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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Passcode: 1421197
Digital Health Center of Excellence (DHCoE) Listening Session

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Director, Digital Health Center for Devices and Radiological Health (CDRH)

October 19, 2020
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.

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

Healthy living  Prevention  Diagnosis  Treatment Recovery  Home care

Leveraging computing power, sensors, connectivity and software
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</th>
<th>Recovery</th>
<th>Home care</th>
<th>Management</th>
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</thead>
<tbody>
<tr>
<td>Used as a medical product</td>
<td>Incorporated into a medical product (include a pharmacologic product)</td>
<td>Used to develop a medical product</td>
<td>Used to study a medical product</td>
<td>Used as a companion or adjunct to a medical product, including diagnostics and therapeutics.</td>
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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
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

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
- Industry partnership
- Academic partnership
- Federal partnerships:

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

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

Supplementing bench strength @ FDA

www.fda.gov/digitalhealth
<table>
<thead>
<tr>
<th>Functions</th>
<th>Resources coordinated by Digital Health Center of Excellence</th>
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<tbody>
<tr>
<td>DH Policy Development/ support</td>
<td>Dedicated DHCoE Resources + Virtual DHCoE Resources</td>
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<tr>
<td>• Policy development and support</td>
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<td>• DH inquiries</td>
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<td>• Submission support</td>
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<td>• Guidance/Policy Development</td>
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<td>DP Technology Support</td>
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<td>• Submission support</td>
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<td>• Wearables</td>
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<td>• Software development practices</td>
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<td>• Software and digital health standards</td>
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<td>• External engagement</td>
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<td>Regulatory innovation/Strategic initiatives</td>
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<td>• Pre-Cert</td>
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<td>• Wearables</td>
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<td>• Interoperability</td>
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<td>• Digital Biomarkers</td>
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<td>DHCoE Operations &amp; Coordination/ Partnerships</td>
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<tr>
<td>• Internal: Steering Committee, Advisory Group</td>
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<td>• External: collaborations and partnerships</td>
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<td>AI/ML in medical products</td>
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<td>• Policy development and support</td>
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<td>• IMDRF collaborations</td>
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<td>Medical Device Cybersecurity</td>
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<td>• External engagement/ collaboration</td>
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<td>Advancing Regulatory Science</td>
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<td>• Digital Pathology</td>
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<td>• Patient-Generated Data</td>
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<td>• Virtual Reality/Augmented Reality</td>
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<td>Regulatory review support</td>
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<td>• Day – day review support</td>
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<td>• Implement DH policies</td>
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<td>• Training to front line review</td>
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<td>• Implement competency tiers</td>
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<td>Advanced Manufacturing</td>
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<td>• Case for Quality (Software in Manufacturing)</td>
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<td>• Software used to manufacture medical device</td>
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<td>• Digital Twin</td>
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<td>• Clearinghouse</td>
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<td>Advanced clinical studies and RWE</td>
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<td>• In silico modeling</td>
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<td>• Use of RWE in DH devices</td>
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<td>• RWE from digital health technology</td>
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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

Dedicated DHCoE Resources

- DH Policy support
- DH Technology Support
- Regulatory Review support
- Regulatory Science and Research
- AL/ML in medical products
- Regulatory innovation/Strategic initiatives
- Medical Device Cybersecurity
- Advanced Manufacturing
- RWE and Advanced clinical studies

Virtual DHCoE Resources

Coordinating DH efforts

Aligning strategies Within FDA

Aligning strategies Within CDRH
Digital Health Center of Excellence Services

**External to FDA**
- Partner
- Coordinate
- Voice

**FDA - Wide**
- Support
- Align
- Promote
- Amplify

**CDRH Specific**
- Lead
- Build
- Coordinate
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

- 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

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Following is our 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

#### Build Partnerships

#### Build and Sustain Capacity
Further Questions or Feedback

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Center for Devices and Radiological Health, U.S. Food and Drug Administration

Slide Presentation, Transcript and Webinar Recording will be available at:
http://www.fda.gov/training/cdrhlearn Under the Heading: Specialty Technical Topics; Sub heading: IT and Software

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