Welcome to today's FDA/CDRH Webinar

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

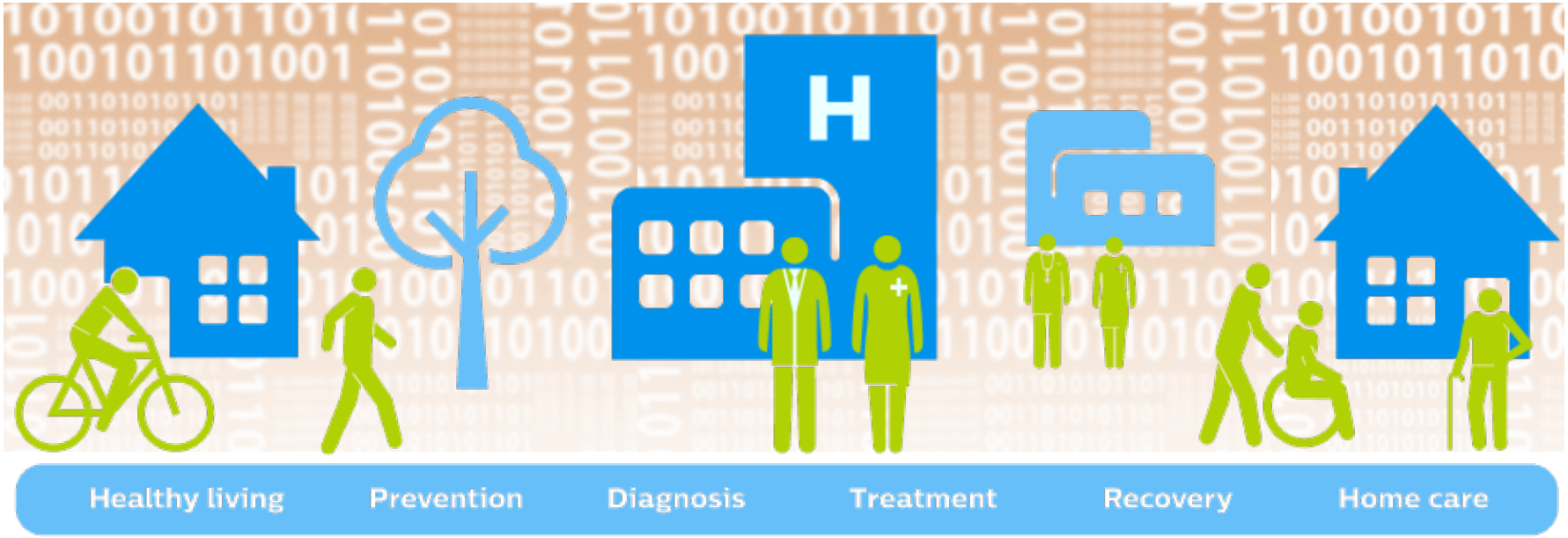
If you have not connected to the audio portion of the webinar, please do so now:

Dial: 800-988-9674
International: 1-773-756-4812
Passcode: 2374123
Conference Number: PWXW4874924

Digital Health

SOFTWARE PRECERTIFICATION PILOT PROGRAM

Digitization Across the Health Care Continuum



Moving health care from the Clinic to the Patient.

Understanding patient's behavior and physiology "*In the wild*".

Focusing on prevention for early/smaller interventions.

Leveraging computing power, sensors, connectivity *and* software.

CDRH Objectives

- Enable “**patient centered**” public health as digitization touches every aspect of health care.
- Foster **trust in innovative technologies** as an enabler of a new health care paradigm.
- **Partner with customers** to be "digital-future ready”.

Smart Regulation Principles

Platform Independent

Promote Innovation

Promote Patient Engagement

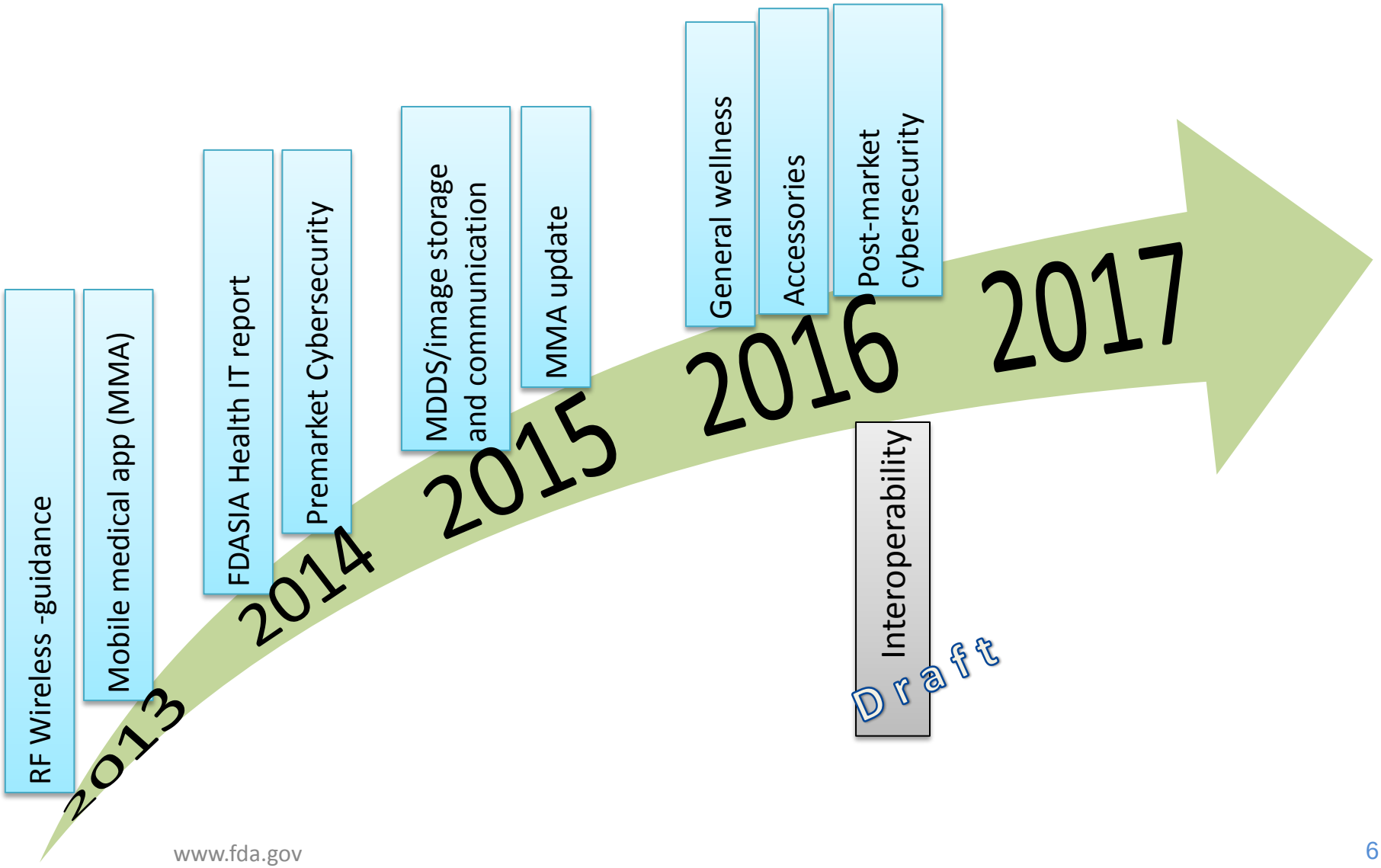
Protect Patient Safety

Functionality Focused

Narrowly Tailored

Risk Based

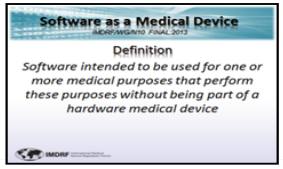
Digital Health Foundational Policies



International Convergence on Software as a Medical Device (SaMD)

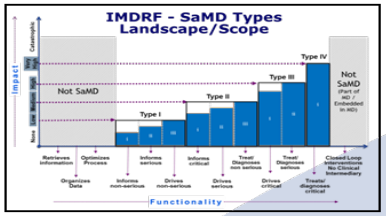
IMDRF goal - a converged SaMD framework and associated controls.

A prioritized building blocks strategy



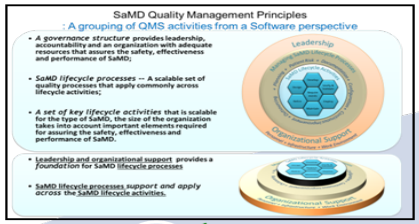
2013

Foundational vocabulary



2014

Risk framework based on impact to patients



2015

QMS control ➔Translating Software development practices to regulatory QMS

2016/2017

Application of clinical evaluation

21 Century Cures Act – Codifies FDA Policies

The new law amended the definition of "device" in the Food, Drug and Cosmetic Act to exclude certain software functions intended...

- *(A) for administrative support;*
- *(B) for maintaining or encouraging a healthy lifestyle;*
- *(C) to serve as a electronic patient records;*
- *(D) for transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results and certain other related information; and*
- *(E) to provide recommendations to health care professionals for clinical decisions, where the user can independently review the basis of the recommendation.*

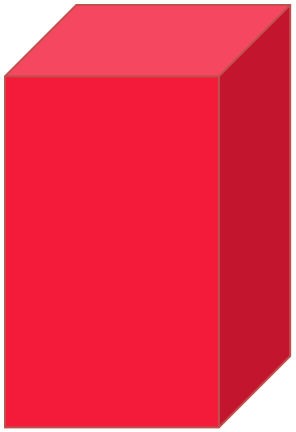
Rapidly Evolving Situation

Current Regulatory Paradigm

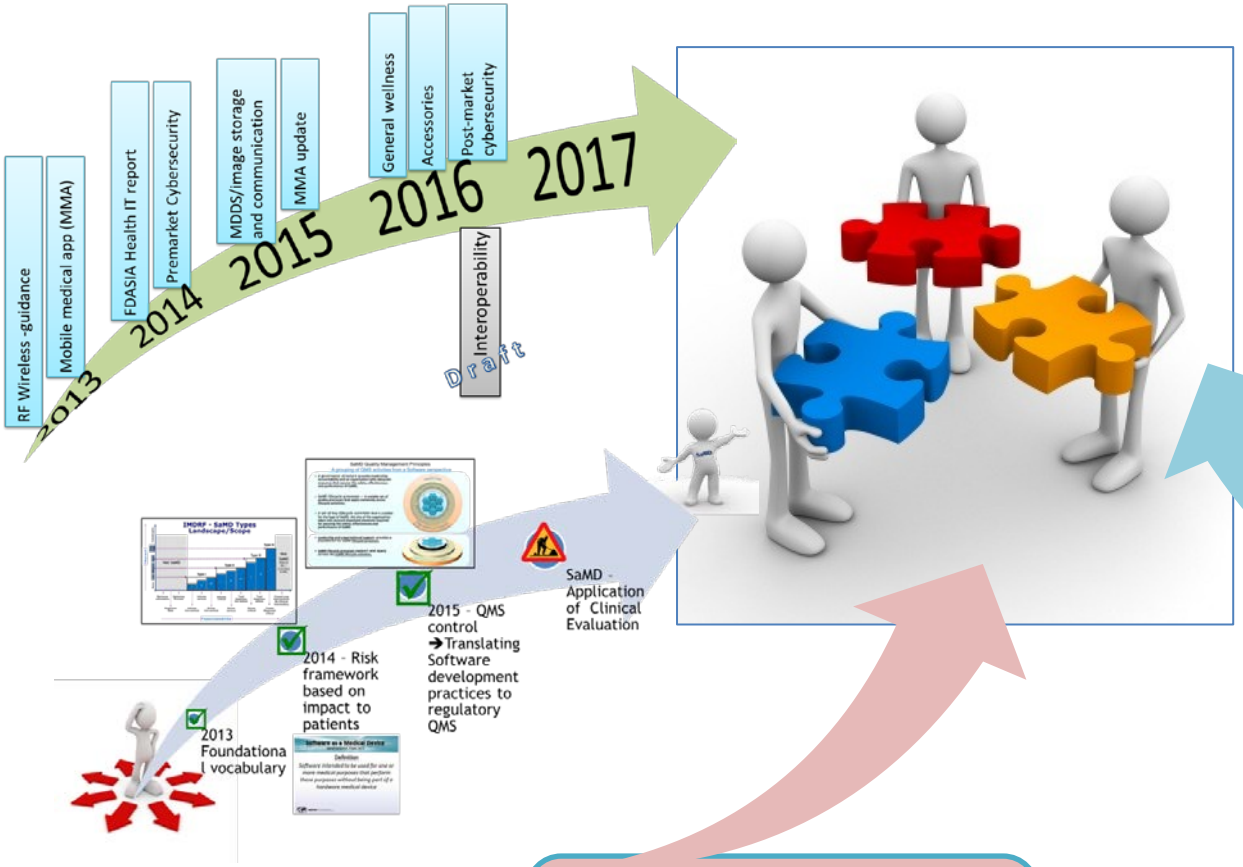
- Premarket timeline suited for hardware based products
- Deterministic risks, known responsibilities, physical products
- Current program volume – 3,500 510(k) submissions / 2200 pre-submissions

Unique Aspects of Digital Health

- software development timelines + software development practices + rapid iterations
- Emerging issues – (cybersecurity; distributed responsibilities, non-physical products)
- Potential for exponential increase in volume of submissions



An Opportunity to Foster Digital Health Innovation and Further Public Health



Considering current FD&C act authorities and implementing regulations

Unique aspects of Digital Health

- software development timelines + software development practices + rapid iterations
- Emerging issues – (cybersecurity; distributed responsibilities, non-physical products)
- Support (review and consults) for increasing volume of submissions

Digital Health Innovation Action Plan

An Integrated Approach

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

Explore new streamlined pathway for software

- Launch an innovative pilot Precertification (Pre-Cert) program to build a new approach to digital health technology, working with our customers and leveraging internationally harmonized principles for software regulation

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

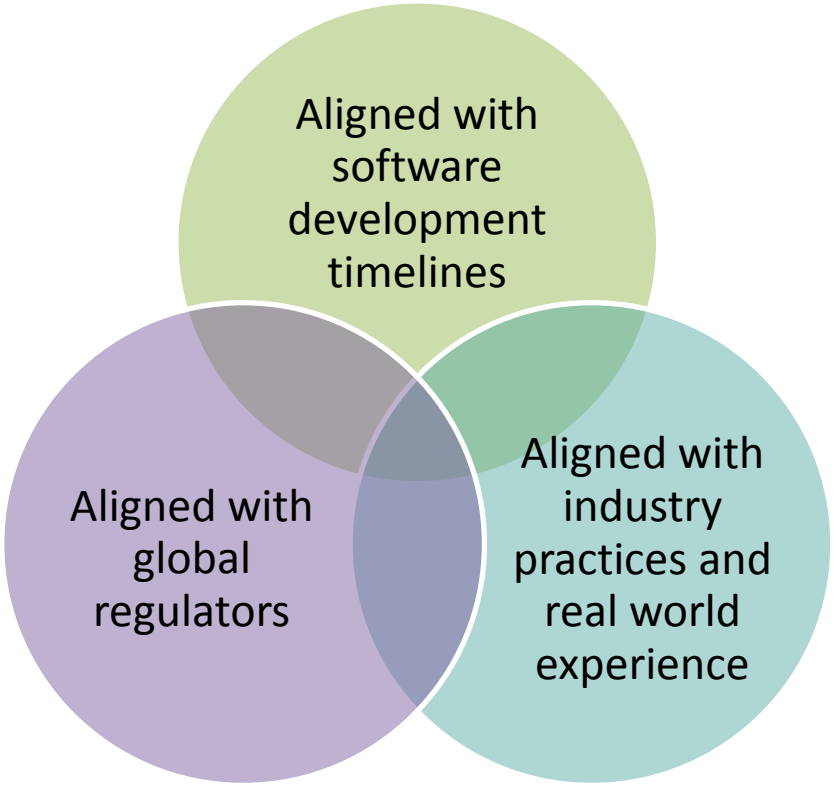
Digital Health Innovation Action Plan

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.	Withdraw regulations for products that are no longer devices based on the 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 SaMD.	
2018	**Publish draft Clinical Decision Support Software guidance** that delineates the clinical decision support software that is no longer under FDA's jurisdiction	
	Publish draft guidance: FDA review of products with some software functions that are devices and some functions that are not.	

Envisioning a New DH Paradigm

An agile and learning regulatory paradigm that is:



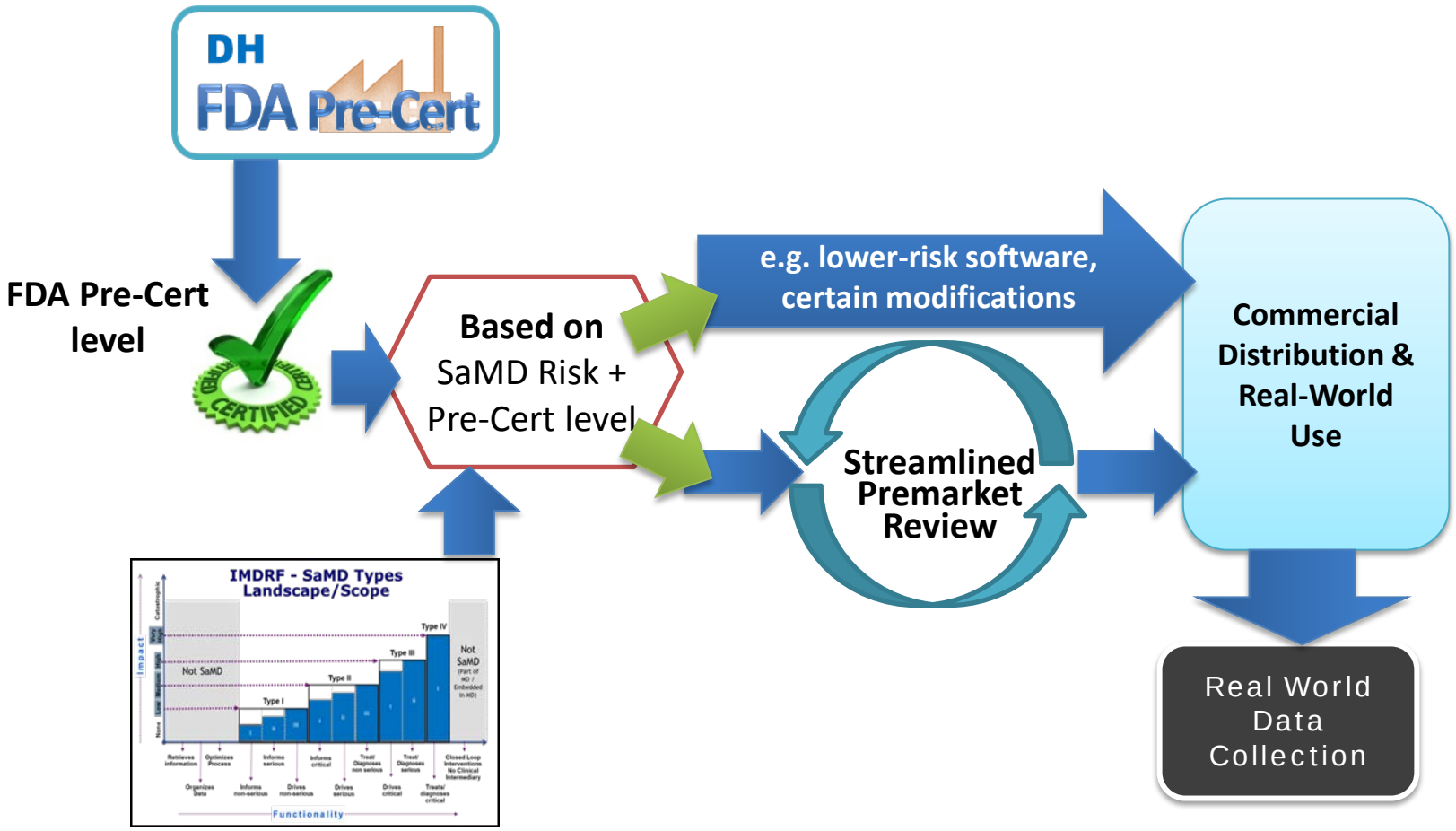
An opportunity to work together with customers to build and prepare for a digital health future

Concept

FDA Pre-Cert for Software

A company 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 Pre-Cert*



FDA Pre-Cert for SaMD

A voluntary program that allows manufacturers of Software as a Medical Device ("SaMD") to demonstrate their embedded Culture of Quality and Organizational Excellence (CQOE) to ultimately participate in a streamlined and predictable FDA regulatory pathway.

Purpose/Goal

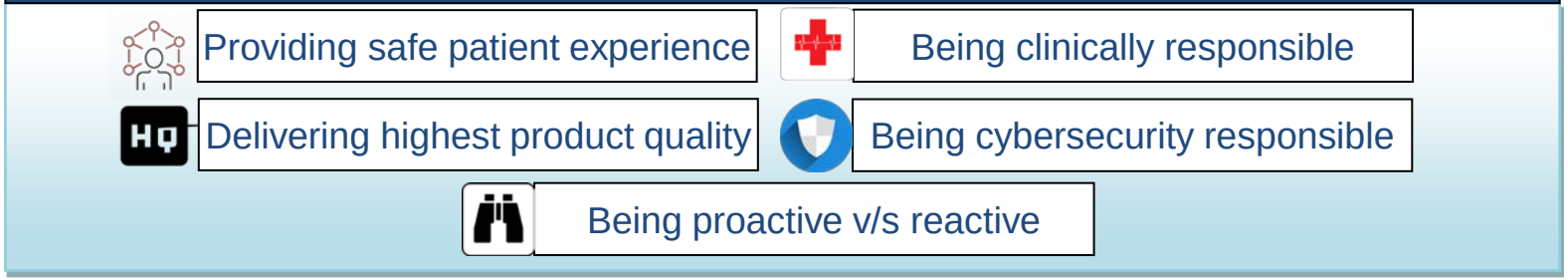
Allows manufacturers of SaMD with **FDA Pre-Cert** status (demonstrated culture of quality and organization excellence):

- To have the ability to get SaMD to market faster;
- To iterate based on real world experience;
- To have an excellent regulatory experience; and
- To have regulatory predictability.

Public health/innovation outcomes

1. Companies strive for excellence rather than compliance;
2. Promotes high quality and effective innovation;
3. Transparent **FDA Pre-Cert** status increases user confidence beyond regulatory oversight; and
4. Allows FDA to focus resources on higher risk digital health products.

Example of CQOE scorecard elements of interest where a company shows commitment towards ...



A possible framework to measure excellence

PERSPECTIVES

Organizational resource

KPI that demonstrates outcome measures in leadership, employee training, organizational support, infrastructure, employee empowerment, etc.

Customer

KPI that demonstrates outcome measures in revenue, marketing, support, etc.

Learning and growth

KPI that demonstrates outcome measures in product support, innovation, employee training, stakeholder engagement, etc.

Internal process

KPI that demonstrates outcome measures in product engineering, management support, risk management commitment, efficiency, revenue, etc.

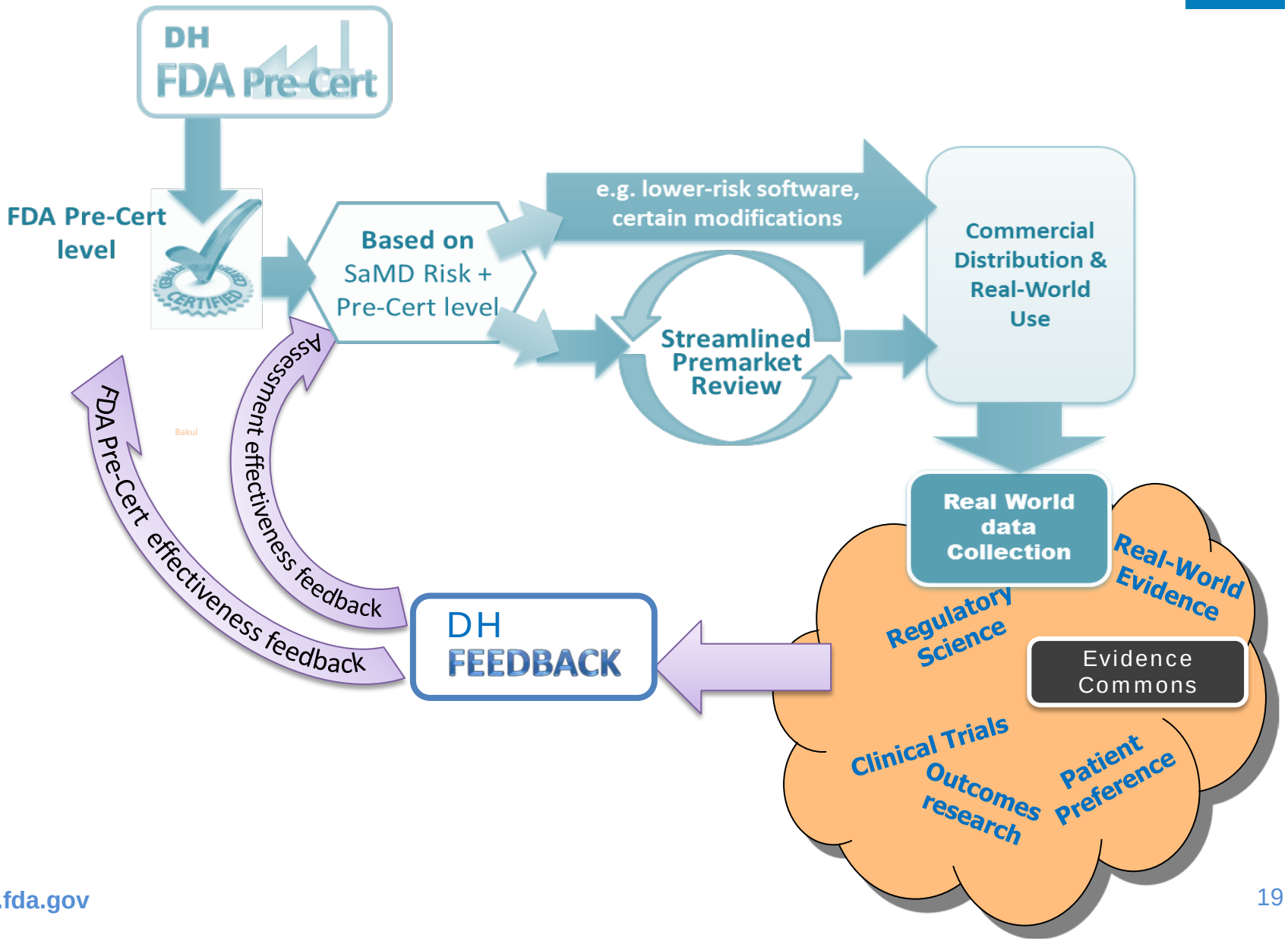
Aggregate KPI

- Providing safe patient experience
- Being clinically responsible
- Delivering highest product quality
- Being cybersecurity responsible
- Being proactive v/s reactive

FDA Pre-Cert Goals

1. Enables a modern and efficient regulatory framework that allows software iterations and changes to occur in a timely fashion;
2. Is an easy to follow process for obtaining FDA Pre-Cert and is easily maintained by the FDA and industry;
3. Ensures high quality and safe and effective software throughout the life of the product by enabling companies to demonstrate their embedded culture of quality and organization excellence (CQOE);
4. Enables measurement of “Key Performance Indicators” (KPI) independent of organization size, deployment strategies, or computing platforms and provides credit for what a company is doing “right”;
5. Enables for scalability, variation and evolution of software development and management processes in use today or others that may exist in the future; and
6. Is a program that learns and adapts (i.e., adjusts/tweaks/evolves scorecard elements and key dimensions and measures) based on the effectiveness of the program.

A Learning Regulatory Paradigm



Empowering Developers and Software Makers

SaMD
Regulatory
Development
Kit

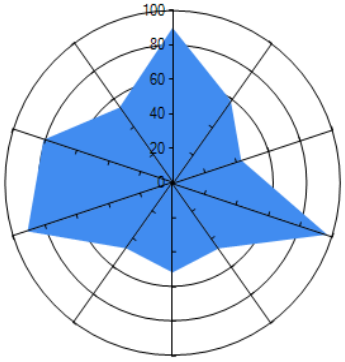
- The RDK would function and have components similar to a Software Development Kits ("SDK") that enables SaMD manufacturers to efficiently and successfully develop high quality safe and effective products; and

- The RDK would aid in access to relevant regulatory resources and considerations that focus on protecting patient safety and complying with regulatory expectations.

- A toolkit for digital health entrants that is usable in an interactive manner (not a paper-only guidance document or checklist);
- Comprehensively includes regulatory intent, expectations and principles across the SaMD lifecycle;
- Relies on and references existing resources and documents (e.g., FDA guidance, standards, etc.); and
- Amplifies regulatory objectives of patient safety and the intent of the regulatory requirements.

Key Building Blocks

DH FDA Pre-Cert



Regulatory
Development
Kit

DH FEEDBACK

Software Precertification Pilot Program

Scope of the Pilot

- Manufacturers developing or planning to develop software as a medical device (SaMD) as defined by IMDRF.

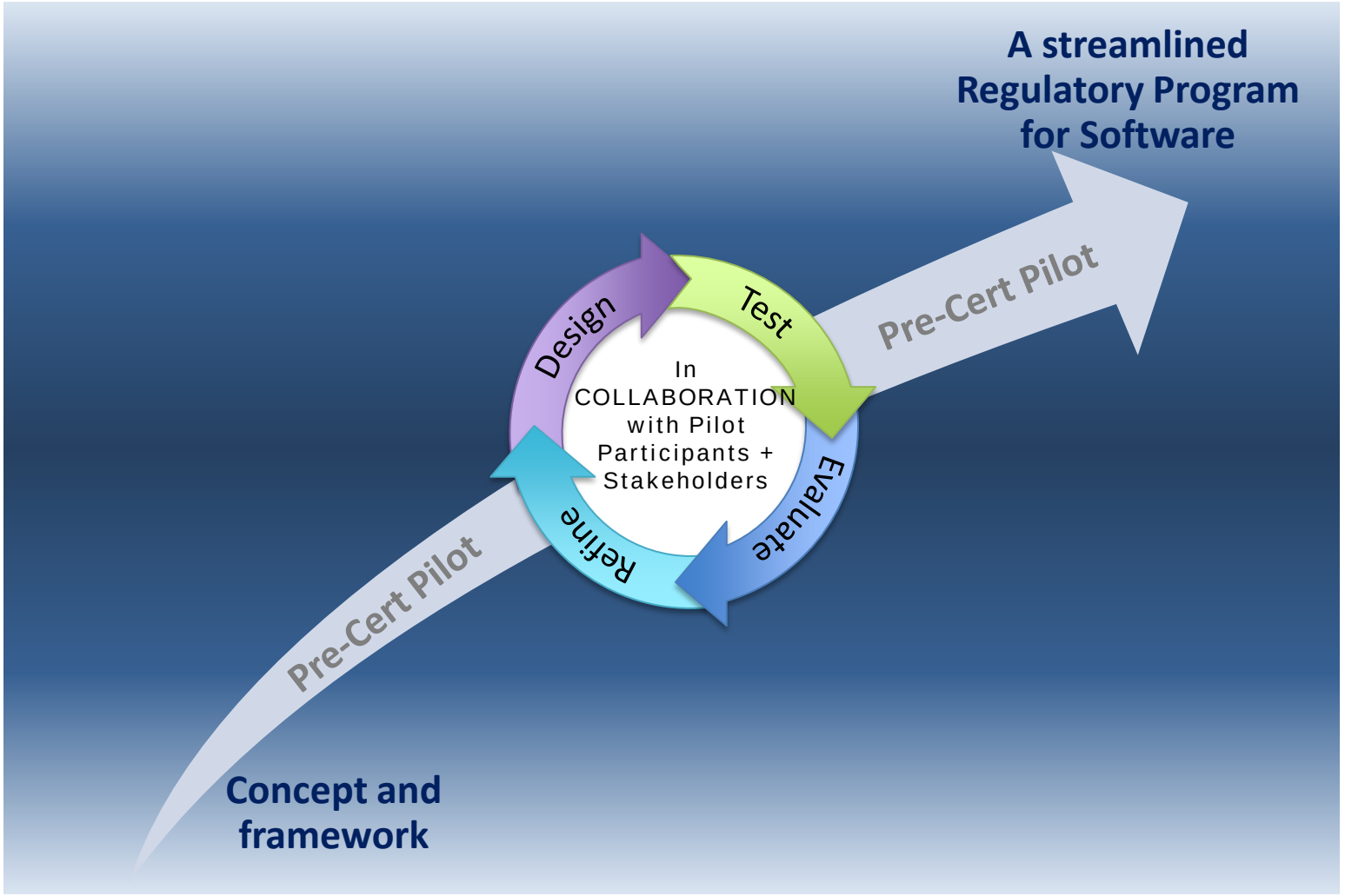
> ***IMDRF SaMD Definition***
> *Software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device*

- Limited to maximum of 9 pilot participants.
- Software function not excluded from medical device definition by 21st Century Cures Act.

Software is a SaMD when …

- Software's output on its own has a medical purpose as defined by FD&C act;
- Can run on any computing platform regardless of the location of the platform such as generic PC on a network, mobile phone, generic computer located within a hardware medical device, cloud infrastructure.
- Can receive/use input from any general purpose peripheral of a computer or a sensor that is not specifically intended for a medical purpose;
- Can receive/use data generated by other medical devices or in-vitro devices as input;
- Does not control, or alter functions or other parameters of another medical device.

From Concept to A Program: *An Iterative Approach*



Key Pilot Program Goals

Program component	Deliverable/outcomes of Pilot
Pre-certification components	Leverage industry measures to benchmark CQOE elements
	Develop and evaluate measure criteria
	Develop levels of certification correlated to SaMD risk type
	Prototype mechanism for companies to collect measures for pre-certification as part of their business operations
	Develop and test to mechanics to obtain and maintain certification
Pathway decision criteria	Develop criteria using IMDRF SaMD risk framework and levels of certification
	Develop and test mechanism/tools for pathway determination
Independent assessment flow	Develop optimal submission method and content
	Explore options for decreasing / aligning to Pre-Cert status
Post market evidence collection	Identify use scenarios and collection scope and methods
Feedback	Identify appropriate metrics and KPIs to measure effectiveness of the program

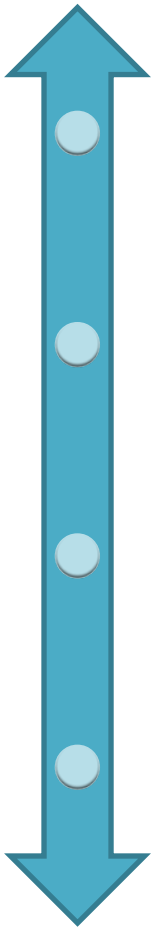
Pilot Participation

- Applications open August 1, 2017 and will remain open throughout the duration of the program.
- Companies submit statement of interest including agreement to selection qualities.
- Phased approach expected to run from September 2017 through September 2018.
- 1st phase targeting participation with 3 companies.

Statement of Interest Selection Qualities

- Company must be in the process of developing or planning to develop a software product that meets the definition of a device in 201(h) of the FD&C Act.
- Company has an existing track record in developing, testing and maintaining software products demonstrating a culture of quality and organizational excellence (CQOE) measured and tracked by Key Performance Indicators (KPIs) or other similar measures.
- While participating in the pilot, the company must agree to:
  - Provide access to CQOE measures, KPIs or similar measures.
  - Collect real-world postmarket performance data and provide it to FDA.
  - Be available for real-time consultations with FDA.
  - Be available for site visits from FDA officials.
  - Provide information about the firm's quality management system.

Expected Pilot Participants Spectrum



Organization size	Large → small
Industry	Traditional *(medical device + IVD)* → New entrant to MedTech
Best in class	Shown by known track record / market success in software
SaMD risk profile	Low → high

Pilot Roles and Responsibilities

CDRH Staff role

- Work collaboratively with the participating company
- Work alongside with entrepreneurs in residence candidates
- Available to answer questions or concerns that may arise
- Maintain confidentiality of commercial and proprietary information

Pilot participants role

- Actively help develop criteria for precertification and process
- Dedicate resources to partner with FDA staff
- Provide access to KPIs or similar measures
- Engage in sharing their experiences with the Pre-Cert pilot to improve the program

Participant will also …

- Collect real-world postmarket performance data and provide it to FDA.
- Be available for real-time consultations with FDA.
- Be available for site visits from FDA officials.
- Provide information about the firm's quality management system.

Pilot Overview

Collect statements of interest	Select no more than 9 participants	Develop program elements
• Applications accepted beginning August 1, 2017 • Program will begin September 1, 2017 • Enrollment ongoing throughout the duration of the program	• Best meet selection criteria • Reflect broad spectrum of software developers • Include companies that develop a range of both low and high risk software devices	• Conduct Site visits • Refine precertification elements in collaboration with participants • Share findings and solicit public input

Interested parties should email their statement of interest with subject line "Pre-Cert Pilot: statement of interest" to FDAPre-CertPilot@fda.hhs.gov

Key Points

- Pilot is an important first step to help us explore elements of the program
- Program is part of the FDA's ongoing efforts to develop pragmatic approaches to balance benefits and risks of digital health products
- Collaborate and learn from companies and stakeholders who perform high-quality software design, testing and maintenance
- Pilot participants will engage with the FDA to explore:
  - Elements of a precertification program that may replace the need for premarket submission in some cases; and
  - May allow for decreased submission content and/or faster review of marketing applications in other cases.

Questions?

For questions related to Digital Health, please contact the Digital Health Team: digitalhealth@fda.hhs.gov

For general question, please contact the Division of Industry and Consumer Education: DICE@fda.hhs.gov

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