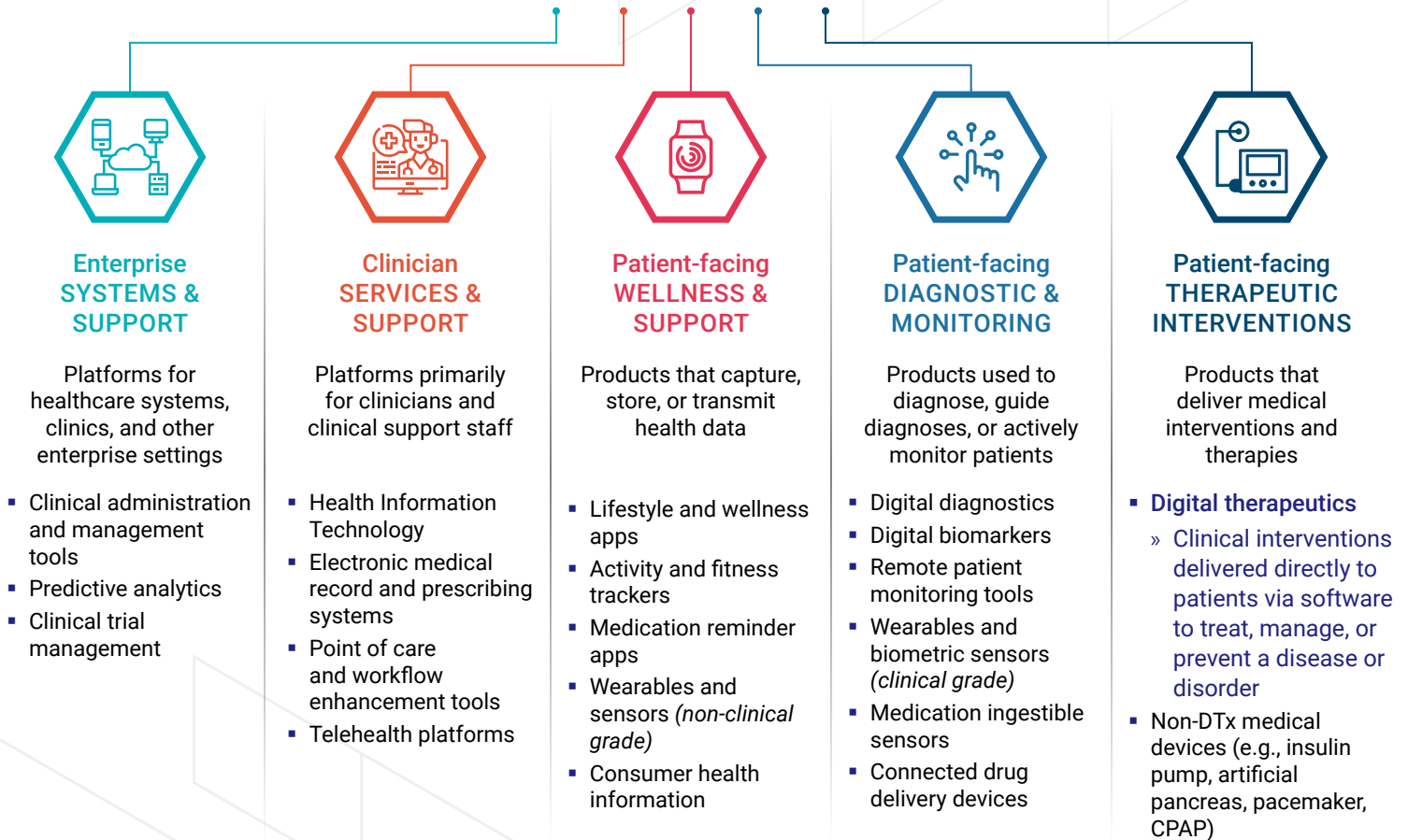**DIGITAL THERAPEUTICS ALLIANCE**

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	Clinician SERVICES & SUPPORT	Patient-facing WELLNESS & SUPPORT	Patient-facing DIAGNOSTIC & MONITORING	Patient-facing THERAPEUTIC INTERVENTIONS
Platforms for healthcare systems, clinics, and other enterprise settings	Platforms primarily for clinicians and clinical support staff	Products that capture, store, or transmit health data	Products used to diagnose, guide diagnoses, or actively monitor patients	Products that deliver medical interventions and therapies

Enterprise SYSTEMS & SUPPORT
- Clinical administration and management tools
- Predictive analytics
- Clinical trial management

Clinician SERVICES & SUPPORT
- Health Information Technology
- Electronic medical record and prescribing systems
- Point of care and workflow enhancement tools
- Telehealth platforms

Patient-facing WELLNESS & SUPPORT
- Lifestyle and wellness apps
- Activity and fitness trackers
- Medication reminder apps
- Wearables and sensors (non-clinical grade)
- Consumer health information

Patient-facing DIAGNOSTIC & MONITORING
- 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
- 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)

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

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