Digital Health Technology Landscape

Products across the digital health ecosystem serve different, but complementary purposes. Depending on each product’s intended use and risk, it is subject to increasing degrees of clinical evaluation, regulatory oversight, and real-world data requirements.

**DIGITAL HEALTH TECHNOLOGIES**

- **Enterprise SYSTEMS & SUPPORT**
  - Platforms for healthcare systems, clinics, and other enterprise settings
  - Clinical administration and management tools
  - Predictive analytics
  - Clinical trial management

- **Clinician SERVICES & SUPPORT**
  - Platforms primarily for clinicians and clinical support staff
  - Health Information Technology
  - Electronic medical record and prescribing systems
  - Point of care and workflow enhancement tools
  - Telehealth platforms

- **Patient-facing WELLNESS & SUPPORT**
  - Products that capture, store, or transmit health data
  - Lifestyle and wellness apps
  - Activity and fitness trackers
  - Medication reminder apps
  - Wearables and sensors (non-clinical grade)
  - Consumer health information

- **Patient-facing DIAGNOSTIC & MONITORING**
  - Products used to diagnose, guide diagnoses, or actively monitor patients
  - Digital diagnostics
  - Digital biomarkers
  - Remote patient monitoring tools
  - Wearables and biometric sensors (clinical grade)
  - Medication ingestible sensors
  - Connected drug delivery devices

- **Patient-facing THERAPEUTIC INTERVENTIONS**
  - Products that deliver medical interventions and therapies
  - Digital therapeutics
    - Clinical interventions delivered directly to patients via software to treat, manage, or prevent a disease or disorder
  - Non-DTx medical devices (e.g., insulin pump, artificial pancreas, pacemaker, CPAP)

*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 as required to support product claims of risk, efficacy, and intended use
9. Make claims appropriate to clinical validation and regulatory status
10. Collect, analyze, and apply real world evidence and/or product performance data

* *Categorizations of the digital health technology ecosystem will continue to evolve. This is a select representation of a broad, diverse ecosystem.*