U.S. FOOD & DRUG ADMINISTRATION

Welcome to today's FDA/CDRH Listening Session

Thank you for your patience while additional time is provided for participants to join the call.

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U.S. FOOD & DRUG ADMINISTRATION

Digital Health Center of Excellence (DHCoE) Listening Session

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Center for Devices and Radiological Health (CDRH)

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Objectives

- Provide an overview of the FDA's Digital Health Center of Excellence (DHCoE)
  - Goals
  - Outcomes
  - Areas of Focus
  - Roadmap
- Opportunity to gain insight and input from stakeholders as the Digital Health Center of Excellence is built and begins to prioritize efforts while maintaining standards of safety and effectiveness

Digital Health Center of Excellence

Empowering digital health stakeholders to advance health care

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

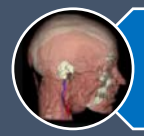
Digital Health Technology

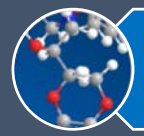
Healthy living	Prevention	Diagnosis	Treatment Recovery	Home care	Management

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
  - Protect patients and maintain the FDA standards of safety and effectiveness

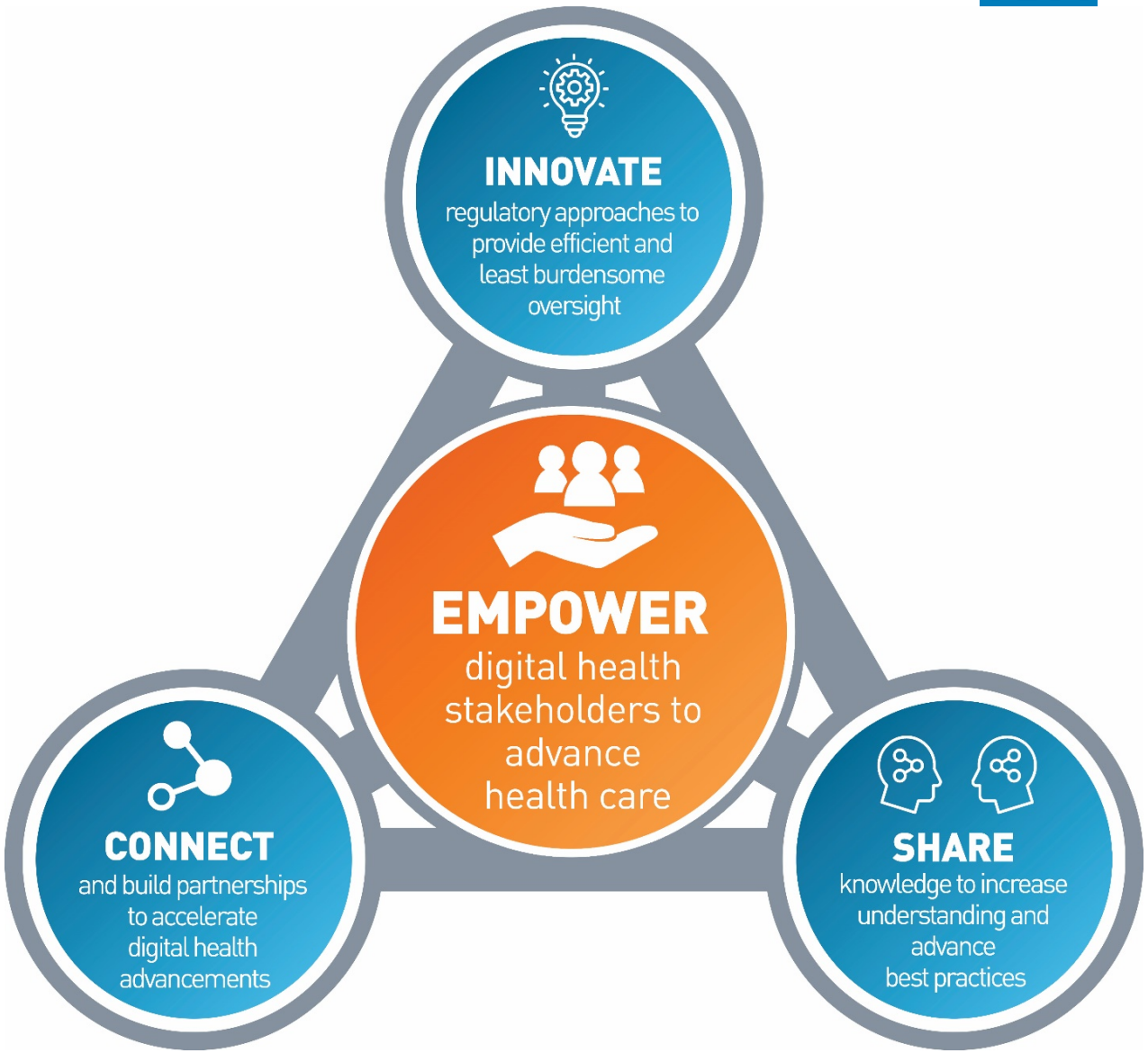
FDA's Digital Health Center of Excellence

Empowering All to Advance Healthcare

Our goal: Empower stakeholders to advance health care by fostering responsible and high-quality digital health innovation that meets FDA standards of safety and effectiveness.

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 that maintain standards of safety and effectiveness.
- 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.

Digital Health Center of Excellence Operations

Unified and collaborative environment; applying best practices, conducting research, support, training for digital health technologies.

DIGITAL HEALTH CENTER OF EXCELLENCE

Supplementing bench strength @ FDA

POLICY & TECH SUPPORT

- Regulatory submissions support
- Policy Implementation and intelligence
- Identify and develop staff training
- Access to digital health experts

STRATEGIC PARTNERSHIP

- Harmonization through IMDRF

IMDRF International Medical Device Regulators Forum

- Industry partnership
- Academic partnership
- Federal partnerships:

HealthIT.gov FC

STRATEGIC INITIATIVES

- Reimagining a new regulatory paradigm
- Interoperability

POLICY DEVELOPMENT

- Software as a Medical Device
- Artificial Intelligence / Machine Learning
- Software Policies under 21st Century Cures Act
- Standards and best practices

DHCOE OPERATIONS

- Governance, operations
  - CDRH DHSC
  - FDA Digital Health Advisory Board
- Regulatory Research / Science coordination
- Strategy alignment and coordination

Functions

Resources coordinated by Digital Health Center of Excellence

Dedicated DHCoE Resources + Virtual DHCoE Resources

DH Policy Development/ support

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

DH Technology Support

- Submission support
- Wearables
- Software development practices
- Software and digital health standards
- External engagement

Regulatory innovation/Strategic initiatives

- Pre-Cert
- Wearables
- Interoperability
- Digital Biomarkers

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

Medical Device Cybersecurity

- Policy development and support
- IMDRF collaborations
- External engagement/ collaboration

Advancing Regulatory Science

- Digital Pathology
- Patient-Generated Data
- Virtual Reality/Augmented Reality

Regulatory review support

- Day – day review support
- Implement DH policies
- Training to front line review
- Implement competency tiers

Advanced Manufacturing

- Case for Quality (Software in Manufacturing)
- Software used to manufacture medical device
- Digital Twin
- Clearinghouse

Advanced clinical studies and RWE

- In silico modeling
- Use of RWE in DH devices
- RWE from digital health technology

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

Aligning strategies Within FDA

Aligning strategies Within CDRH

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

Coordinating DH efforts

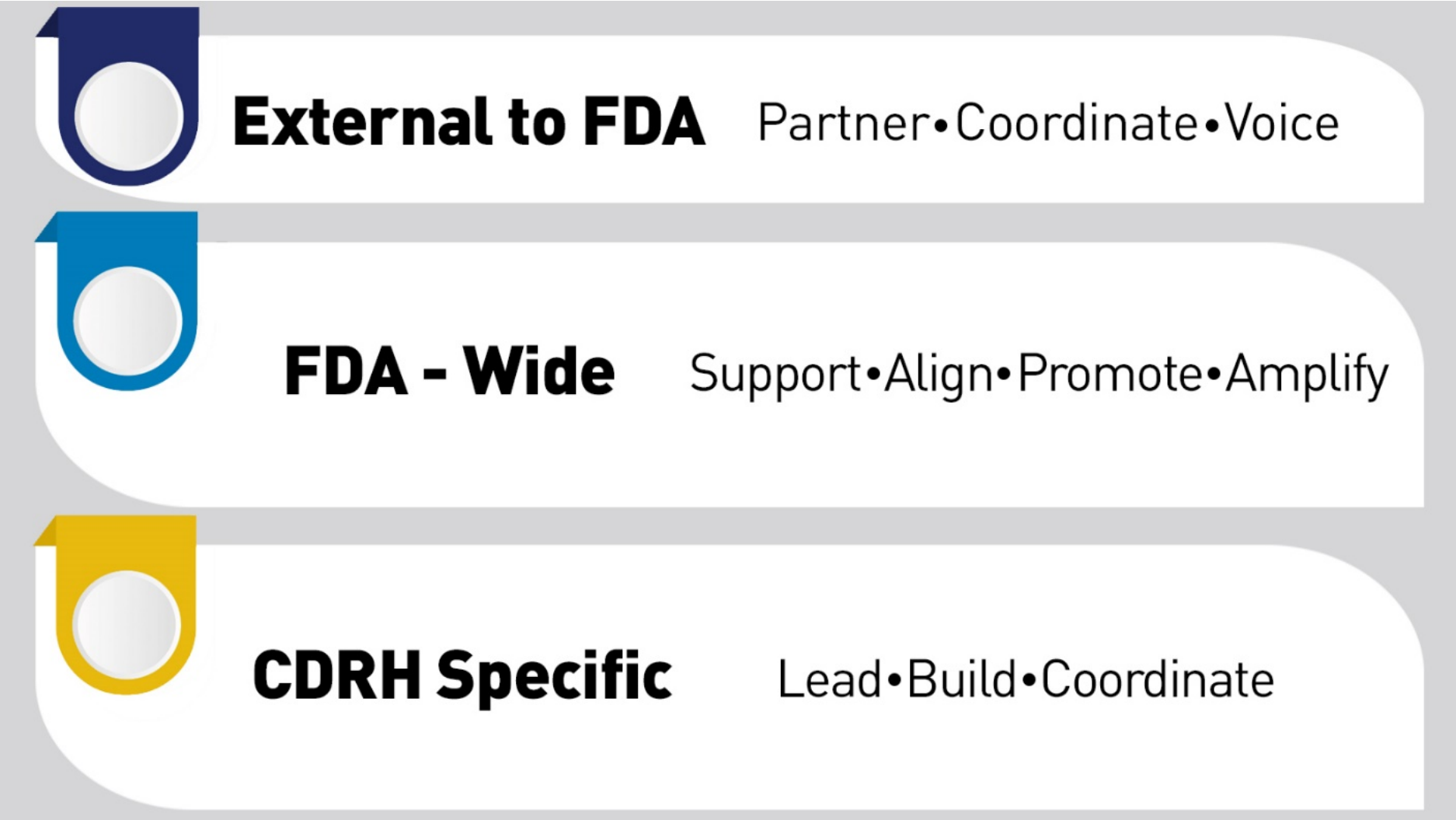
Dedicated DHCoE Resources

- DH Policy support
- DH Technology Support
- AL/ML in medical products
- Regulatory innovation /Strategic initiatives

Virtual DHCoE Resources

- Regulatory Review support
- Regulatory Science and Research
- Medical Device Cybersecurity
- Advanced Manufacturing
- RWE and Advanced clinical studies

Digital Health Center of Excellence Services



Digital Health Center of Excellence Services

- ✓ Set and lead strategic direction in digital health
- ✓ Launch strategic initiatives
- ✓ 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

Digital Health Center of Excellence Services

FDA - Wide Support•Align•Promote•Amplify

- ✓ Provide scientific 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

Digital Health Center of Excellence 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

Current Areas of Focus

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 Data	Digital Biomarkers	Digital Pathology	

Digital Health Center of Excellence Roadmap

Following is our roadmap for bringing the benefits of digital health to all Americans, efficiently and collaboratively:

Raise Awareness and Engage Stakeholders

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

Build Partnerships

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

Build and Sustain Capacity

Phase III: Amplify

Winter 2021 onwards

- Continued strategic partnership building and communication
- Update and implement regulatory framework for digital health
- Harmonization with other regulators

Further Questions or Feedback

www.fda.gov/digitalhealth

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http://www.fda.gov/training/cdrhlearn Under the Heading: Specialty Technical Topics; Sub heading: IT and Software

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