Digital Health Center of Excellence
Empowering digital health stakeholders to advance health care
Digital Health Center of Excellence (DHCoE)

- Digital Health Landscape and Areas of Application (Spectrum)
- Goals and Outcomes
- Current Areas of Focus
- Planned Services & Launch Plan
Digital Health

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

Healthy living  Prevention  Diagnosis  Treatment Recovery  Home care

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

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Digital Health Technology

Convergence of computing power, connectivity, sensors, and software used in healthcare.

- 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.
Why a Digital Health Center of Excellence?

- Part of the planned evolution of the digital health program
- Intent to
  - Drive synergy for digital health efforts
  - Align strategy with implementation
  - Prepare the FDA for the digital health future
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.
Anticipated Outcomes

- Strategically advance science and evidence for digital health technologies that meets the needs of stakeholders.
- Efficient access to a highly specialized expertise, knowledge, and tools to accelerate access to digital health technology.
- Aligned regulatory approach to harmonize international regulatory expectations and industry standards.
- Increased awareness and understanding of digital health trends.
- Consistent application of digital health technology policy and oversight approaches.
- Reimagined medical device regulatory paradigm tailored for digital health technologies.
DHCoE Functional Areas

Coordinated by Digital Health Center of Excellence
Dedicated functions + Virtual functions

Regulatory Innovation/Strategic Initiatives
- Pre-Cert
- Wearables
- Interoperability

DH Technology Support
- Submission policy support
- Wearables
- Software development practices
- Software and digital health standards

Advancing Regulatory Science
- Digital Pathology
- Patient-Generated Data
- Virtual Reality/Augmented Reality

Advanced Manufacturing
- Case for Quality (Software in Manufacturing)
- Software used to manufacture medical device
- Digital twin for manufacturing

DHCoE Operations & Coordination/Partnerships
- Internal: Steering Committee, Advisory Group
- External: collaborations and partnerships

DH Policy Development/Support
- Policy development and support
- DH inquiries
- Guidance/Policy development
- Submission support

Regulatory Review Support
- Day – day review support for OHTs
- Implement DH policies
- Training for reviewers
- Implement competency tiers

Advanced Clinical Studies and RWE
- In silico modeling
- Use of RWE in DH devices
- RWE from digital health technology

AI/ML in Medical Products
- Policy development and support
- IMDRF collaborations
- External engagement/collaboration

Medical Device Cybersecurity
- Policy development and support
- IMDRF collaborations
- External engagement/collaboration

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DHCoE Concept of Operations

**FDA DH Advisory Group**
- **Objectives:**
  - Provide Advice to DHCoE
  - Identify common interest topics
  - Develop FDA regulatory science agenda
  - Identify and staff strategic partnerships

**CDRH Digital Health Steering Committee**
- **Objectives:**
  - Provide input to DH policy agenda
  - Provide input to horizon scanning
  - Align external partnerships agenda
  - Provide input to regulatory science agenda

**DHCoE Operations & Coordination/Partnerships**

**Aligning strategies within FDA**

**Aligning strategies within CDRH**

**Coordinating DH efforts**

**Dedicated DHCoE Resources**
- DH Policy support
- DH Technology Support
- Regulatory review support
- Advancing Regulatory Science
- AL/ML in medical products
- Regulatory innovation/Strategic initiatives
- Medical Device Cybersecurity
- Advanced Manufacturing
- Advanced clinical studies and RWE

**Virtual DHCoE Resources**

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DHCoE Services

**CDRH Specific**

- Set and lead strategic direction in digital health
- Identify and coordinate regulatory science priorities for CDRH
- 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
- Create more shared resources
- Coordinate the development of cross cutting DH policies
DHCoE Services

External to FDA  Partner • Coordinate • Voice

FDA - Wide  Support • Align • Promote • Amplify

CDRH Specific  Lead • Build • Coordinate
DHCoE Services

- 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

- 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 digital health
- Leverage, share, and avoid duplication of work
- Promote and showcase existing work at the Centers
DHCoE Roadmap

Following is our initial 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

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Further Questions or Feedback

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