

Digital Therapeutics Definition and Core Principles

Digital therapeutics definition:

Digital therapeutics (DTx) deliver evidence-based therapeutic interventions that are driven by high quality software programs to prevent, manage, or treat a medical disorder or disease. They are used independently or in concert with medications, devices, or other therapies to optimize patient care and health outcomes.

DTx products incorporate advanced technology best practices relating to design, clinical evaluation, usability, and data security. They are reviewed and cleared or certified by regulatory bodies as required to support product claims regarding risk, efficacy, and intended use.

Digital therapeutics empower patients, clinicians, and payers with intelligent and accessible tools for addressing a wide range of conditions through high quality, safe, and effective data-driven interventions.



All products claiming to be a digital therapeutic must adhere to these foundational principles:

- Prevent, manage, or treat a medical disorder or disease
- Produce a medical intervention that is driven by software
- Incorporate design, manufacture, and quality best practices
- Engage end users in product development and usability processes
- Incorporate patient privacy and security protections
- Apply product deployment, management, and maintenance best practices
- Publish trial results inclusive of clinically-meaningful outcomes in peer-reviewed journals
- Be reviewed and cleared or certified by regulatory bodies as required to support product claims of risk, efficacy, and intended use
- Make claims appropriate to clinical evaluation and regulatory status
- Collect, analyze, and apply real world evidence and/or product performance data

Learn more about digital therapeutics at www.dtxalliance.org/aboutdtx