COLLABORATING WITH THE DHCOE: *AN OVERVIEW*

Gloria Nyankima, PhD – Digital Health Policy Advisor, DHCoE

www.fda.gov/digitalhealth

The Food and Drug Administration (FDA)

Centers within the Agency include:

1. Center for Biologics Evaluation and Research (CBER)
2. **Center for Devices and Radiological Health (CDRH)**
3. Center for Drug Evaluation and Research (CDER)
4. Center for Food Safety and Applied Nutrition (CFSAN)
5. Center for Tobacco Products (CTP)
6. Center for Veterinary Medicine (CVM)
7. National Center for Toxicological Research (NCTR)
8. Office of Regulatory Affairs
9. Office of Operations

www.fda.gov

FDA White Oak Image:
https://dynaimage.cdn.cnn.com/cnn/c_fill,g_auto,w_1200,h_675,ar_16:9/https%3
A%2F%2Fcdn.cnn.com%2Fcnnnext%2Fdam%2Fassets%2F200811105852-fda.jpg

CDRH's Digital Health Center of Excellence

is advancing health care by fostering responsible and high-quality digital health innovation.

FDA

Digital Health Technologies play an increasingly significant role in health care.

- Digital therapy device to reduce sleep disturbance for psychiatric conditions
- Digital therapy device for Attention Deficit Hyperactivity Disorder
- Electrocardiograph software for over-the-counter use
- Self-fitting over-the-counter hearing aids
- Virtual reality behavioral therapy device for pain relief

In 2022, CDRH's DHCoE focused on …

Fostering Innovation

Authorized more than **500 AI/ML-enabled medical devices**, and more are under development.

Omnibus provision allows for changes to a device consistent with an approved **Predetermined Change Control Plan** without supplemental action.

Advancing Transparency and Equity

Patient Engagement Advisory Committee met to discuss **Augmented Reality/ Virtual Reality medical devices** and factors to consider when evaluating them.

Strengthening Cybersecurity

There was **a 17-fold increase** in device - related vulnerabilities from 2016 to 2020.

… And more is on the horizon.

Publish draft guidance on **Predetermined Change Control Plans** for **Artificial Intelligence / Machine Learning** –enabled devices.

Continued focus on how **DHTs can support decentralized trials and remote patient monitoring**, which will help underserved populations access health care.

Engage with stakeholders, including patients, users, and industry to explore regulatory approaches to digital health technologies.

Continue to **develop software and digital health technical expertise**.

Continue to **participate in international harmonization efforts**.

How can I collaborate with the DHCoE?

FDA

CERSIs

FDA's Center of Excellence in Regulatory Science and Innovation

- Collaborations between FDA and academic institutions through innovative research, training, and scientific exchanges
- Visit website for more information

Collaborative Communities

- Continuing forums in which private- and public-sector members work together on medical device challenges
- Can invite CDRH to participate
- Visit website for more information
- Email questions to CDRHCollabCommunities@fda.hhs.gov

NoDEx

FDA Network of Digital Health Experts

- A pool of vetted experts who share knowledge and experience regarding digital health issues with FDA staff on an as-needed basis
- Visit website for more information on participating

FDA Digital Health Inbox

- Help navigating the FDA's current policies on digital health products and providing informal feedback
- Visit website for more information
- Email questions to digitalhealth@fda.hhs.gov

Resources for Regulatory Science Researchers

FDA-funded mechanisms for Regulatory Science Research

- Regulatory Science is the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of all FDA-regulated products.
  - FDA's Advancing Regulatory Science webpage

- FDA's Office of Regulatory Science and Innovation released a report in 2022: Advancing Regulatory Science at FDA: Focus Areas of Regulatory Science
  - Public health preparedness and response
  - Increasing choice and competition through innovation
  - Unleashing the power of data
  - Empowering patients and consumers

- Mechanisms for research at FDA
  - Broad Agency Announcement (BAA)
  - Centers of Excellence in Regulatory Science and Innovation (CERSIs)

CDRH-funded mechanisms for Regulatory Science Research

FDA

- CDRH Regulatory Science Priorities: CDRH's regulatory science priorities serve as a catalyst to improve the safety, effectiveness, performance, and quality of medical devices and radiation-emitting products, and to facilitate introducing innovative medical devices into the marketplace (*see table*)

- Digital Health Research and Partnerships

- In addition to BAA and CERSI, CDRH may interact with researchers through:
  - Public-Private partnerships
  - Collaborative communities
  - Contracts and/or agreements
  - Grants

www.fda.gov/digitalhealth

Area	Priority
"Big Data"	Leverage "Big Data" for regulatory decision-making
Biocompatibility	Modernize biocompatibility and biological risk evaluation of device materials
Real-world evidence	Leverage real-world evidence and employ evidence synthesis across multiple domains in regulatory decision-making
Clinical performance	Advance tests and methods for predicting and monitoring medical device clinical performance
Clinical trial design	Develop methods and tools to improve and streamline clinical trial design
Computational modeling	Develop computational modeling technologies to support regulatory decision-making
Digital Health and cybersecurity	Enhance the performance of Digital Health and medical device cybersecurity
Healthcare-associated infections	Reduce healthcare associated infections by better understanding the effectiveness of antimicrobials, sterilization and reprocessing of medical devices
Patient input	Collect and use patient input in regulatory decision-making
Precision medicine and biomarkers	Leverage precision medicine and biomarkers for predicting medical device performance, disease diagnosis, and progression

Spotlight: Digital Health Regulatory Science Opportunities

Issued in October 2022

The Spotlight highlights important scientific research areas in digital health aimed at:

- advancing patient engagement;

- leveraging connectivity; and

- improving health care through software.

Research Areas   *Advanced Manufacturing Technologies, Artificial Intelligence/Machine Learning, Cybersecurity, Digital Imaging, Interoperability, Medical Extended Reality, Patient Generated Health Data, and Wireless Connectivity*

How do I engage with CDRH?

If you have questions about regulatory science and the CDRH:

CDRHRegScience@fda.hhs.gov

Resources for Device Developers

Interactive Overview of Digital Health Policies

FDA

The **Digital Health Policy Navigator** helps product developers consider whether a software function is potentially subject to or the focus of FDA's regulatory oversight as a device.

Digital Health Policy Navigator

Interactive questions guide product developers to one of four different outcomes, reflecting policies described in relevant digital health guidances.

Interactive Questions

Step 1: Intended for a medical purpose?

Step 2: Intended for administrative support of a health care facility?

Step 3: Intended for maintaining or encouraging a healthy lifestyle?

Step 4: Intended to serve as electronic patient records?

Step 5: Intended for transferring, storing, converting formats, or displaying data and results?

Step 6: Intended to provide clinical decision support?

Step 7: Does the Device Software Function and Mobile Medical Application Guidance apply?

Navigator Outcomes

Icon	Outcome
🚫	LIKELY NOT A MEDICAL DEVICE
✓	LIKELY FDA INTENDS TO EXERCISE ENFORCEMENT DISCRETION
FDA	LIKELY THE FOCUS OF FDA'S REGULATORY OVERSIGHT
➤	Your product may be a device. Go to Step #.

www.fda.gov/digitalhealth

Resources

FDA

To learn more about device regulation, we encourage you to visit the [Device Advice](#) webpage.

For helpful resources on deices, biologicals, and drugs, please see the following resources:

- [CDRH Learn](#)
- [CBER Contacts](#)
- [CDER Learning and Education](#)

How do I engage with CDRH?

Engage with the FDA early in development!

Informal inquiries with relevant CDRH inboxes for device developers:
- **Digital Health Inbox** (Digital Health Policy Questions): digitalhealth@fda.hhs.gov
- Device Determination Inbox (Informal Device Determination): DeviceDetermination@fda.hhs.gov
- Division of Industry and Consumer Education (General Questions): DICE@fda.hhs.gov, 1(800) 638-2041

Further Questions or Feedback

www.fda.gov/digitalhealth

DigitalHealth@fda.hhs.gov

Gloria Nyankima

Digital Health Policy Advisor, Digital Health Center of Excellence (DHCoE)

Center for Devices and Radiological Health (CDRH),

U.S. Food and Drug Administration (FDA)

Email: gloria.Nyankima@fda.hhs.gov