Distinguishing between digital health, medicine, and therapeutic products

Products in these three categories serve different purposes. They cannot be interchanged and are subject to different degrees of rigor, security, privacy, clinical evaluation, and regulatory oversight.

DIGITAL HEALTH

Data and information capture, storage, transmission, and display products
- Lifestyle apps & fitness trackers
- Medication reminder apps
- Health Information Technology (HIT)
- Consumer health information
- Telehealth
- Enterprise support

DIGITAL MEDICINE

Measurement and intervention products
- Digital diagnostics
- Digital biomarkers
- Electronic clinical outcome assessments
- Remote patient monitoring
- Medication adherence tools
- Ingestible sensors
- Connected drug delivery devices

DIGITAL THERAPEUTICS

Therapeutic intervention products
Medical claims include:
- Treat a disease
- Manage a disease
- Prevent a disease and/or improve a health function

ALL PRODUCTS CLAIMING TO BE A DIGITAL THERAPEUTIC MUST ADHERE TO THESE FOUNDATIONAL PRINCIPLES:

1. Prevent, manage, or treat a medical disorder or disease
2. Produce a medical intervention that is driven by software
3. Incorporate design, manufacture, and quality best practices
4. Engage end users in product development and usability processes
5. Incorporate patient privacy and security protections
6. Apply product deployment, management, and maintenance best practices
7. Publish trial results inclusive of clinically-meaningful outcomes in peer-reviewed journals
8. Be reviewed and cleared or approved by regulatory bodies
9. Make claims appropriate to clinical validation and regulatory status
10. Collect, analyze, and apply real world evidence and/or product performance data