FDA's Digital Health Center of Excellence: *An opportunity to collaborate*

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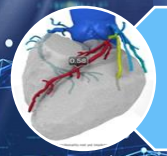
Patients are at the Heart of What We Do

CDRH Vision

Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance first in the world

Digital Health Technology

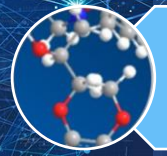
"A system that uses computing platforms, connectivity, software, and sensors for healthcare and related uses"*



Used as a medical product

Incorporated into a medical product (include a pharmacologic product)

Used to develop a medical product



Used to study a medical product

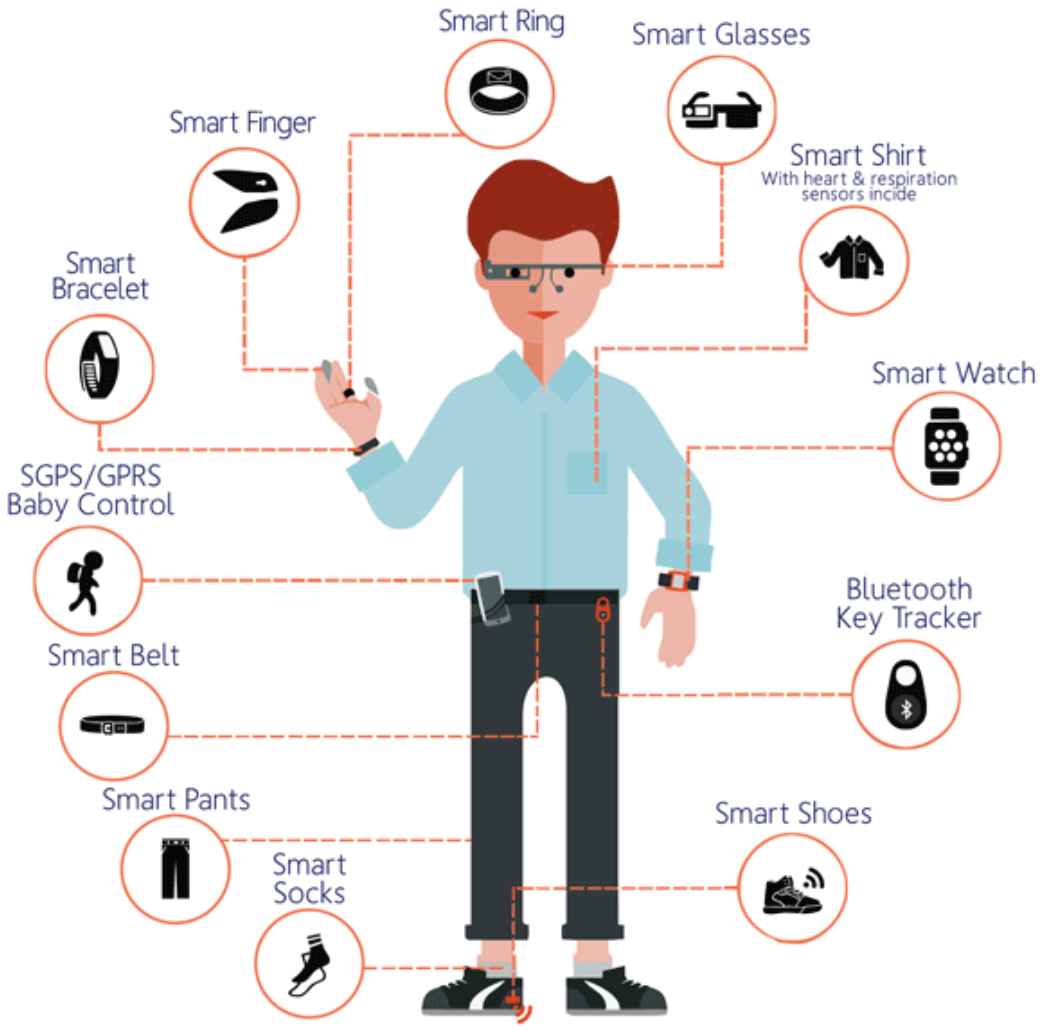
Used as a companion or adjunct to a medical product, including diagnostics and therapeutics.

*Definition from FDA-NIH BEST Glossary. Available at https://www.ncbi.nlm.nih.gov/books/NBK338448/

Digital Health Technologies (DHTs)

Digital tools can provide consumers with valuable health information.

Consumers who are better informed about health make better decisions.

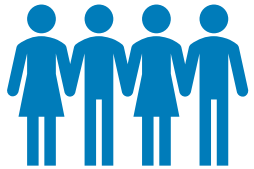


What qualifies as a digital health product?

What digital health technologies need regulation?

DHTs can be used in a variety of ways when evaluating medical products

Remote data collection



Clinical investigation enrichment strategies

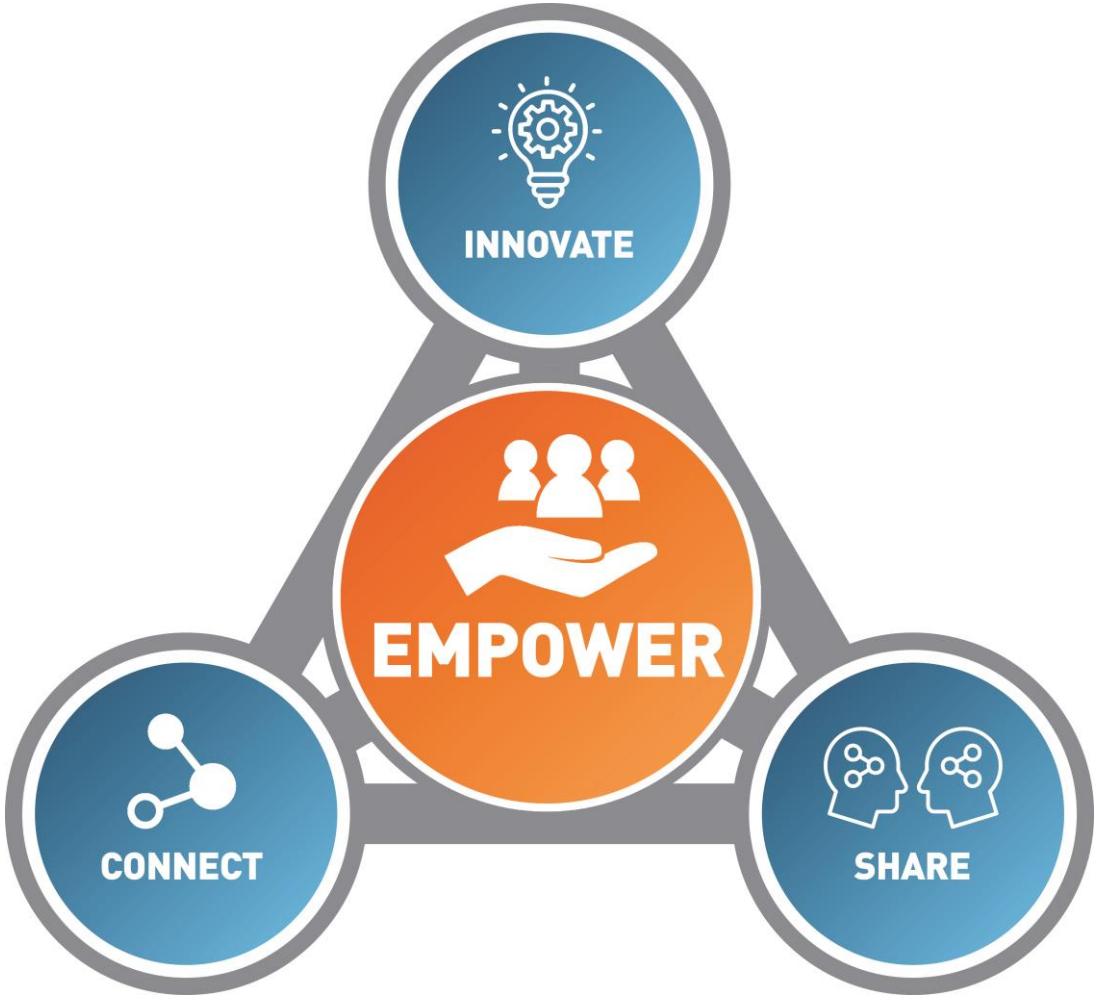
Electronic informed consent

Fostering Responsible Innovation

Launched in 2020

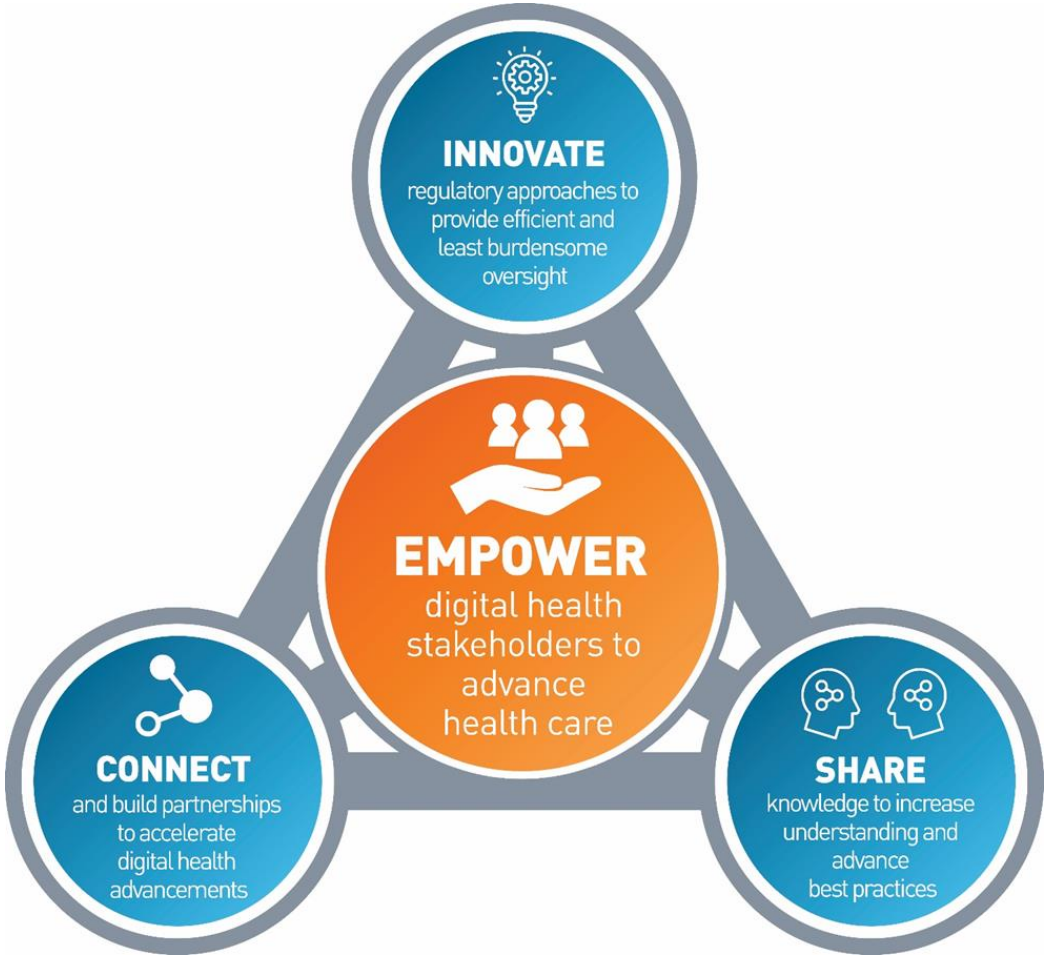
FDA's Digital Health Center of Excellence

- Part of the planned evolution of the digital health program
- Aligning strategy with implementation
- Driving synergy for digital health efforts
- Preparing FDA for the digital health future



CDRH Digital Health Center of Excellence

Empowering All to Advance Healthcare



- 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 Health Data

DHCoE Goals and Objectives

In support of the DHCoE mission and vision, the below three overarching goals illustrate the DHCoE's desired achievements for the next three years. Under each goal are measurable objectives that the DHCoE plans to reach in pursuit of the three goals.

Goal 1: Foster digital health-focused collaboration and coordination within and beyond FDA

Objective 1: Forge new and fortify existing external partnerships that support the DHCoE's mission and vision

Objective 2: Work with other FDA Centers and Offices to align and integrate digital health work

Goal 2: Promote awareness, transparency, and consistent application of digital health regulatory policies within and beyond FDA

Objective 1: Equip FDA staff with the skills, knowledge, and tools needed to consistently identify and apply digital health regulatory policies

Objective 2: Provide external stakeholders with information that introduces FDA's digital health processes, policies, and communication channels

Goal 3: Pioneer the development and enhancement of digital health regulatory paradigms that continue to uphold FDA standards for safety and efficacy

Objective 1: Clarify existing regulations and develop new policies, tools, and review approaches

Objective 2: Work with international regulatory bodies to develop and streamline digital health regulatory paradigms

DHCoE: What We Do

External to FDA Partner•Coordinate•Voice

- ✓ 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 Support•Align•Promote•Amplify

- ✓ 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 Build•Coordinate

- ✓ 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

DHCoE: Coordinating Operations

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 Advisory Board, subcomittees are charged to coordinate efforts on digital health topic areas affecting submissions to FDA

Current topics identified:

- AI/ML
- Digital Health technology

Digital Health Steering Committee

CDRH level steering committee estbliahsed 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 withing CDRH on digital health including cybersecurity, advanced manufacturing and patient science.

Training and Education

Forums bringing speakers and though leaders to FDA.

Digital Health Collaborations

Collaboration efforts focus on digital health technology, artificial intelligence / machine learning, health equity, measurement, and real-world evidence

FDA's Centers of Excellence in Regulatory Science and Innovation

CERSI Johns Hopkins University | CERSI UCSF-Stanford | CERSI University of Maryland | CERSI Yale-Mayo Clinic

CERSI's are collaborations between FDA and academic institutions to advance regulatory science through innovative research, training, and scientific exchanges.

DATAcc Digital Health Measurement Collaborative Community

MedTechColor

XAVIER HEALTH

NEST Collaborative Community An initiative of MDIC

CCOI

Pathology Innovation Collaborative Community PICC The Alliance for Digital Pathology

Collaborative Communities are continuing forums in which private- and public-sector members, which can include the FDA, work together on medical device challenges to achieve common objectives and outcomes

Other Digital Health Standards Activities

The DHCoE is also focusing on the following standards work:

Develop a formal DHCoE standards engagement strategy strengthening our partnership with the Standards and Conformity assessment program (S-CAP)

Develop better digital health tools for FDA reviewers

Work to ensure digital health standards have regulatory utility

DHCoE Standards Partnerships

We strive to be as innovative with our approach to digital health standards efforts as the digital health devices being dreamed up for tomorrow

- Partner with other Federal Agencies
- Ensure different parts work together efficiently

Good Machine Learning Practice (GMLP)

- Standards Development:
  - IEEE AI Medical Device Working Group P2801
  - ISO/IEC SubCommittee on AI 42 (ISO/ IEC JTC 1/SC 42)
  - AAMI/ BSI Initiative on AI in Medical Technology
- Collaborative Communities:
  - Xavier AI World Consortium Collaborative Community
  - Collaborative Community on Ophthalmic Imaging
  - Pathology Innovation Collaborative Community
- Other Collaborations:
  - IMDRF AI Medical Devices WG

Xavier AI World Consortium Collaborative Community

Collaborative Community on Ophthalmic Imaging

Pathology Innovation Collaborative Community

Good Machine Learning Practice Principles

U.S. FOOD & DRUG ADMINISTRATION | Health Canada Santé Canada | Medicines & Healthcare products Regulatory Agency

We envision these guiding principles may be used to:

- Adopt good practices that have been proven in other sectors;
- Tailor practices from other sectors so they are applicable to medical technology and the health care sector; and
- Create new practices specific for medical technology and the health care sector.

Good Machine Learning Practice for Medical Device Development: Guiding Principles	
Multi-Disciplinary Expertise are Leveraged Throughout the Total Product Life Cycle	**Good Software Engineering and Security Practices are Implemented**
Clinical Study Participants and Data Sets are Representative of the Intended Population	**Training Data Sets are Independent of Test Sets**
Selected Reference Datasets are Based Upon Best Available Methods	**Model Design is Tailored to the Available Data and Reflects the Intended Use of the Device**
Focus is Placed on the Performance of the Human-AI Team	**Testing Demonstrates Device Performance during Clinically Relevant Conditions**
Users are Provided Clear, Essential Information	**Deployed Models are Monitored for Performance and Re-training Risks are Managed**

https://www.fda.gov/medical-devices/software-medical-device-samd/good-machine-learning-practice-medical-device-development-guiding-principles

Patient-Centered Approach Incorporating Transparency to Users

AI/ML-enabled devices have unique considerations that necessitate a proactive patient-centered approach:

- that takes into account issues including usability, equity, trust, and accountability
- that promotes transparency to all users and to patients more broadly

Patient Engagement Advisory Committee (PEAC) Meeting held Oct 2020

Workshop on Transparency of AIML-enabled devices held Oct 2021

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

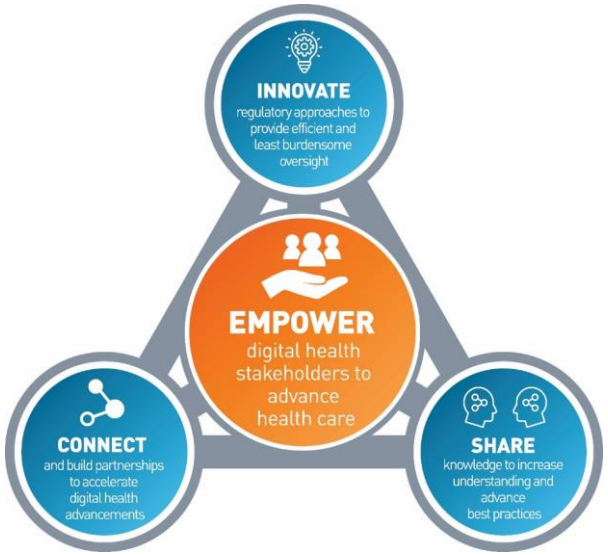
FDA Network of Digital Health Experts

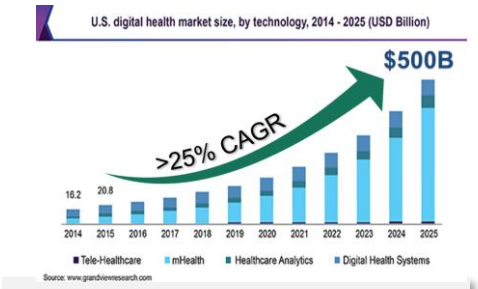
- A pool of vetted experts who share knowledge and experience regarding digital health issues with FDA staff on an as-needed basis
- Visit website for more information on participating

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

Highlights





https://www.grandviewresearch.com/industry-analysis/digital-health-market

FDA's Digital Health Center of Excellence

- Fostering responsible and high-quality digital health innovation

Ongoing Clarity

- **12 Digital health guidance documents** published since FY 2018

Select Accomplishments

26	80+	2500+	<70	**Notable authorizations for:**
Public Documents	Access to experts Network of Digital Health Experts	Inquiries addressed since FY18	FDA Days to decision for 510(k) with DH content	Substance use disorder Opioid use disorder Diabetes management

Internationally Harmonized framework for Software as a Medical Device (SaMD)

- Foundational vocabulary (2013)
- Risk Framework (2014)
- Regulatory QMS (2015)
- SaMD Clinical Evaluation

Pre-Certification Program

- Move from **episodic** oversight to **continuous** oversight that **enables trust** in the organization using a pragmatic check-in with **real-world performance** data

AI/ML

- AI/ML-SaMD Discussion Paper and participation in AI/ML-related Collaborative Community (2019)
- Public Workshop and PEAC meeting (2020)
- AI/ML Plan of Action (2021)
- Published list of currently marketed AI/ML-enabled medical devices (2021)