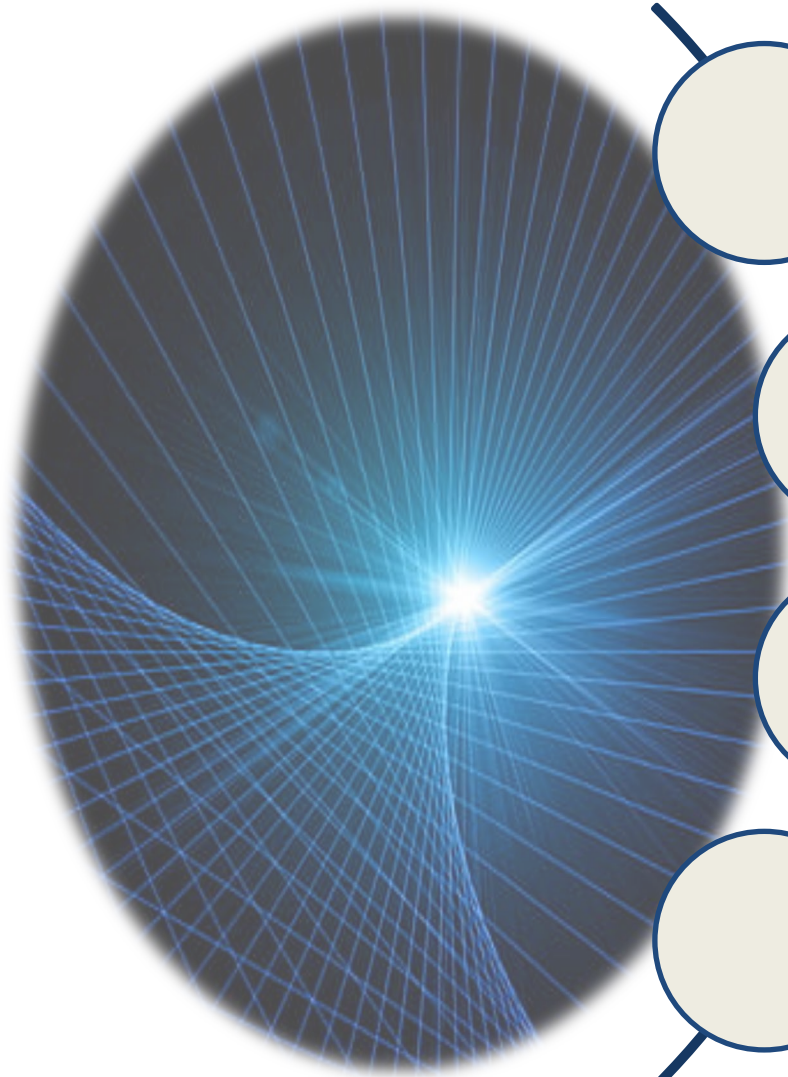


# Digital Health Center of Excellence

Empowering digital health stakeholders to advance health care



# Digital Health Center of Excellence (DHCoE)



# 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***



# Digital Health Technology

Healthy living

Prevention

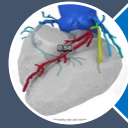
Diagnosis

Treatment Recovery

Home care

Management

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



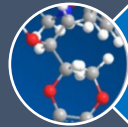
Used as a medical product



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



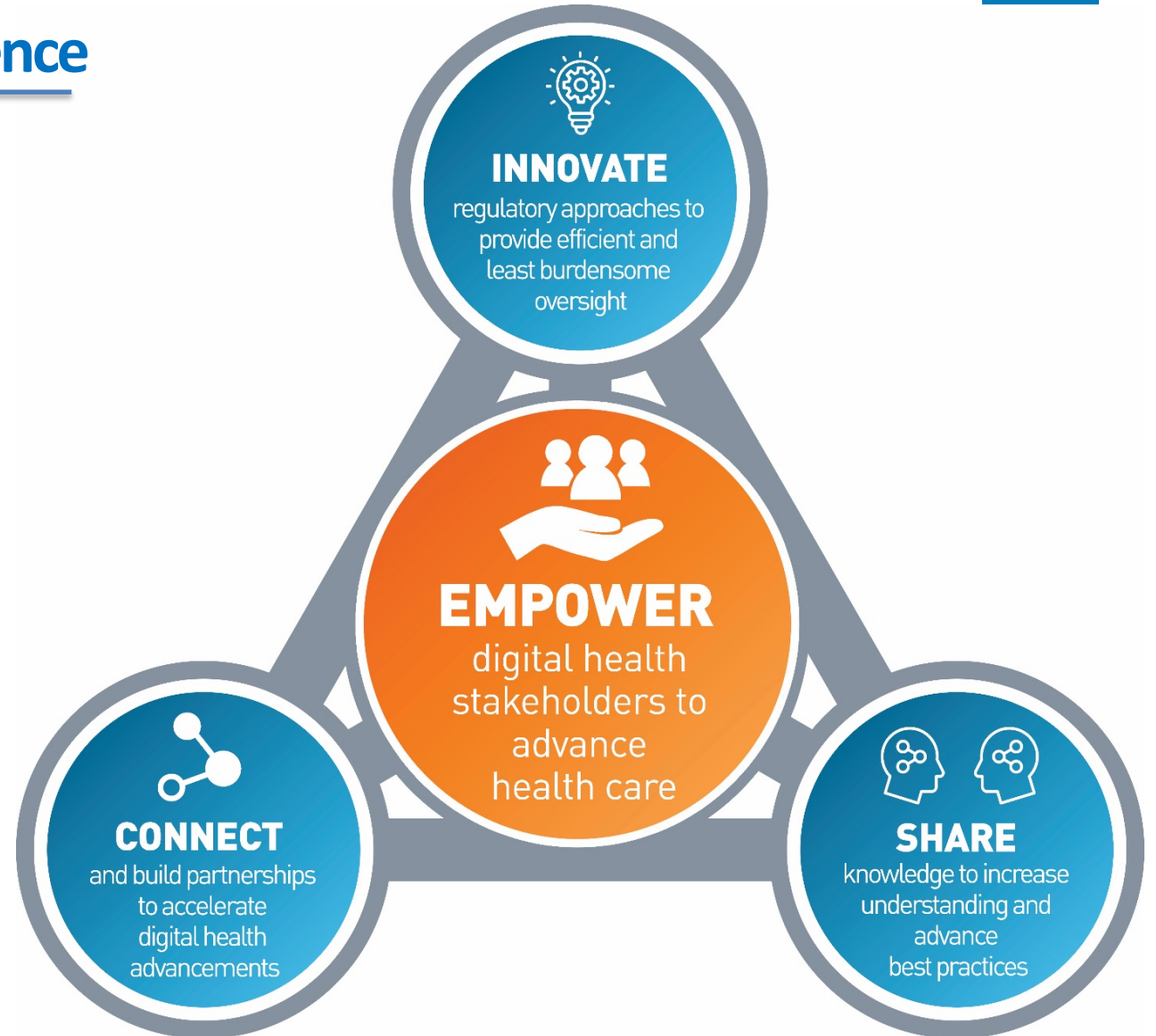
# FDA's Digital Health Center of Excellence

*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

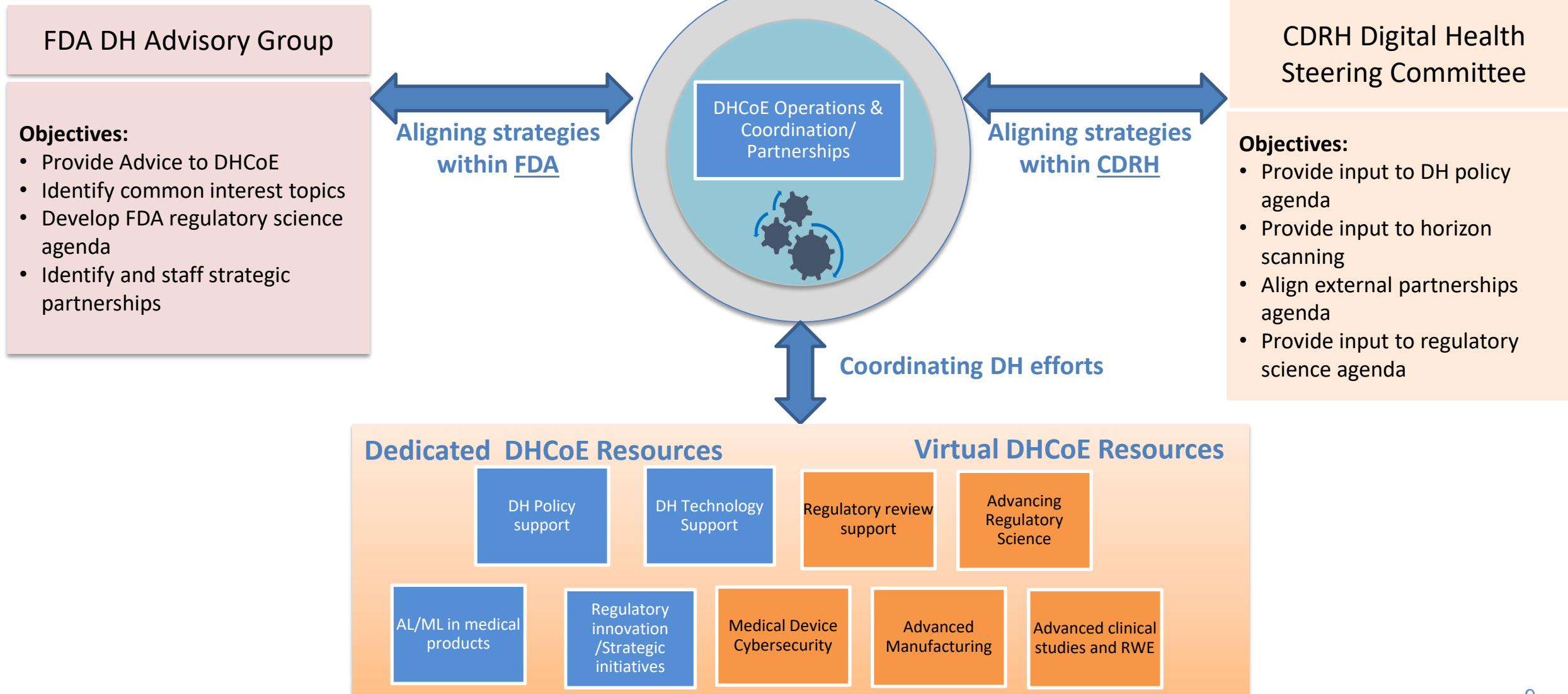
- Policy development and support
- IMDRF collaborations
- External engagement/collaboration

## Medical Device Cybersecurity

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



# DHCoE Concept of Operations



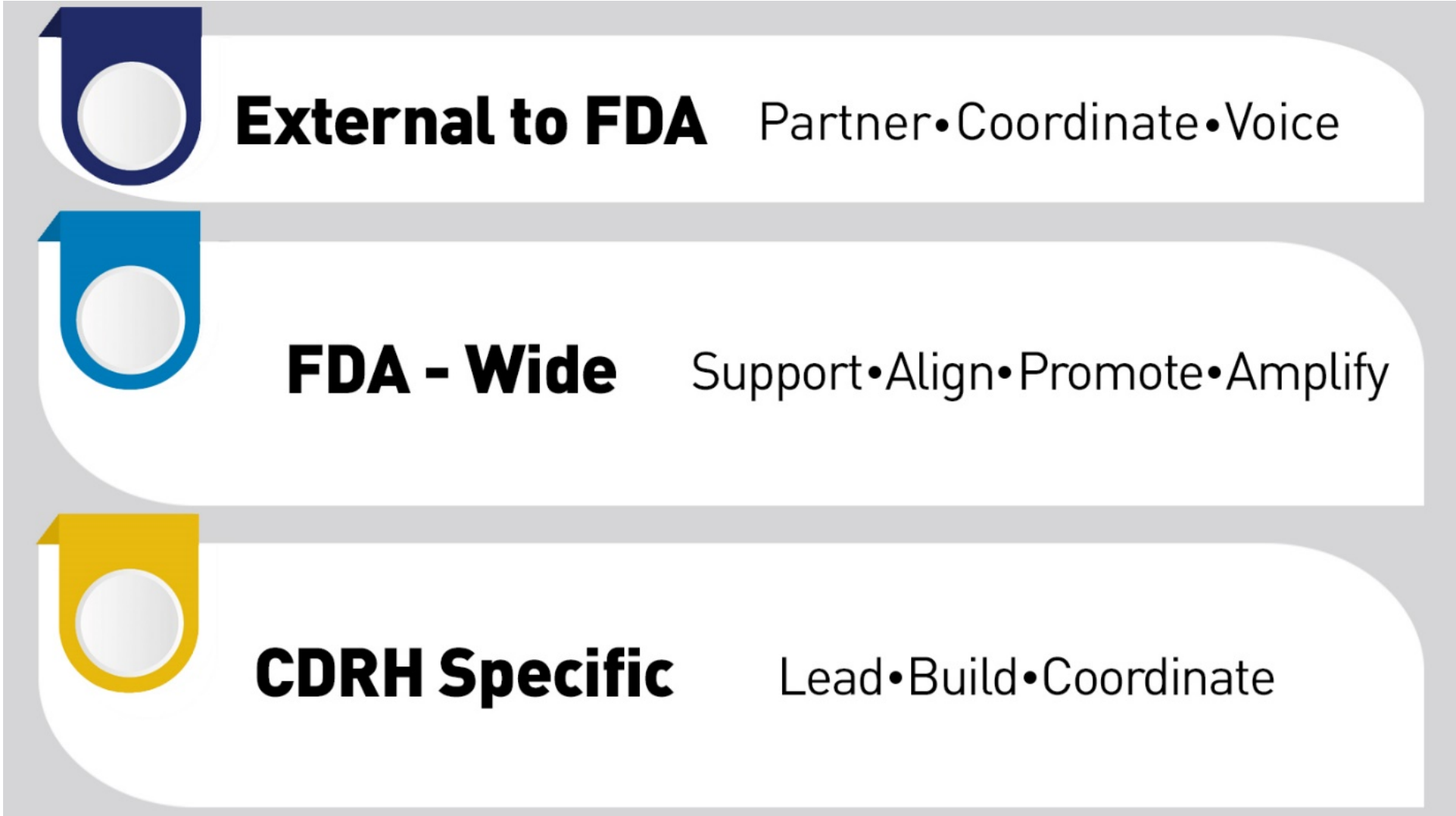


## **CDRH Specific**

Lead•Build•Coordinate

- ✓ 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

- ✓ 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:*

## 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](http://www.fda.gov/digitalhealth)

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