is sparking a paradigm shift



Current Regulatory Paradigm

Pre-market timeline suited for **hardware** based products

Deterministic risks, known responsibilities, physical products

Stable program volume: ~3,500 510(k) submissions / 2200 pre-submissions

Digital Health Paradigm Shift

Software development timelines, software development practices + rapid iterations

Evolving issues: cybersecurity; distributed responsibilities, non-physical products

Potential for **exponential** increase in volume of submissions



FDA Precertification Program

An organization-based streamlined regulatory approach

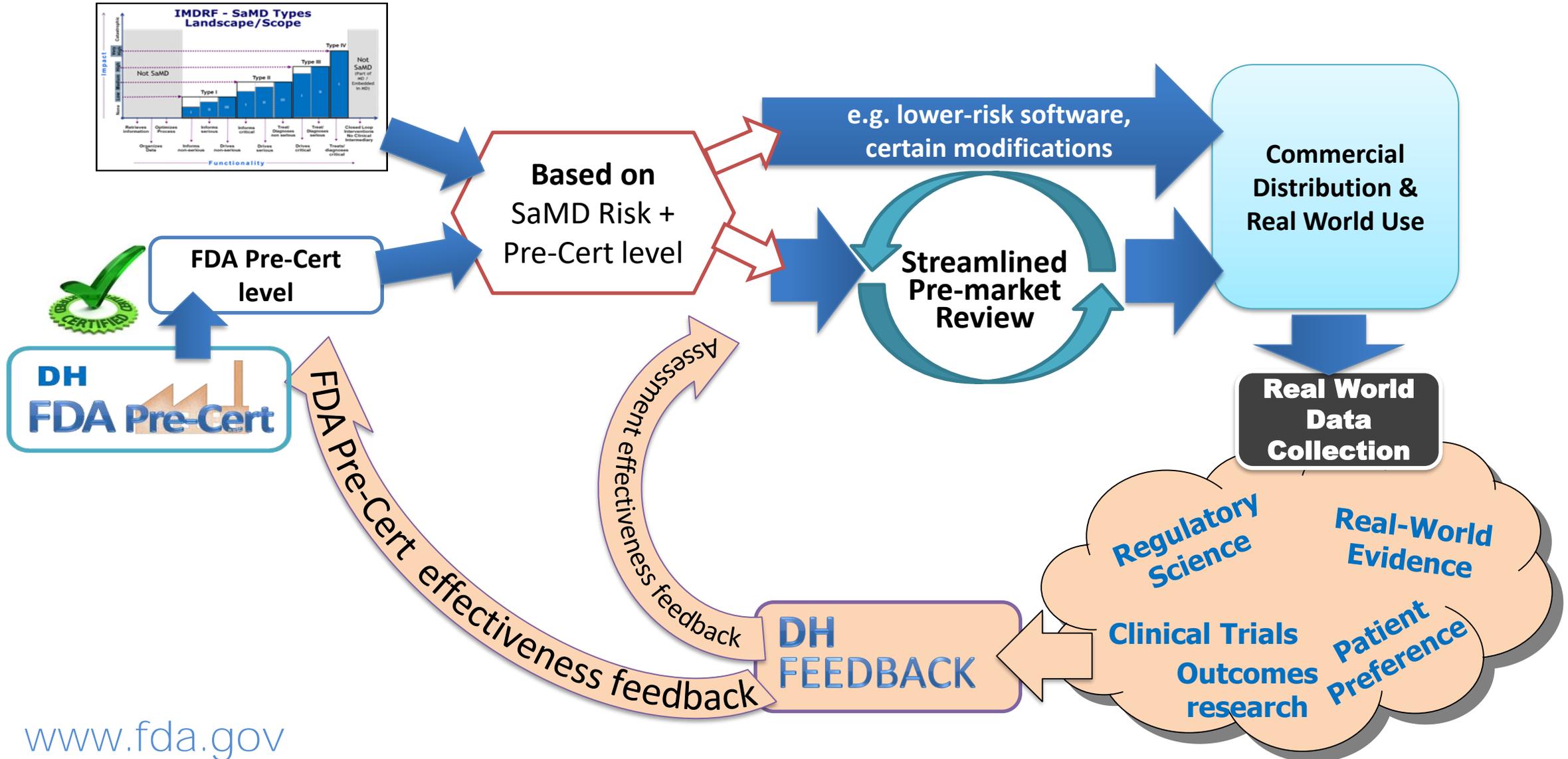
for

Software as a Medical Device

that relies on a demonstrated

Culture of Quality and Organizational Excellence

Concept: A reimagined approach using FDA Precertification





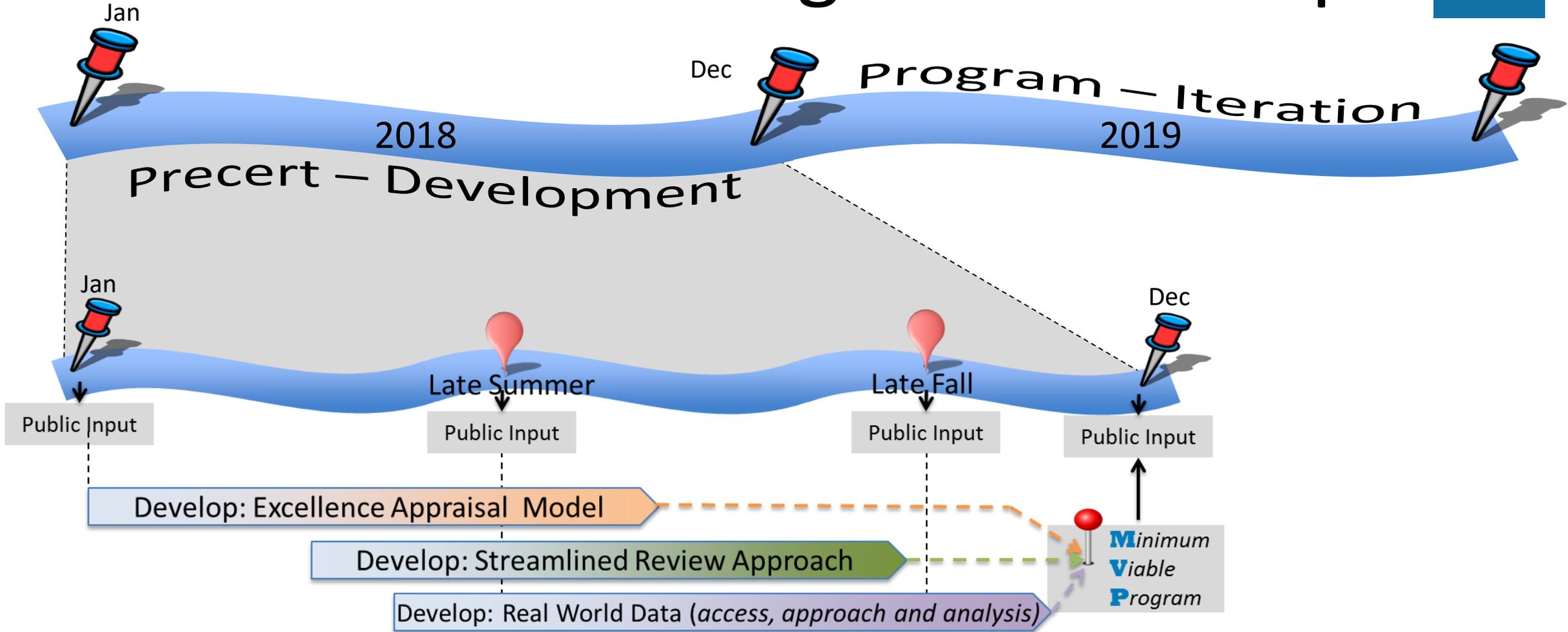
FDA Precertification Program Goals

1. Enable **a modern and efficient regulatory framework** that allows software iterations and changes to occur in a timely fashion;
2. Develop a tailored and pragmatic regulatory oversight that **trusts organizations** with a demonstrated culture of quality and organizational excellence to **develop high quality, safe and effective software products**
3. Leverage **transparency** regarding an organization's product performance across the entire lifecycle of SaMD
4. Utilize 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.
5. Be a program that **learns and adapts** (i.e., adjusts/tweaks/evolves scorecard elements and key dimensions and measures) and can adjust key elements and measures based on the effectiveness of the program.

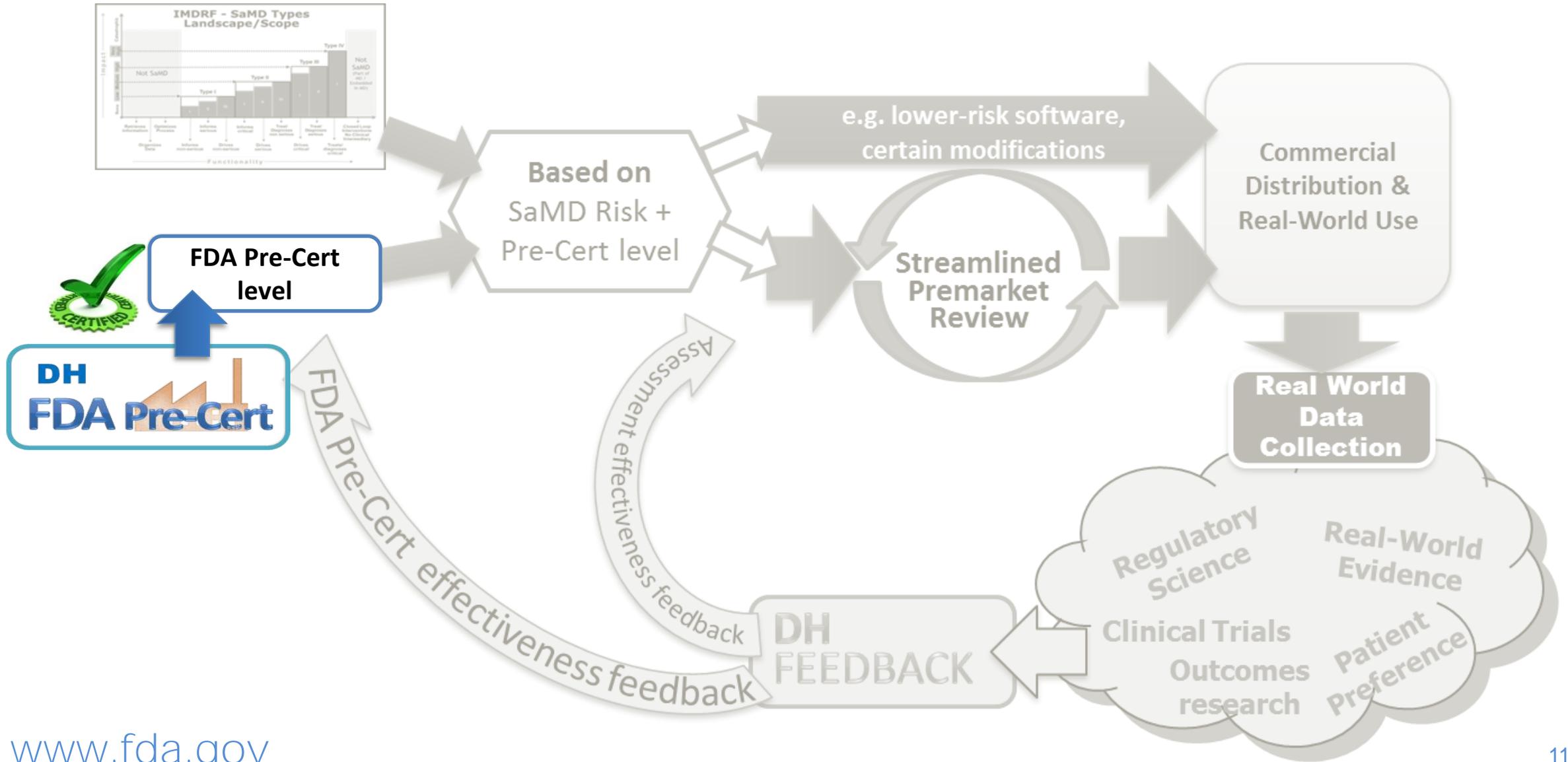
All of our work stems from five Excellence Principles

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

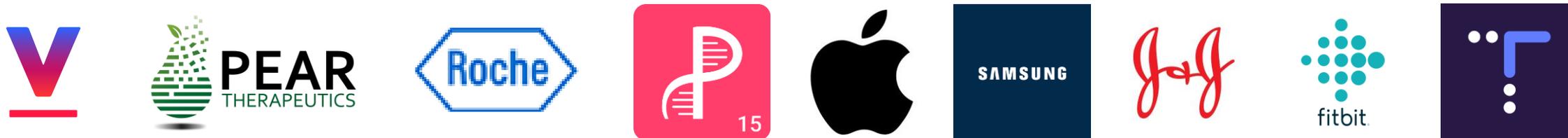
Precertification Program Roadmap



Building the first component of the program



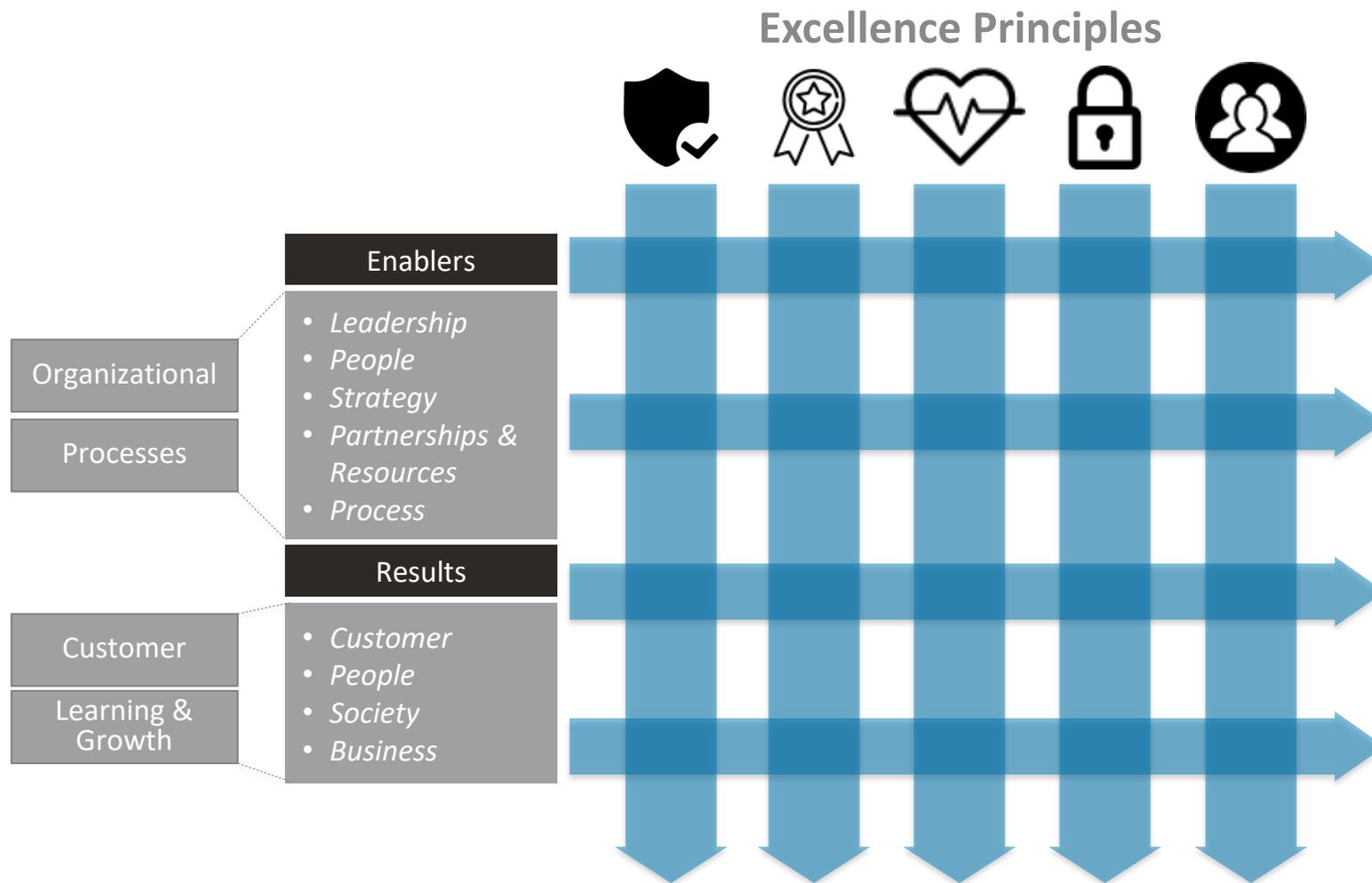
Co-creating the program with stakeholders



- In July 2017, we **announced** the Precertification Pilot Program
- In Sept, we **selected nine organizations** to help build the program
- Proposed a framework to understand excellence
- From Oct-Dec, we **conducted 2-day site visits** – in 7 weeks:
 - Understanding desired program benefits
 - Clarifying program questions
 - Identifying common traits
 - Understanding appraisal challenges/opportunities

Culture of Quality and Organizational Excellence (CQOE)

A framework for identifying CQOE aligned to business approaches



Integrating appraisal with how an organization is managed to create and maintain products and services.

Minimizing translation needed for precertification appraisal.



Across the nine precertification pilot organizations, we saw some shared themes ...

Leadership

- Promoting a culture of learning and empowerment
- Values demonstrated across the organization
- Engaged leadership and empowered staff

People

- Cross-disciplinary product teams inclusive of medical expertise
- Ensuring right-fitting to skills/expertise
- Engrained culture of accountability for product quality,
- Right skills, expertise and capacity

Strategy

- Staying at cutting edge in clinical / scientific / technology

Partnership & Resources

- Know their product's users and the use environment
- Actively engage with stakeholders

Processes

- Transparency in communicating issues to users
- Continual monitoring of products
- Agile processes
- Highly effective, open, internal communications
- New product launches are intensively monitored and managed
- Leverage connectivity, social media and user feedback to monitor product performance and safety; and
- Have vigilant cybersecurity processes and practices, and treat user data responsibly

Medical Devices

Home > Medical Devices > News & Events (Medical Devices) > Workshops & Conferences (Medical Devices)

Workshops & Conferences (Medical Devices)

2018 Medical Device Meetings and Workshops

2017 Medical Device Meetings and Workshops

Medical Device Webinars, Stakeholder Calls

Public Workshop - Fostering Digital Health Innovation: Developing the Software Precertification Program - January 30

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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 input 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 are 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...



Developing a Software Precertification Program: A Working Model

(v0.1- April 2018)

Fostering Medical Innovation: A Plan for Digital Health Devices; Software Precertification Pilot Program

Docket Folder Summary View all documents and comments in this Docket

Docket ID: FDA-2017-N-4301 Agency: Food and Drug Administration (FDA) Parent Agency: Department of Health and Human Services (HHS)

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62 Comments Received*

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Primary Documents View All (10)

	Developing a Software Precertification Program Road Map Next Steps towards a Pre-Cert 1.0	Comment Period Closed
Other	Posted: 04/27/2018 ID: FDA-2017-N-4301-0051	
	Developing a Software Precertification Program Challenge Questions April 2018	Comment Period Closed
Other	Posted: 04/27/2018 ID: FDA-2017-N-4301-0050	
	Developing a Software Precertification Program A Working Model v 0.1 April 2018	Comment Period Closed
Other	Posted: 04/27/2018 ID: FDA-2017-N-4301-0049	
	Transcript (Final) Precertification Workshop	Comment Period Closed
Other	Posted: 03/08/2018 ID: FDA-2017-N-4301-0042	
	Transcript (Final) Precertification Workshop(2)	Comment Period Closed

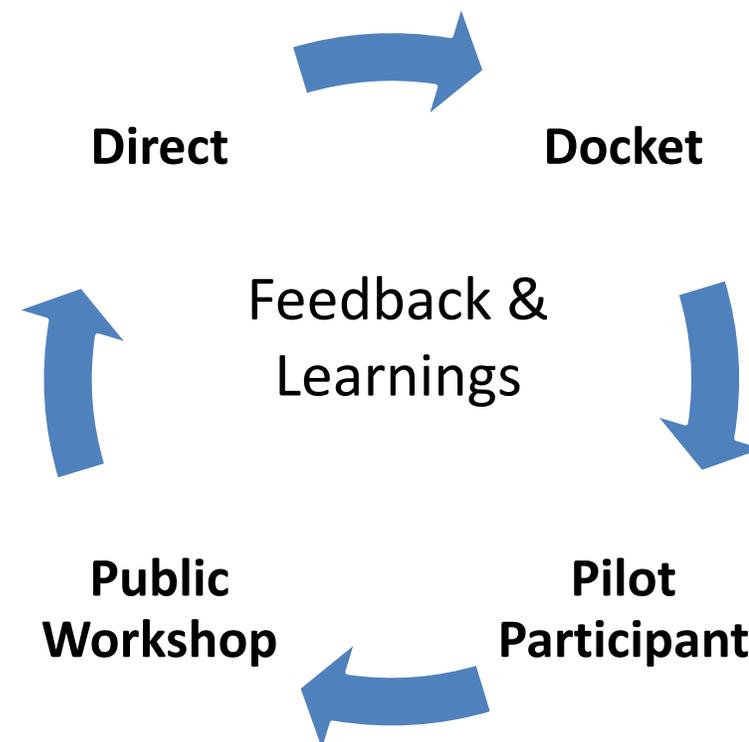
Themes from our 10th participant – the public



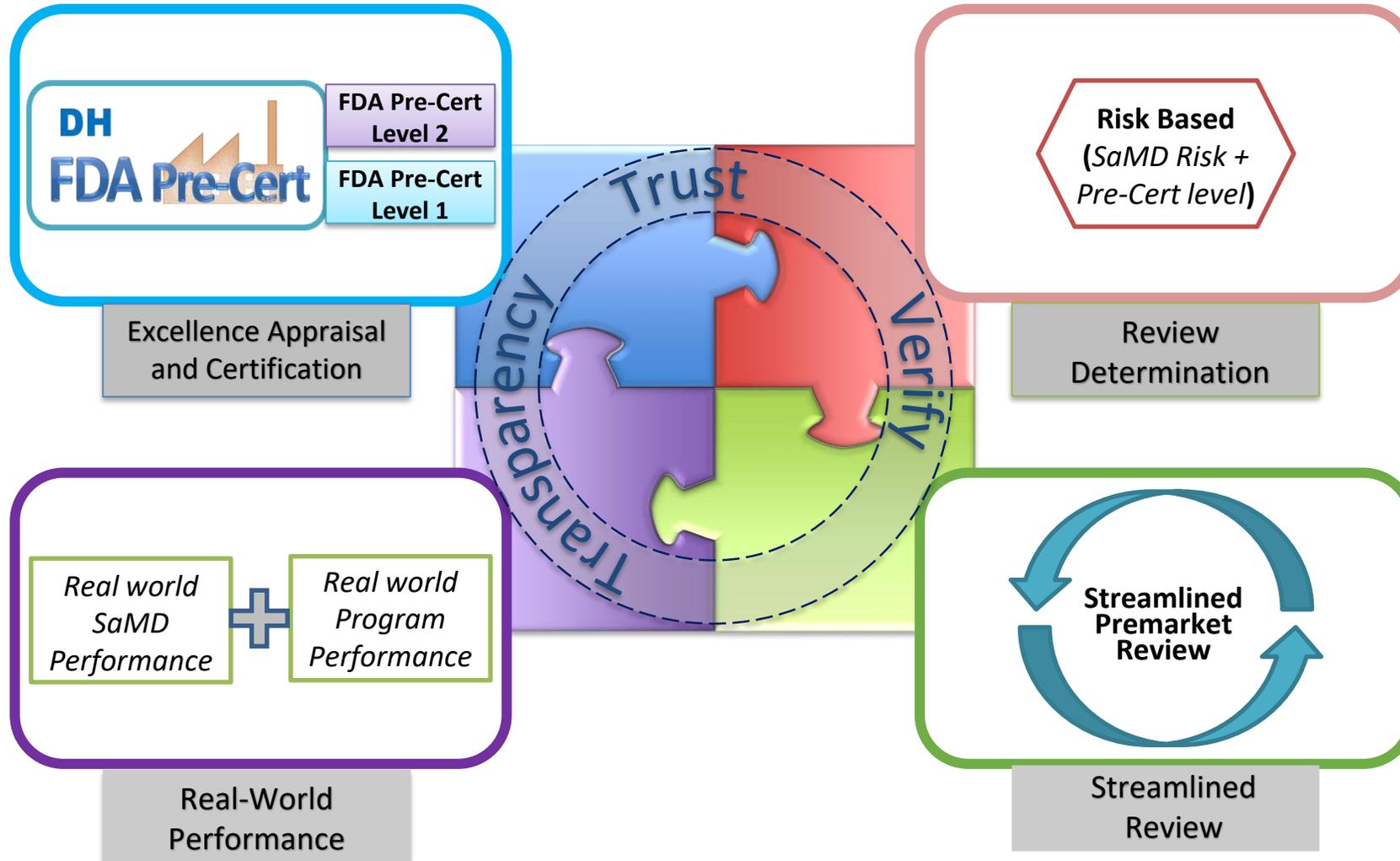
- Support for the program's mission and vision to better adapt to the realities of software development (e.g., be more iterative and allow for changes at a faster rate)
- A strong desire to adhere to existing standards & unification internationally (e.g., IMDRF, existing cybersecurity standards, data standards)
- Theme of concern that start-ups could be at a disadvantage
- There are open questions on the following:
 - Requests for additional details / use cases of how the Pre-Cert vision would work in practice (e.g., more detail around product-risk classifications)
 - How this program overlaps or not with existing QMS initiatives at the FDA and elsewhere (e.g., references to 21 CFR 820 and others).

Our Collaborative Approach

- FDA is building the Software Precertification Program using a **collaborative** and **transparent** approach.
- The collaborative process must fall within federal guidelines:
 - Federal Advisory Committee Act (FACA)
 - Paperwork Reduction Act (PRA)
 - Federal Register (process for public comment)



Four Key Program Components in Proposed Framework



Excellence Appraisal and Certification

- Principal objective is to develop the process of precertification, and the elements necessary for the excellence appraisal process.

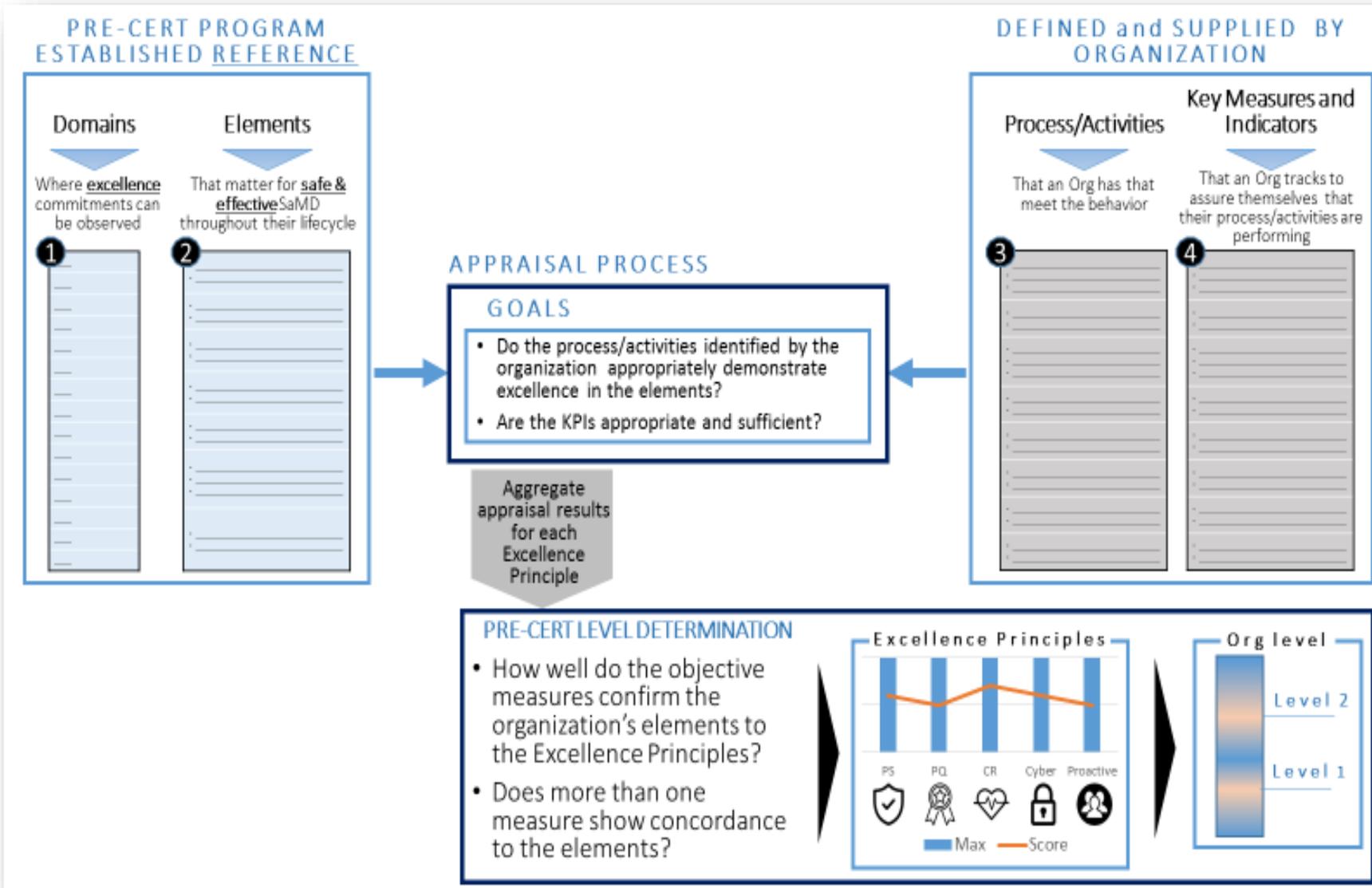
Development principles

- 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., QSR, ISO 13485, ISO 12207, ISO 62304, ISO 14971, ISO 9001) and outcomes achieved by following those processes

Elements

- Eligibility: identifying characteristics of an organization to participate in precertification.
- Pre-Cert Application: identifying the elements necessary and the process of requesting appraisal for precertification.
- Appraisal: identifying reference “domains” and “elements” necessary for the process of collecting/observing an organizations’ information for Pre-Cert 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.

Excellence Appraisal Development



- Discrete elements aligned to organizational domains that demonstrate Excellence Principles identified
- Additional granularity on the appraisal process and how the Pre-Cert elements and organization fulfillment (activities and KPIs) come together in the appraisal to demonstrate excellence provided

Precertification levels



- **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 in the healthcare space. This level of certification may benefit an organization with limited or no experience in delivering SaMD, but with established organizational elements and strategies in place that indicate they have or can acquire the capability to deliver and maintain high quality software products 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 track record in successfully marketing and maintaining products to suggest a level of assurance in the development of safe and effective software.



Asks

- **Seeking input on the discreet elements identified**

Review Determination

- Principal objective is to develop a risk-based framework to determine the need for premarket review and to clearly communicate to stakeholders how premarket and postmarket requirements apply to each category of SaMD products
- Process will include:
 - Identifying elements, methods, and process for precertified organizations to use in determining review pathway based on risk of the product
 - 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

Leveraging the IMDRF risk-category framework for SaMD

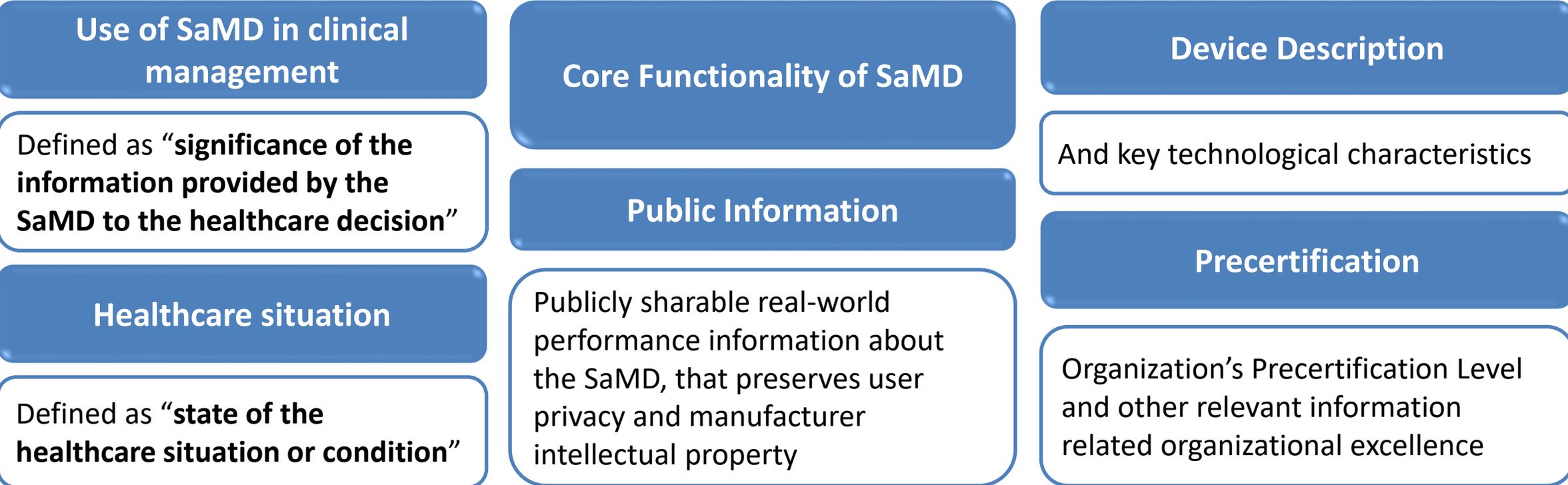


IMDRF Risk Categorization			Level of Review for Level 1 and Level 2 Precertified Organizations' SaMD		
Type	Sub type	Description	Initial product	Major changes	Minor changes
Type IV	(9)	Critical x diagnose/treat	SR	SR	No Review
Type III	(8)	Critical x drive		L1 – SR L2 – No Review	
Type III	(7)	Serious x diagnose/treat			
Type II	(6)	Serious x drive	L1 – SR L2 – No Review	No Review	
Type II	(5)	Non-serious x diagnose/treat			
Type II	(4)	Critical x inform			
Type I	(3)	Non-serious x drive	No Review	No Review	
Type I	(2)	Serious x inform			
Type I	(1)	Non-serious x inform			

Risk categorization

Goal: Develop a risk-based framework for precertified organizations to determine the premarket pathway for their SaMD products.

Precertified software manufacturers should use the following to determine the risk-category of their SaMD product:





Asks

- SaMD – what additional clarification is needed? Use cases on SaMD and SaMD vs. SiMD?
- Risk-category framework refinement and pressure-testing with use cases – what clarification can be added or removed? What is the framework for the submitted elements?

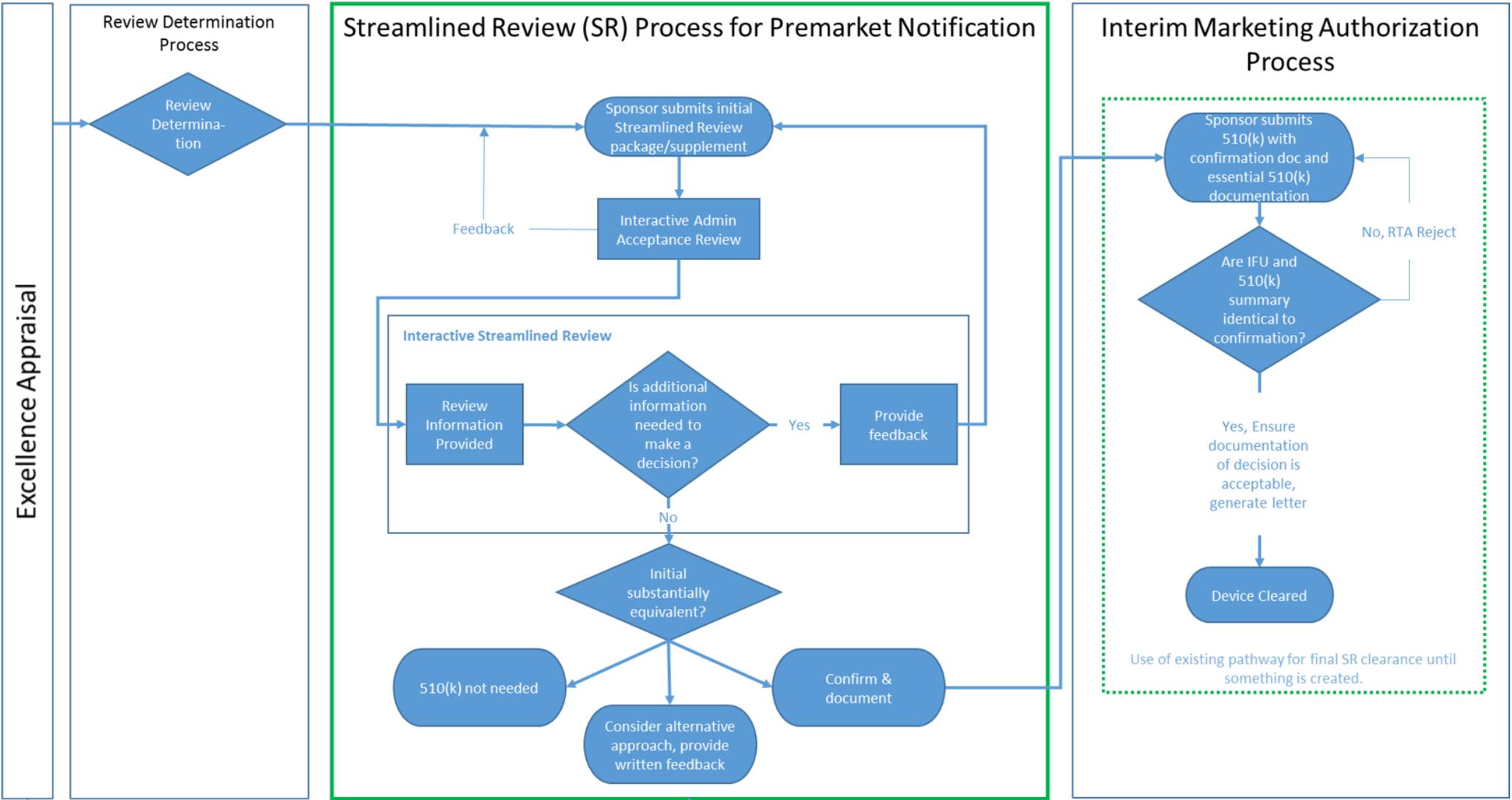
Streamlined Review

- Principal objective is 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
- Intend to conduct an interactive review supported by automated analysis, where appropriate, and aspire to provide a decision on the marketing of the precertified organization's SaMD product within a shorter timeline than other premarket review processes

Considerations

- Maintaining standard for reasonable assurance of safety and effectiveness
- Developing review processes for premarket notification, De Novo, and PMA submissions
 - Initial concepts are for premarket notification
 - Putting forward a proposed option for an iterative, early engagement review process
- For 2019 relying on leveraging existing regulations

Proposed iterative, early review process



Current Software Review Elements & “Asks”

Element
3rd party software
Anomalies / Bugs
Clinical algorithm
Clinical performance
Configuration management
Cover letter
Cybersecurity
Declarations of conformity and summary reports
Development environment
Developmental testing (e.g., code review, unit test reports, integration testing)
Device description
Device summary
Executive summary
Indications for use/Claims
Instructions for use
Intended use population
Labeling review
Life cycle
Modifications made since clearance
Requirements
Revision history
Risk analysis
SaMD product demo
Server performance / Load testing
Software architecture
Software bill of materials
Substantial equivalence comparison
Traceability
User interface / Story / Workflow
Verification and validation

- Which elements are absolutely necessary for assuring safety and effectiveness?
- What elements are missing and how should elements for various product types be determined?
- How could Excellence Appraisal and Real World Performance be used to provide assurance of these elements?



Additional Asks

- **Seeking input on the premarket notification review process** including any suggested modifications to this option or alternative solutions

Real World Performance

- Principal objective is to develop real-world performance data domains and analytic methodologies needed for Precertification Program activities.
- Identify and address expectations for use of real-world performance analytics (RWPA) by both precertified organizations and FDA in the Precertification Program

How does product-level monitoring benefit Precert organizations and public health?

Using Real World Performance Analytics (RWPA) would increase ...

- ✓ **Precertified organizations' ability to support** changes to SaMD products, including claim modifications, changes in intended use, or expansions of product functionality.
- ✓ **Public confidence** in the Pre-Cert Program and in the SaMD products marketed by precertified organizations, based on the organizations' demonstrated ability to leverage RWP analytics in the continuous improvement of their products and processes.
- ✓ **FDA's ability to support industry** in taking proactive actions to address emerging safety or cybersecurity issues.

What specific Real World Performance Analytics would be shared with FDA?

Analytic Type	Domain	Value	Excellence Principle(s)					Example KPIs
Real World Health Analytics	Human Factors and Usability Engineering	<p>PreCert Organization: Support product claims by understanding user ability to comprehend and correctly navigate user interface</p> <p>All stakeholders: Demonstrate continuous improvement in usability engineering to drive health benefits and safety</p>	X		X		X	<ul style="list-style-type: none"> User error rate
	Clinical Safety	<p>PreCert Organization: Benefit from early safety signal detection across PreCert organizations</p> <p>All stakeholders: Provide assurance that safety risks are managed and mitigated in a timely way</p>	X	X	X	X	X	<ul style="list-style-type: none"> Anticipated AE rate/severity Time to resolve anticipated AE Unanticipated AE rate/severity Time to resolve unanticipated AE
	Health Benefits	<p>PreCert Organization: Support product claims and future claim modifications by understanding clinical benefits</p> <p>All stakeholders: Demonstrate positive impact on health outcomes</p>	X		X		X	<ul style="list-style-type: none"> Rate of change in targeted health outcome by user demographic

How would FDA use the shared Real World Performance analytics?

- **Continuous improvement and refinement** of the Pre-Cert Program
 - Evidence that precertified organizations are tracking product-level RWPA and responding to emerging issues in a timely manner may further streamline the review process and/or increase the number of products that can be introduced directly to market.
- **Benchmarking and standards development** for emerging technologies
- **Supporting timely responses** to emerging safety or cybersecurity issues affecting multiple products
- **Transparency** around SaMD product performance



Asks

- **Identify and share product-specific KPIs** from your organization that could represent a hypothetical RWPA plan
 - Aligned to the domains in the v 0.2 framework
 - Including, if possible, targets and frequency of collection
- **Share concepts for analytics and trend data**, to further development of a methodology for interpreting RWPA

Planned Activities by December 2018



Planned Activities by December 2018

- Develop and informally test the **excellence appraisal** framework and possible appraisal outcomes including certification tiers.
- Develop a **review determination** schema for pre-certified companies and details they would submit about their company and the product.
- Develop and informally test a review methodology using FDA reviewers and pilot participants to explore how **streamlined review** might look.
- Develop and informally test domains of **real world performance** for SaMD products and the submission process for program participants.

Goals for refining the program in 2019

- Conduct excellence appraisal using the criteria and methodologies designed in 2018.
- Conduct streamlined review and provide 510(k) clearances based on current authorities
- Create mechanisms to access real world performance data from participating organizations, perform analysis, and identify benefits and risks of SaMD products.
- Refine or confirm types of SaMD products that require review prior to marketing.
- Work with participating organizations to quickly correct adverse events related to products cleared through the program.
- Transparently share test results with the public and ongoing revisions to the program.



<https://www.fda.gov/MedicalDevices/DigitalHealth/DigitalHealthPreCertProgram/default.htm>

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