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

www.fda.gov/digitalhealth
Convergence of computing power, connectivity, sensors, and software used in healthcare.

<table>
<thead>
<tr>
<th>Healthy living</th>
<th>Prevention</th>
<th>Diagnosis</th>
<th>Treatment Recovery</th>
<th>Home care</th>
<th>Management</th>
</tr>
</thead>
</table>

- 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
Our goal: Empower stakeholders to advance healthcare 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

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

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

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

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

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

www.fda.gov/digitalhealth
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

**DHCoE Operations & Coordination/Partnerships**

**Aligning strategies within FDA**

**Aligning strategies within CDRH**

**Coordinating DH efforts**

**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

**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**
DHCoE Services

- 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

**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 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

Raise Awareness and Engage Stakeholders

Build Partnerships

Build and Sustain Capacity
Further Questions or Feedback

www.fda.gov/digitalhealth

DigitalHealth@fda.hhs.gov
Bakul Patel, (Bakul.Patel@fda.hhs.gov)
Director, Digital Health Center of Excellence