Overview

- What is Digital Health?
- Current Digital Health Activities
- Potential Needs to Advance Science
THE GUIDE TO THE FUTURE OF MEDICINE

HEALTHCARE PROFESSIONALS

VIRTUAL DISSECTION
DIGITAL LITERACY IN MEDICAL EDUCATION
ARTIFICIAL INTELLIGENCE IN PUBLIC HEALTH
MEDICAL A.I. POLICY
ARTIFICIAL INTELLIGENCE IN MEDICAL DECISION SUPPORT
EVIDENCE-BASED MOBILE HEALTH
DIGESTIBLE SENSORS
MEDICAL TRICORDER
AUGMENTED REALITY
ROBOTIC INTERVENTIONS
FULL PHYSIOLOGICAL SIMULATION
MEDICAL DRONES
NANOROBOTS IN BLOOD
IN-SILICO CLINICAL TRIALS
3D PRINTED DRUGS
PAPERLESS HOSPITALS
BLOCKCHAIN IN PHARMA
ALREADY AVAILABLE
IN PROGRESS
STILL NEEDS TIME

PATIENTS

GAMIFICATION BASED WELLNESS
DTC GENOMICS
 FOOD SENSORS
 SMARTWATCH
 NUTRIGENOMICS
 SLEEP TRACKERS
 DTC ARTIFICIAL INTELLIGENCE
 IMPLANTED MICROCHIPS
 WEARABLE E-SKINS
 DIGITAL HEALTH-BASED INSURANCE
 VIRTUAL REALITY
 BIOPRINTED HUMAN TISSUE
 BRAIN-COMPUTER INTERFACES
 ROBOTIC NURSE ASSISTANT
 DIGITAL PILL BOX
 HUMANOID ROBOTS
 RECREATIONAL CYBORGS
 LIFE-LIKE PROSTHETICS

Source: https://medicalfuturist.com/what-would-make-every-doctor-use-digital-health/
Digital Health

The convergence of connectivity, data and computing power for healthcare and related uses across the life of an individual or a patient.

Moving healthcare 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.
Tech allows for early and smaller interventions which can be:

1. Less costly
2. Less Invasive
3. Potentially change the course of a disease before it’s onset
Convergence of computing power, connectivity, sensors, and software used in healthcare.
Digital Health Solutions

Digital tools can provide consumers with valuable health information.

Consumers who are better informed about health make better decisions.

What qualifies as a digital health product?

What digital health technologies need regulation?
FDA’s Digital Health Center of Excellence

Empowering All to Advance Healthcare

Our goal: Empower stakeholders to advance health care by fostering responsible and high-quality digital health innovation that meets FDA standards of safety and effectiveness.

The Digital Health Center of Excellence aims to:

- Connect and build partnerships to accelerate digital health advancements.
- Share knowledge to increase awareness and understanding, drive synergy, and advance best practices.
- Innovate regulatory approaches to provide efficient and least burdensome oversight.
Current Areas of Focus

- Software as a medical device (SaMD)
- Artificial Intelligence/Machine Learning
- Wearables
- Software in a medical device (SiMD)
- Wireless Connectivity
- Interoperability
- Medical Device Cybersecurity
- Virtual Reality/Augmented Reality
- Real-world Evidence and Advanced Clinical Studies
- Advanced Manufacturing
- Patient-Generated Data
- Digital Biomarkers
- Digital Pathology
Digital Health Center of Excellence Roadmap

Following is our roadmap for bringing the benefits of digital health to all Americans, efficiently and collaboratively:

Phase I: Communication
Fall 2020
- Stakeholder Listening Sessions
- Update and develop resources for FDA staff
- Begin operationalizing the DHCoE and outcome measurement
- Amplify current work being done at FDA in digital health

Phase II: Coordinate
Fall and Winter 2020
- Build strategic partnerships for policy, regulatory science, and fellowships
- Develop resources for external stakeholders
- Create a digital health community of practice
- Assemble FDA and CDRH advisory groups

Phase III: Amplify
Winter 2021 onwards
- Continued strategic partnership building and communication
- Update and implement regulatory framework for digital health
- Harmonization with other regulators

Raise Awareness and Engage Stakeholders

Build Partnerships

Build and Sustain Capacity
Guidances Interpret Cures Act (520(o))

Administrative Support
General Wellness
Electronic Patient Records
Transfer, store, convert formats, display

Decision support software intended for healthcare professionals

Regulation and assessment of software products that contain multiple functions

Risk-based policy for device-CDS, including those intended for patients

Guidance applies to ALL medical devices (including hardware-based)
Final Guidances – Cures Act

Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act
Guidance for Industry and Food and Drug Administration Staff

Document issued on September 27, 2019.
The draft of this document was issued on December 8, 2017.

Off-The-Shelf Software Use in Medical Devices
Guidance for Industry and Food and Drug Administration Staff

Document issued on September 27, 2019.

General Wellness:
Policy for Low Risk Devices
Guidance for Industry and Food and Drug Administration Staff

Document issued on September 27, 2019.

Multiple Function Device Products:
Policy and Considerations
Guidance for Industry and Food and Drug Administration Staff

The draft of this document was issued on April 27, 2018.
Digital Health Policies Related to COVID-19

- Cites examples of software functions that are not regulated as medical devices that may be useful in the response to COVID-19.
- Cites examples of lower-risk device software functions for which the FDA does not intend to enforce requirements.
- Clarifies how manufacturers of higher-risk digital health devices that are outside the FDA’s COVID-19 policy may leverage the Emergency Use Authorization Process.

See Digital Health Policies and Public Health Solutions for COVID-19
Domains of Digital Health Work

Policy Clarity
- Not a Device
- Enforcement Discretion
- For Oversight Focus (Device)

Practical Oversight

Global Convergence

IMDRF: International Medical Device Regulators Forum
The Need for a Tailored Approach

Current Device World

**Product Development Timeline**
- Months to years +
- Less frequent modifications

**Postmarket Data**
- Limited availability and access to real world data (522, PAS, MDRs, MedSun)

**FDA Premarket Program Volume:**
- Stable (~3,500 510(k) submissions / 2200 pre-submissions)

Evolving Digital Health Device World

**Weeks to months** + (incremental, iterative) and potentially frequent modifications

**Potential for high availability** and access to rich real world data *(benefits and risks)*

**Potential for exponential** increase in volume of submissions
Getting Ready for the Digital Future
Goals for a Tailored Regulatory Framework

- Enhance patients access to high quality digital medical products
- Enable manufacturers to rapidly improve software products with minor changes
- Maintain a reasonable assurance of safety and effectiveness
- Minimally burdensome
Move from **episodic** oversight to **continuous** oversight that **enables trust** in the organization using a pragmatic check-in with **real-world performance** data.
2020 Update on “Pre-Cert”

- Released 2020 Update on Software Precertification (Pre-Cert) Program in September 2020.
- Highlights learnings to date from the ongoing building / testing of the Pre-Cert Program.
- Depicts phases of Program development.
- Outlines how Pre-Cert is leveraging learnings for the next iteration of testing including simulations.
Development Phases for Pre-Cert

- **Idea**
  - Initial vision on how Pre-Cert would create value with a lens towards patient safety and digital health innovation.

- **Concept**
  - Collect initial insights from stakeholders
  - Select 9 pilot participant companies to help inform development.

- **Research**
  - Publish Working Model, v0.1 for public input from stakeholders.
  - Iterate Working Model with public input

- **Build & Iterate**
  - Iterate and publish Working Model, v1.0 and Test Plan.
  - Expand stakeholder test cases to help test for a reasonable assurance of safety and effectiveness.
  - Integrate Program workstreams, iterating to a Total Product Lifecycle (TPLC) approach.
  - Develop objective measures.
  - Identify infrastructure needs for statutory authority.

- **ASSESSING**
  - Transition from Pilot to Program
  - TBD

- **FORMING**
  - Idea
  - Concept
  - Research

- **MODELING**
  - Idea
  - Concept
  - Research

- **ASSESSING**
  - Build & Iterate

- **Transition from Pilot to Program**
  - Beta-Testing
  - Scaling up testing of the program.

- **2017**
  - Idea
  - Concept
  - Research

- **2018**
  - Idea
  - Concept
  - Research

- **2019**
  - Idea
  - Concept
  - Research

- **2020+**
  - Idea
  - Concept
  - Research

- **…**
  - Idea
  - Concept
  - Research
FDA’s Proposed TPLC Approach Overlaid on AI/ML Workflow

Good Machine Learning Practices

Data selection and management → Model training and tuning

Model validation
- Performance evaluation
- Clinical evaluation

Data for re-training

Premarket Assurance of Safety and Effectiveness

Review of SaMD Pre-Specifications and Algorithm Change Protocol

Model monitoring
- Log and track
- Evaluate performance

Real-World Performance Monitoring

Legend
- AI Model Development
- AI Production Model
- Proposed TPLC Approach
- AI Device Modifications
Artificial Intelligence / Machine Learning

Background

FDA published a Discussion Paper on April 2, 2019 seeking early stakeholder input on a potential regulatory approach to medical devices that use artificial intelligence (“AI”) and machine intelligence (“ML”). A statement from then Commissioner Scott Gottlieb, M.D., outlined the following goals for a new, tailored review framework:

- Enhance patient access to high quality digital medical products
- Maintain a reasonable assurance of safety and effectiveness
- Enable manufacturers to rapidly improve software products with minor changes
- Minimally burdensome

Summary of Comments

- General support for idea of Good Machine Learning Practices (GMLP)
- Outline what a Real-World Performance plan looks like for AI/ML-based SaMD
- Calls for FDA to encourage harmonization through consensus standard efforts
- Received lots of suggestions on proposed ACP/SPS and Focused Review content
- Received suggestions for additional modification categories
- Calls for FDA to support a public-facing policy on transparency

979 Comments Received To Date
AI/ML-Based Medical Devices: Challenges

- Need for large, high-quality, well-curated data sets
- Explain-ability of these “black box” approaches
- Identifying and removing bias
Open Questions

Coexistence of multiple products in rapidly evolving conditions—for example, rapid approval of DH products for EUA considerations—how to ensure RASE when our current review paradigm is blind to presence of other products in the real-world.

Hidden bias in AI can negatively impact decision-making. But transparent bias (e.g. tuning a model trained on a national population to align with local factors) can improve personalized medicine and have lessons for tweaking national models.

- How can we use biased AI/ML to improve our decision-making?
- How can we use digital health approaches to address knowledge gaps related to co-morbidities and poly-pharmacies.
- Opportunities for standards creation:
  - To ensure interoperability within the complete ecosystem: EHR, Clinical Devices, Personal devices?
  - Ensure safe and effective autonomous AI systems in healthcare?
Opportunities and Challenges

- **Identifying key measures** at an individual and ensemble level
- **Developing a common vocabulary** for connecting data
- **Consumer technology** in healthcare and clinical trials
- **Enabling user-centric labeling**
- **Decision-making** between multiple AI systems with competing interests
- **Longitudinally learning** AI systems as digital clinical trials