Digital Health
A PRAGMATIC REGULATORY APPROACH

BAKUL PATEL
ASSOCIATE DIRECTOR FOR DIGITAL HEALTH

www.fda.gov

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.

www.fda.gov
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”.

Types of Medical Device Software

- Software in a device
- Software as a Medical device (SaMD)
- Software used in the manufacturing process of a device
Digital Health Functionality, Technology, and Issues

Software as a Medical Device (SaMD)
- Diagnostics
- Therapeutics
- Clinical Decision Support
- Telemedicine
- mHealth / Telehealth / ehealth

Advanced Analytics
Cloud Computing
Cybersecurity
Interoperability
Wireless

Mobile Medical App (MMA)
Medical Device Data System (MDDS)

Digital Health Foundational Policies

2013
2014
2015
2016
2017

RF Wireless - guidance
Mobile medical app (MMA)
FDASIA Health IT report
Premarket Cybersecurity
MDPS/image storage and communication
MMA update
General wellness
Accessories
Post-market cybersecurity
Interoperability

www.fda.gov
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

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

Ottawa, September 2017
A Converged Framework and Principles for (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.

**Categorization Based on Definition Statement**

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

**Significance of Information**
- To treat or to diagnose
- To prevent therapy to a human being
- To change or eliminate a disease or condition
- To improve health or health care management
- To assess the disease or condition
- To inform clinical management
- To provide clinical decision support

**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 an 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

FDASIA Categories of Health IT

Health Management functionality

Policy for Clinical Decision Support Software included in Health Management functionality

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

An Opportunity to Foster Digital Health Innovation and Further Public Health

Considering current FD&C act authorities and implementing regulations
An agile and learning regulatory paradigm that **Focused on Higher Risk Products** and is:

- Aligned with software development timelines
- Aligned with industry practices
- Aligned with global regulators

**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**
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.
Excellence Principles

Demonstration of a commitment to providing a safe patient experience, and to 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 to ensure that patient-centric issues including labeling and human factors are appropriately addressed.

Demonstration of a commitment to protect cybersecurity, and to 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.

Company Specific – Common Validating Perspectives

Process Perspective
How do we ensure our processes support our commitment to the excellence principle?

Customer Perspective
How does our consideration of customer needs and customer satisfaction support our commitment to the excellence principle?

Learning and Growth Perspective
How will we employ continuous learning and improvement to support our commitment to the excellence principle?

Organizational Resource Perspective
How do we empower employees to meet the excellence principle by providing necessary tools, training, and infrastructure?
Scorecard Framework

Excellence Principles
- Product Quality
- Proactive
- Patient Safety
- Clinically Responsible
- Cyber Responsible

Common Validating Perspectives
- Process Perspective
- Organizational Resource Perspective
- Customer Perspective
- Learning and Growth Perspective
  How will we employ continuous learning and improvement to support our commitment to the excellence principle?

Key Performance Indicators
- Library of qualitative and quantitative measures that evaluate excellence

From Concept to A Program: An Iterative Approach

Areas of Focus During Concept Development
- Organizational Excellence
- Streamlined Review
- Real world Data Collection

Pilot Start Sept 2017
Public meeting January 2018
Program proof of concept Late 2018