Digitization Across the Health Care Continuum

Leveraging computing power, sensors, connectivity, and software.

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.
Types of Medical Device Software

Software in a device

Software as a Medical device (SaMD)

Software used in the manufacturing process of a device
Smart Regulation Principles

- Platform Independent
- Promote Innovation
- Promote Patient Engagement
- Protect Patient Safety

- Functionality Focused
- Narrowly Tailored

Risk Based
Ongoing Clarity:
Balancing Innovation and Patient Safety

- MDDS/image storage and communication
- MMA update

- FDASIA Health IT report
- Premarket Cybersecurity

- RF Wireless
- Mobile medical app (MMA)

- General wellness
- Accessories
- Post-market cybersecurity

- Interoperability
- SaMD Clinical Eval
- 21 CC cure policy
- Clinical + patient decision support

- Multifunction
Leading International Convergence effort on Software as a Medical Device (SaMD)

International Medical device Regulators Forum (IMDRF): A converged SaMD framework and associated controls.

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21st Century Cures Act – Codifies FDA Policies

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 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;

(E) to provide recommendations to health care professionals for clinical decisions, where the user can independently review the basis of the recommendation.

FDASIA Categories of Health IT

- Administrative Functionality
- FDA Policy for Low-Risk General Wellness Products
- Health Management Functionality
- Medical Device Data System (MDDS)
- Policy for Clinical Decision Support Software included in Health Management Functionality
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

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 SaMD.

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

...thdraw 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.

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.

2017

2017

2018
OCD DH Unit - Expertise Requirements and Roles

**Expertise Areas**
1. Software Life Cycle Management Processes
2. Mobile Medical Application
3. Interoperability
4. Cybersecurity
5. Wireless
6. Cloud
7. Machine Learning/Artificial Intelligence

**Roles and Responsibilities**
- Provide Technical Expertise
- Coordinate center-wide DH efforts
- Training
- Outreach
- Develop DH Policies
- Participate in creating a New Paradigm
Assurance for Safety and Effectiveness

- High data quality for training
- Algorithm “correctness” (verification)
- Performance testing (validation)
- Generalizability
- Interpretability

IDx-DR is intended for use by health care providers to automatically detect more than mild diabetic retinopathy (mtmDR) in adults diagnosed with diabetes who have not been previously diagnosed with diabetic retinopathy.
## Rapidly Evolving Situation

### Current Regulatory Paradigm
- Premarket timeline suited for hardware based products
- Deterministic risks, known responsibilities, physical products
- Program capacity manages – 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
Challenges

Evaluation of safety and effectiveness:

- **Current hardware devices**: Human modifies, we understand
- **Fixed Algorithm SaMD**: Human/technology modifies, can be explained
- **Deep Learning SaMD**: Technology modifies, cannot be explained

Open questions:
- Continuous learning while ensuring safety and effectiveness
- Availability for large and robust datasets with representable clinical variability
- Continuous Algorithm updates
- Interpretability and explain-ability of the “basis of the recommendation”
FDA Pre-Cert Program

An organization-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

Based on SaMD Risk + Pre-Cert level

e.g. lower-risk software, certain modifications

Commercial Distribution & Real-World Use

Streamlined Premarket Review

Real World Data Collection

FDA Pre-Cert level

DH Feedback

FDA Pre-Cert effectiveness feedback

DH Feedback

IMDRF - SaMD Types Landscape/Scope

FDA Pre-Cert level
All of Our Work Stems from Five 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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Four Key Program Components

1. Excellence Appraisal and Certification

2. Review Determination

3. Streamlined Review

4. Real World Performance

Risk Based (SaMD Risk + Pre-Cert level)

FDA Pre-Cert Level 1

FDA Pre-Cert Level 2

Real world SaMD Performance

Real world Program Performance

Streamlined Premarket Review
Pre-Cert Program Roadmap

Pre-Cert 1.0

Pre-Cert 2.0

Development

Build - Test - Iterate

Integrate

Pre-launch

Launch

2018

2019

Jan

Dec

Jan

Dec

Jan

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Public Input

Develop: Excellence Appraisal Model

Develop: Streamlined Review Approach

Develop: Real World Data (access, approach and analysis)
Engage

- Look for ongoing Program updates: [bit.ly/Precertupdates]
- Ask Questions about the Program: FDAPre-CertPilot@fda.hhs.gov
- Provide ongoing input through the Public Docket: [bit.ly/docketjan18]