Digital Health

A PRAGMATIC REGULATORY APPROACH

BAKUL PATEL
ASSOCIATE DIRECTOR FOR DIGITAL HEALTH

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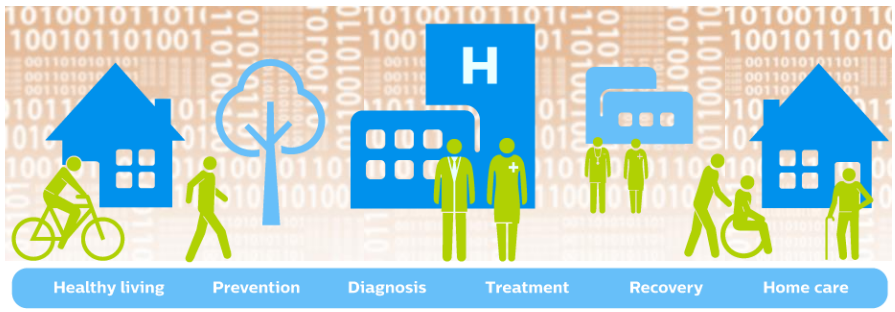
Digitization Across the Health Care Continuum



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".

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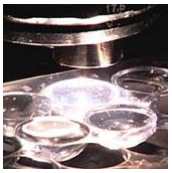
Types of Medical Device Software

Software in a device

in

as

Software as a Medical device (SaMD)



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Software used in the manufacturing process of a device

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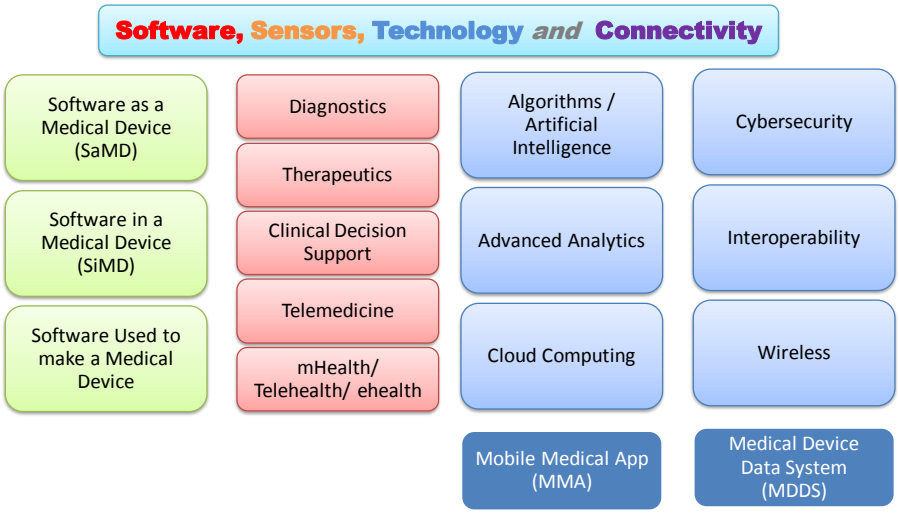
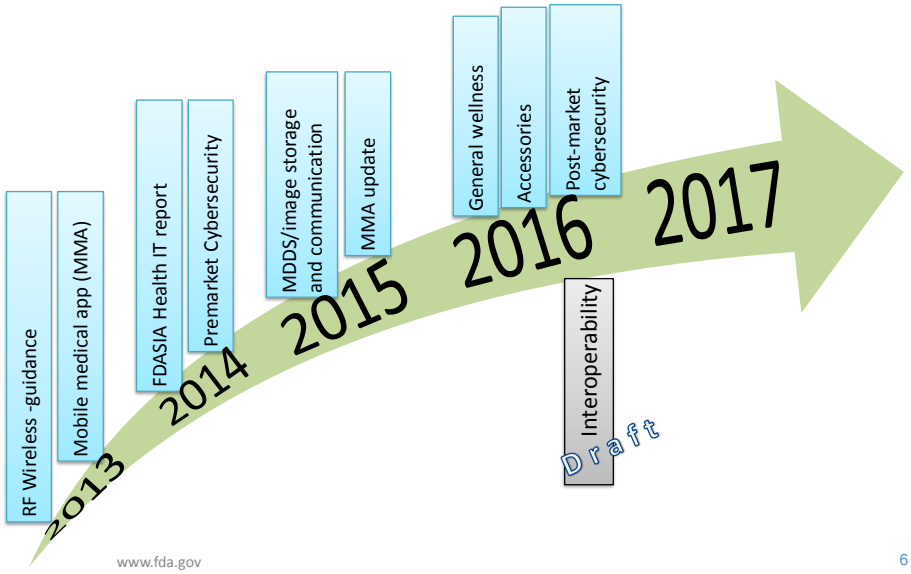
Digital Health Functionality, Technology, and Issues



Digital Health Foundational Policies



Focusing on Higher Risk Functionality

Lower Risk Functionality

May not always enforce regulatory requirements

Lower risks are not likely to exceed the limits of exemption (§886.9)

Higher Risk Functionality

Intend to assure patient safety while encouraging advances in innovative technology and product life-cycle

- De Novo
- 510(k)
- PMA

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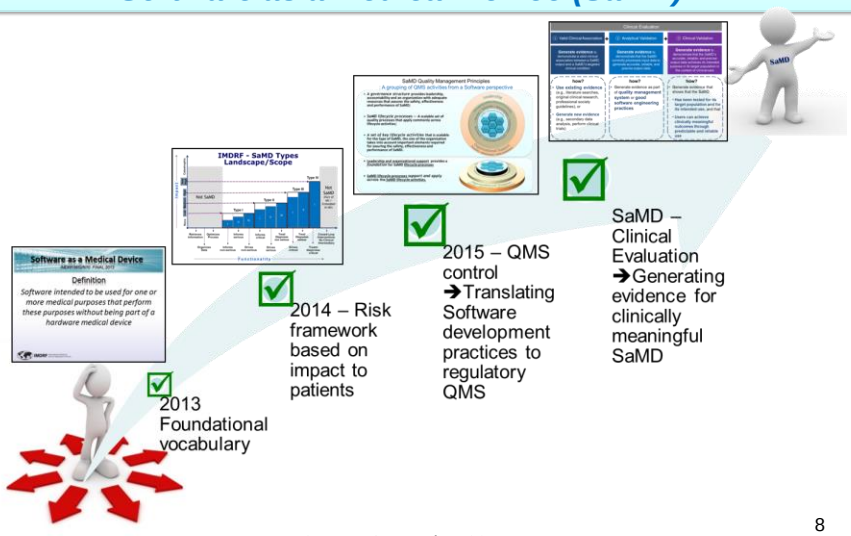
IMDRF International Medical Device Regulators Forum

Global Convergence effort for
Software as a Medical Device (SaMD)



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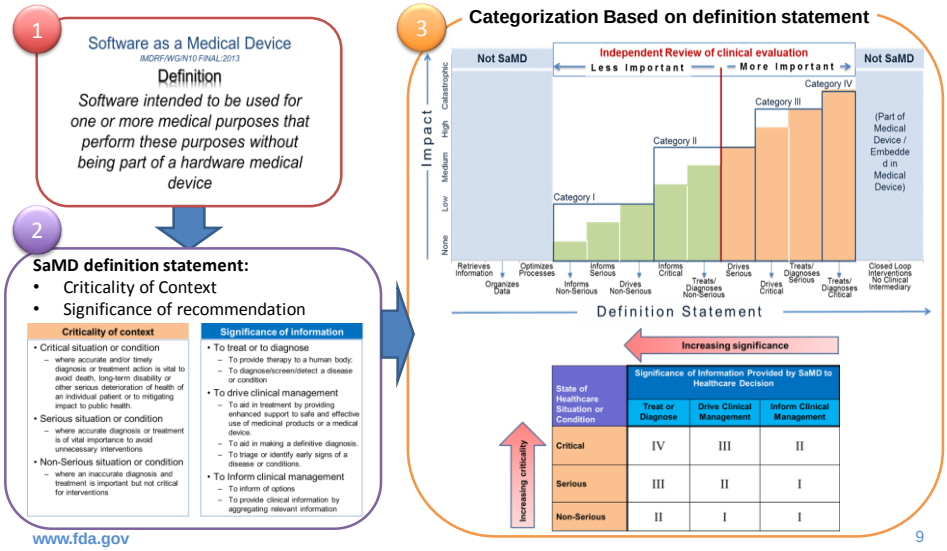
Ottawa, September 2017

IMDRF International Medical Device Regulators Forum

A Converged Framework and Principles for (SaMD)



21 Century Cures Act – Codifies FDA Policies

Amended the definition of "device" in the Food, Drug and Cosmetic Act to exclude certain software functions intended...	FDA Policies affected/codified
(A) *for administrative support;*	**FDASIA Categories of Health IT** – **Administrative Functionality**
(B) *for maintaining or encouraging a healthy lifestyle;*	**FDA Policy for Low risk general wellness products**
(C) *to serve as a electronic patient records;*	**FDASIA Categories of Health IT** – **Health Management functionality**
(E) *to provide recommendations to health care professionals for clinical decisions, where the user can independently review the basis of the recommendation.*	**Policy for Clinical Decision Support Software included in Health Management functionality**
(D) *for transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results and certain other related information;*	Medical Device Data System (MDDS)

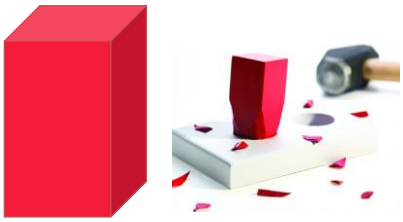
Rapidly Evolving Situation

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



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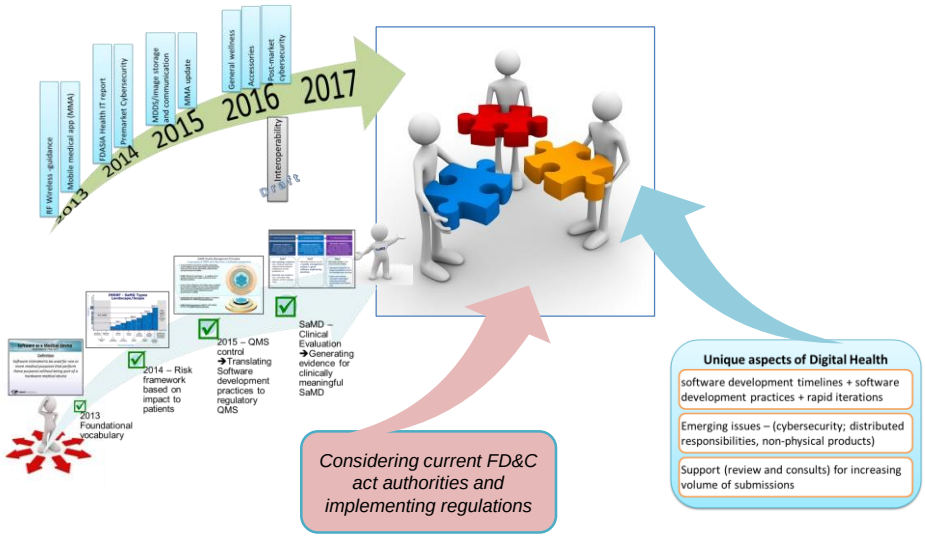
An Opportunity to Foster Digital Health Innovation and Further Public Health



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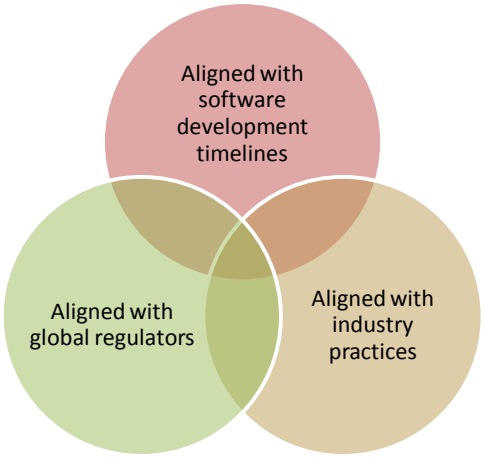
CDRH: Envisioning a New DH Paradigm

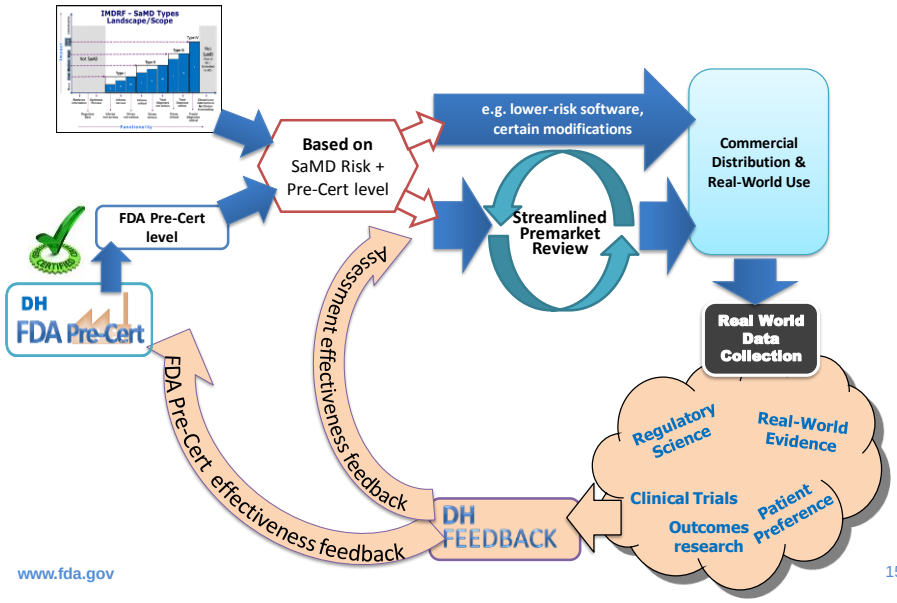
An agile and learning regulatory paradigm that Focused on Higher Risk Products and is:



FDA Pre-Cert Pilot Overview

A company-based, streamlined regulatory approach for Software as a Medical Device that relies on a demonstrated Culture of Quality and Organizational Excellence

FDA Pre-Cert Concept

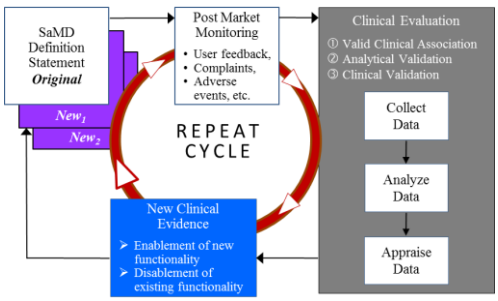


IMDRF International Medical Device Regulators Forum

IMDRF Clinical Evaluation Framework

A Pathway for Continuous Learning Leveraging Real World Performance Data

SaMD manufacturers are encouraged to leverage SaMD's technology capability to capture real world performance data to understand user interactions with the SaMD, and conduct ongoing monitoring of analytical and technical performance to support future intended uses.



Suggested steps

1. Additional clinical data is gathered.
2. The data may create and support new intended use(s).
3. The SaMD manufacturer will update the clinical evaluation and generate a new definition statement.
4. Cycle repeats for future iterations.

Excellence Principles

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.

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Company Specific – *Common Validating Perspectives*

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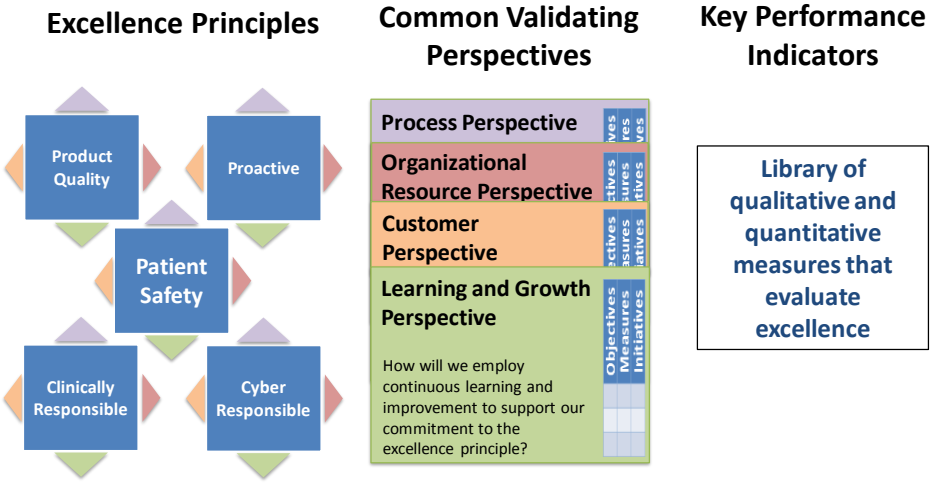
Scorecard Framework



From Concept to A Program: *An Iterative Approach*