Digital Health

INNOVATION ACTION PLAN
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.
Digital health, biotech and medical device trends 2017, CB Insights
Smart Regulation Principles

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

- Functionality Focused
- Narrowly Tailored

Risk Based
Narrow Tailored Approach to Mobile Apps

- Patient self-management apps
- Tools to organize and track their health information (not for treating or adjusting medications)
- Tools to access to health information document and communicate with health care providers
- Tools that automate simple health care providers tasks

Not Subject to Enforcement

MMA

Lower risk mobile apps that meet “device” definition but not considered “MMA”

Mobile apps not considered “medical devices”

Mobile apps that meet “device” definition that are either intended
- To be used as an accessory to already regulated medical device, or
- To transform a mobile platform into a regulated medical device.

focus of oversight
Balancing Innovation and Patient Safety with Foundational Policies

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Leading International Convergence effort 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

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2016/2017
Application of clinical evaluation
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
An Opportunity to Foster Digital Health Innovation and Further Public Health

Considering current FD&C act authorities and implementing regulations
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...

(A) for administrative support;

(B) for maintaining or encouraging a healthy lifestyle;

(C) to serve as a electronic patient records;

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

(D) for transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results and certain other related information;

FDA Policies affected/codified

FDASIA Categories of Health IT

Administrative Functionality

FDA Policy for Low risk general wellness products

Health Management functionality

Policy for Clinical Decision Support Software included in Health Management functionality

Medical Device Data System (MDDS)
A Framework for Software as a Medical Device (SaMD)

**SaMD definition statement:**
- **Criticality of Context**
- **Significance of recommendation**

### Criticality of context
- Critical situation or condition
  - Where accurate and timely diagnosis or treatment action is vital to avoid death, long-term disability or other serious deterioration of health of an individual patient or to mitigating impact to public health.
- Serious situation or condition
  - Where accurate diagnosis or treatment is of vital importance to avoid unnecessary interventions
- Non-Serious situation or condition
  - Where an inaccurate diagnosis and treatment is important but not critical for interventions

### Significance of information
- To treat or to diagnose
  - To provide therapy to a human body;
  - To diagnose/screen/detect a disease or condition
- To drive clinical management
  - To aid in treatment by providing enhanced support to safe and effective use of medicinal products or a medical device.
  - To aid in making a definitive diagnosis.
  - To triage or identify early signs of a disease or conditions.
- To inform clinical management
  - To inform of options.
  - To provide clinical information by aggregating relevant information

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**Independent Review of clinical evaluation**

- Category I: More Important
- Category II: Important
- Category III: Less Important
- Category IV: Not SaMD

**State of Healthcare Situation or Condition**

<table>
<thead>
<tr>
<th>State of Healthcare Situation or Condition</th>
<th>Significance of Information Provided by SaMD to Healthcare Decision</th>
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<tbody>
<tr>
<td>Critical</td>
<td>IV</td>
</tr>
<tr>
<td>Serious</td>
<td>III</td>
</tr>
<tr>
<td>Non-Serious</td>
<td>II</td>
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**IMDRF**
**International Medical Device Regulators Forum**

**www.fda.gov**
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.

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. Then the cycle repeats.
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
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

Assessment effectiveness feedback

FDA Pre-Cert effectiveness feedback

DH FEEDBACK

Regulatory Science
Real-World Evidence
Clinical Trials
Outcomes research
Patient Preference

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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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Pre-Cert Program Roadmap

2018

Jan

2019

Dec

Pre-Cert – Development

Build - Test - Iterate

Integrate

Pre-launch

Launch

Public Input

Late Summer

Public Input

Late Fall

Public Input

Public Input

Develop: Excellence Appraisal Model

Develop: Streamlined Review Approach

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

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OCD DH Unit - Expertise Requirements and Expectations

**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