DHCOE: UPDATES & INITIATIVES

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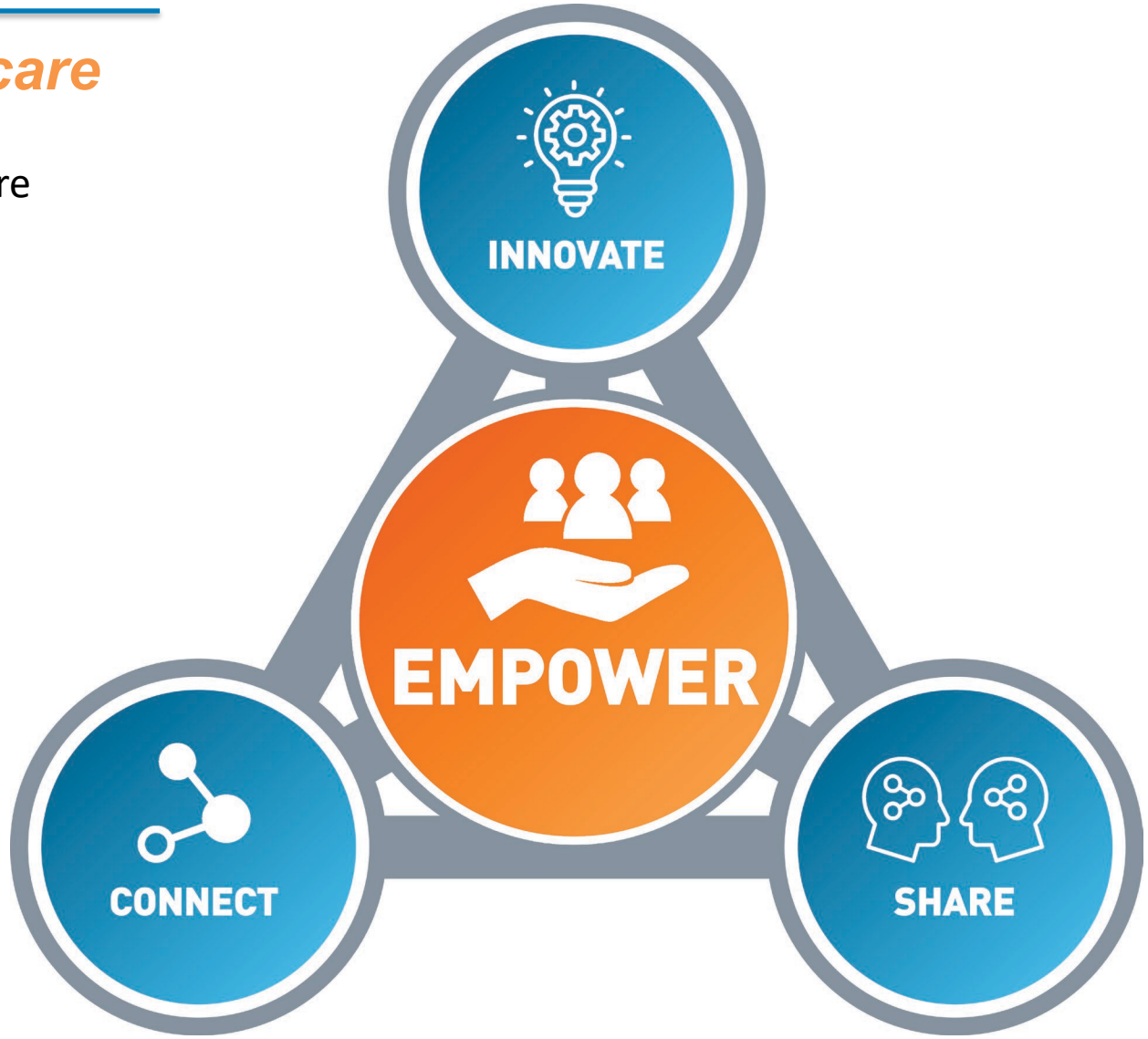
FDA's Digital Health Center of Excellence

Empowering All to Advance Healthcare

Our goal: Empower stakeholders to advance health care by fostering responsible and high-quality digital health innovation.

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.



The DHCoE Continues to Grow

Our team brings extensive experience:

120+ YEARS	105+ YEARS	85+ YEARS	80+ YEARS	70+ YEARS	50+ YEARS	15+ YEARS
DIGITAL HEALTH INDUSTRY	FDA	ACADEMIA	OTHER INDUSTRY (NON-DIGITAL HEALTH)	MEDICAL	NONPROFIT	PATIENT ADVOCACY

Current as of June 2023

Our work extends across the FDA and beyond the Agency, both nationally and internationally

External to FDA

- ✓ Provide clarity on regulation
- ✓ Advance international harmonization on device regulatory policy
- ✓ Facilitate and build strategic partnerships
- ✓ Communicate FDA research interests
- ✓ Advance digital health device international standards

FDA-Wide

- ✓ Provide DH expertise across the Agency
- ✓ Offer training opportunities for FDA staff
- ✓ Disseminate shared resources
- ✓ Foster collaboration across FDA in common interest areas
- ✓ Facilitate synergies in regulatory science research in DH

Medical Device Focus

- ✓ Set/lead strategic direction and launch initiatives in DH
- ✓ Establish and promote best practices
- ✓ Enable efficient, transparent, and predictable product review with consistent evaluation quality
- ✓ Build new capacity to oversee and leverage DH technologies including shared resources
- ✓ Coordinate the development of cross cutting DH policies

Internal Collaboration Touchpoints

FDA Digital Health Advisory Board

Senior leaders from FDA centers advising the DHCoE to identify and drive coordination on topic areas of work of common interest

Subcommittees

Reporting to the DHAB, subcomittees are charged to coordinate efforts on digital health topic areas affecting submissions to FDA.

Current Subcommittees:

- AI/ML
- Digital Health Technology evaluation

CDRH Digital Health Steering Committee

CDRH level steering committee established in 2015 to consistently apply policies to novel medical device submissions related to digital health technologies including software and identify policy development needs.

Program Directors Forum

Forum that brings program directors representing efforts within CDRH to stay coordinated and drive synergy within CDRH on digital health including cybersecurity, advanced manufacturing and patient science.

Training and Education

Forums bringing speakers and thought leaders to FDA.

CDRH's Digital Health Center of Excellence

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

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 final 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.**

We provide digital health stakeholders ongoing clarity through guidance

15 Digital Health Guidance Documents Published Since FY2018

GUIDANCE DOCUMENT

Content of Premarket Submissions for Device Software Functions

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT

GUIDANCE DOCUMENT

Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions

GUIDANCE DOCUMENT

Cybersecurity in Medical Devices: Refuse to Accept Policy for Cyber Devices and Related Systems Under Section 524B of the FD&C Act

GUIDANCE DOCUMENT

Clinical Decision Support Software

GUIDANCE DOCUMENT

Policy for Device Software Functions and Mobile Medical Applications

GUIDANCE DOCUMENT

Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices

GUIDANCE DOCUMENT

Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions

DRAFT

GUIDANCE DOCUMENT

Digital Health Technologies for Remote Data Acquisition in Clinical Investigations

Draft Guidance for Industry, Investigators, and Other Stakeholders

GUIDANCE DOCUMENT

Multiple Function Device Products: Policy and Considerations

GUIDANCE DOCUMENT

Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act

GUIDANCE DOCUMENT

General Wellness: Policy for Low Risk Devices

GUIDANCE DOCUMENT

Off-The-Shelf Software Use in Medical Devices

GUIDANCE DOCUMENT

Medical Device Accessories - Describing Accessories and Classification Pathways

GUIDANCE DOCUMENT

Software as a Medical Device (SAMD): Clinical Evaluation

GUIDANCE DOCUMENT

Deciding When to Submit a 510(k) for a Software Change to an Existing Device

www.fda.gov/digitalhealth

FDA's Collaborative Patient-Centered Approach to AI-Enabled Devices

2019	2020	2021	2022	2023
• Published AI/ML-SaMD Discussion Paper • First joined Collaborative Community related to AI/ML	• Public Workshop on AI/ML in Radiological Imaging • PEAC Meeting on Patient Trust in AI/ML Devices	• Published AI/ML Medical Device Software Action Plan • Posted List of Currently Marketed AI/ML Devices • Public Workshop on Transparency of AI/ML Devices • Published Good Machine Learning Practice: Guiding Principles	• Contributed to IMDRF's Key Terms & Definitions: Machine Learning Enabled Medical Devices • Published Clinical Decision Support (CDS) Final Guidance • Updated List of Currently Marketed AI/ML Devices • Recognized new Consensus Standard on AI/ML	• Published Predetermined Change Control Plan for AI/ML Devices Draft Guidance • Updated List of Currently Marketed AI/ML Devices • Published Predetermined Change Control Plans for Machine Learning-Enabled Medical Devices: Guiding Principles

We recognize that by working collaboratively with stakeholders we can lay out a clear path toward building a proactive patient-centered approach to the development and use of AI-enabled devices.

Predetermined Change Control Plans in 2024

CDRH Proposed Guidances for Fiscal Year 2024 (FY2024)

A-List: Prioritized Guidance Documents that CDRH Intends to Publish in FY2024

Final Guidance Topics

- Remanufacturing of Medical Devices
- Medical Device Shortages - Implementation of Section 506J of the Federal Food, Drug, and Cosmetic Act
- Marketing Submission Recommendations for A Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions

Draft Guidance Topics

- Artificial Intelligence/Machine Learning (AI/ML)-enabled Device Software Functions: Lifecycle Management Considerations and Premarket Submission Recommendations
- Select Updates for the 506J Guidance: Voluntary Notifications of Discontinuance or Interruption of Device Manufacture
- Select Updates for Premarket Cybersecurity Guidance: Cyber Devices
- Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices (revision)
- Pulse Oximeters – Assessing Clinical and Scientific Evidence (revision)
- Predetermined Change Control Plans for Medical Devices

How Can I Collaborate with the DHCoE?

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

EXCITING NEWS!

FDA's DHAC
was formed October 12, 2023

What is an Advisory Committee?

*"The FDA has **49** technical and scientific advisory committees and panels that include scientific experts and members of the public."*

The FDA uses advisory committees to:

- Get advice from experts who work outside the agency.
- Work toward an open and transparent government.
- Encourage patients, health care providers, and other interested people to share their views during the open public hearing or by submitting comments to the open docket.

https://www.fda.gov/consumers/consumer-updates/advisory-committees-give-fda-critical-advice-and-public-voice

Interested in serving or nominating a representative to serve as a voting or non-voting member?

How to Apply to become a member of the DHAC

Electronically:

FDA Advisory Committee Membership Portal:

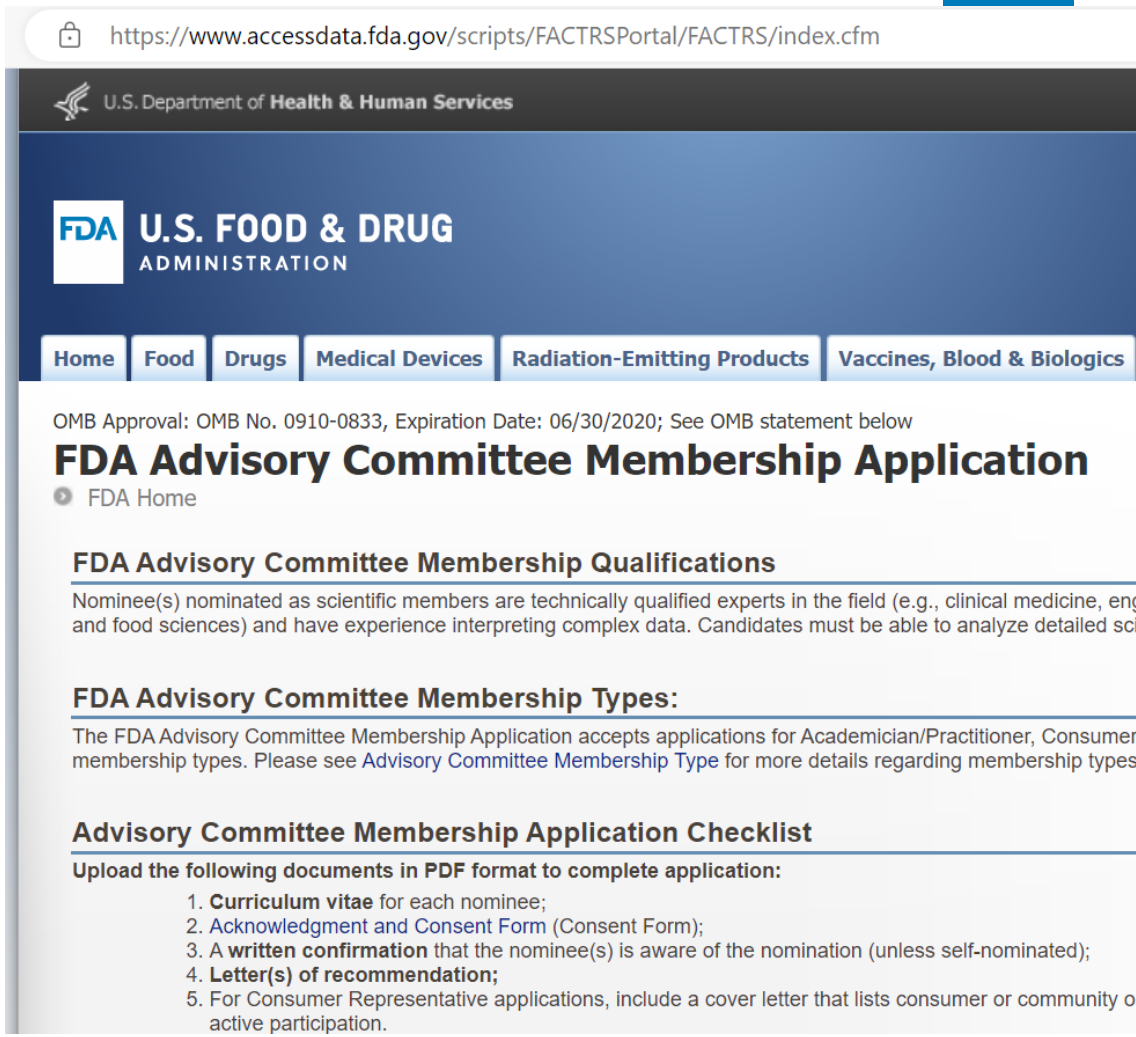
https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm

Mail:

Advisory Committee Oversight and Management Staff
Food and Drug Administration
10903 New Hampshire Ave.
Bldg. 32, Rm. 5103
Silver Spring. 20993-0002.

Apply by:

December 12, 2023



Further Questions or Feedback

www.fda.gov/digitalhealth

DigitalHealth@fda.hhs.gov

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