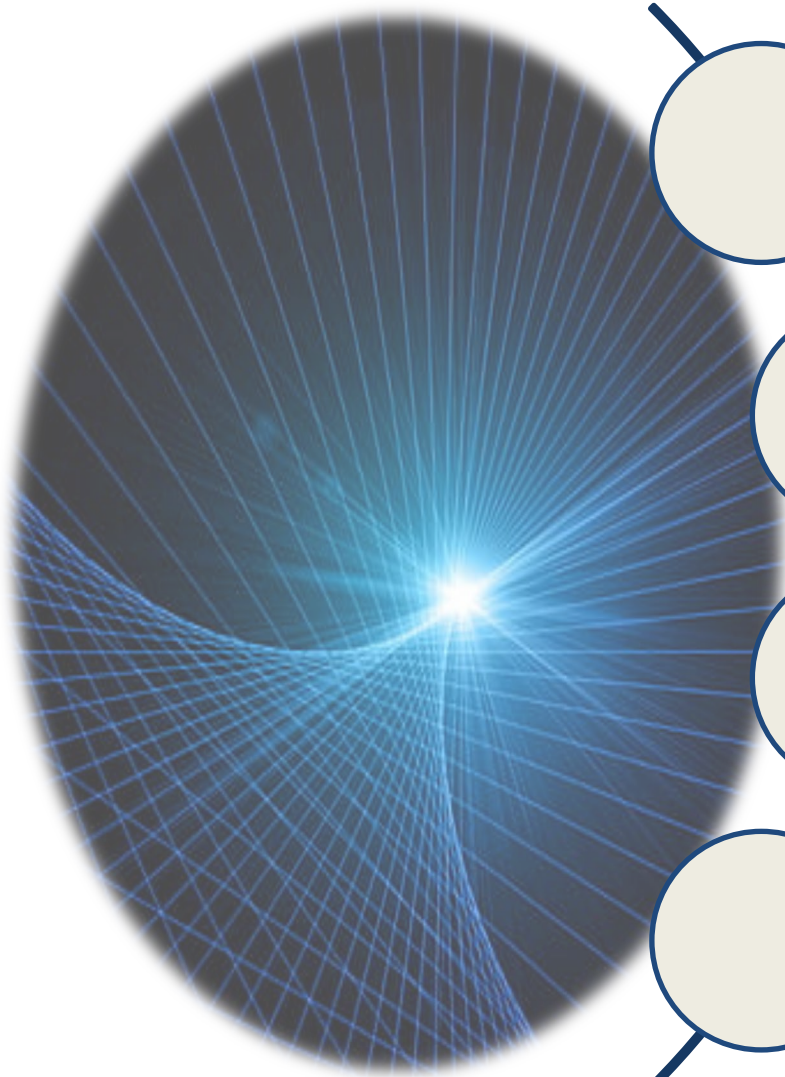


Digital Health Center of Excellence

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

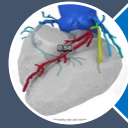
Diagnosis

Treatment Recovery

Home care

Management

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



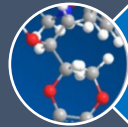
Used as a medical product



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



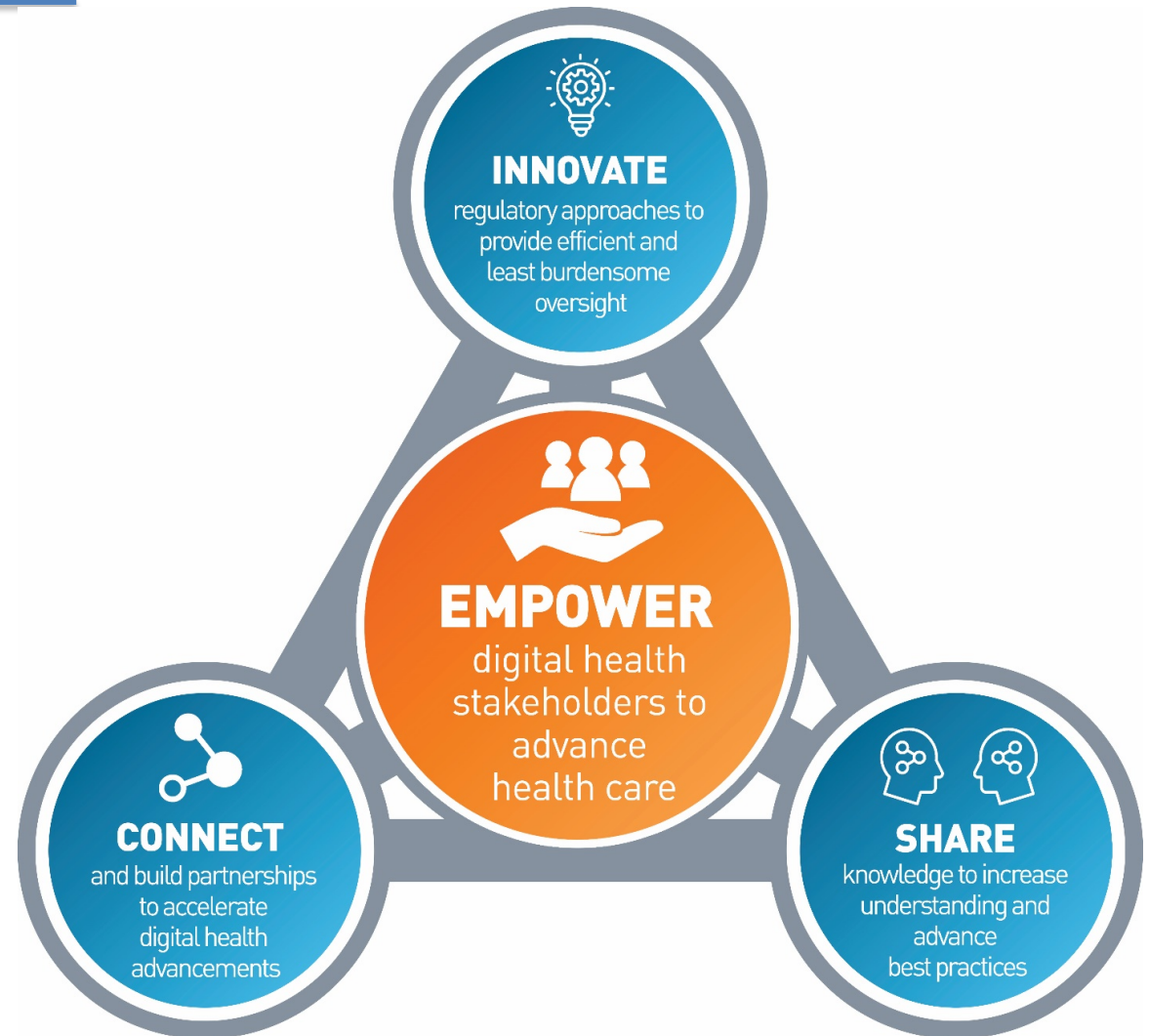
FDA's Digital Health Center of Excellence

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

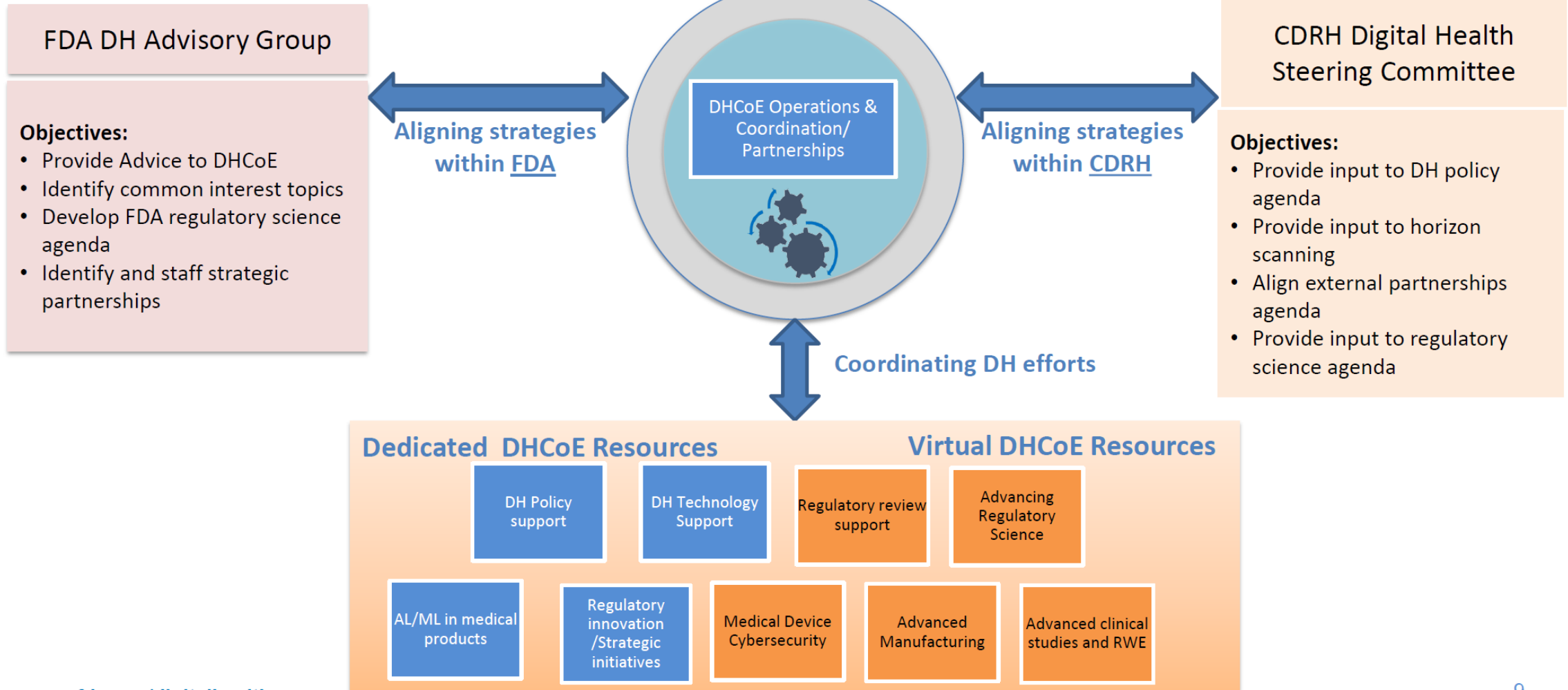
AI/ML in Medical Products

- 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



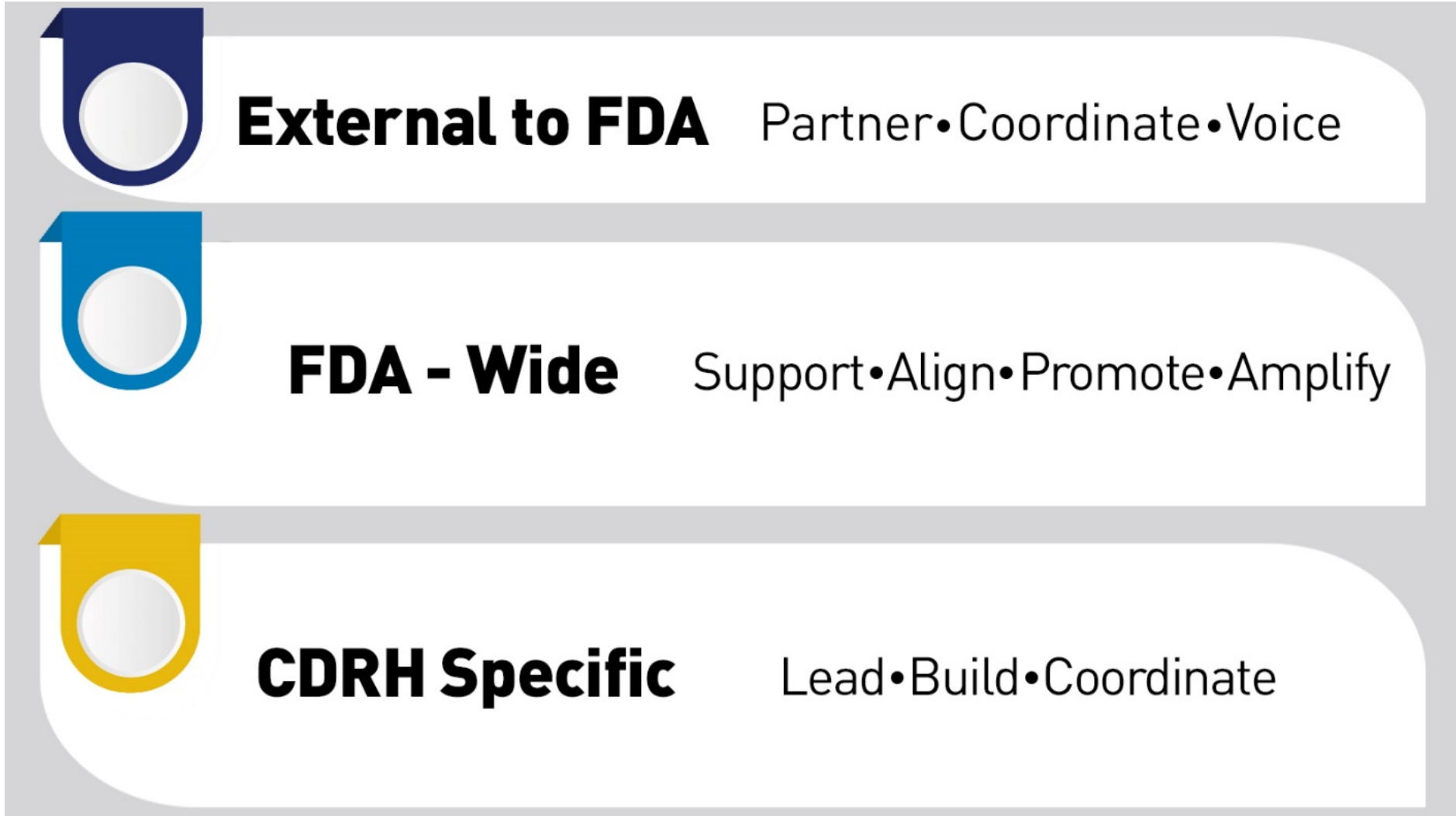


CDRH Specific

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

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