DIGITAL THERAPEUTICS ALLIANCE

Digital Therapeutics in the United States

What is a Digital Therapeutic?

Digital therapeutics (DTx) deliver to patients evidence-based therapeutic interventions that are driven by high quality software programs to treat, manage, or prevent 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 Value in Patient Care

Digital therapeutics equip patients, clinicians, and payors with scalable, data-driven tools to address a wide range of diseases and disorders. DTx products:

- ✓ Are accessible via smartphones, tablets, VR headsets, or other devices
- ✓ Deliver personalized medical interventions to patients in their preferred environments
- ✓ Are provided to patients through prescription or non-prescription authorization
- ✓ Provide secure, meaningful results and insights on patient goals, engagement, and outcomes
- ✓ Extend the reach of clinical care and improve health equity through standardizing therapy and enabling easier access

DTx Intervention Types

DTx products may deliver a variety of high-quality medical interventions, including the ability to:

- ✓ Provide personalized disease treatment, management, and prevention programs
- ✓ Offer therapies to address comorbidities, side effects, or affiliated conditions
- ✓ Provide treatments that produce direct neurologic changes
- ✓ Deliver cognitive behavioral therapy (CBT) and other evidence-based treatments
- ✓ Enhance, support, and optimize current in-person and medication treatments
- ✓ Deliver responsive physical exercises and behavioral interventions

Click here to visit DTA's DTx Product Library.

Safe & Effective Therapies

Digital therapeutics:

- ✓ Publish clinical trial results in peer-reviewed journals
- ✓ Incorporate patient privacy and security protections
- ✓ Are reviewed by regulatory bodies as required to support product claims regarding risk, efficacy, and intended use
- ✓ Collect, analyze, and apply real world evidence and/or product performance data

Regulatory & Product Access Pathways

DTx products in the United States are subject to regulation by the Food and Drug Administration (FDA). Based on the digital therapeutic's intended use and level of risk, each product is subject to varying degrees of oversight, ranging from full 510(k) clearance by FDA's Center for Devices and Radiological Health (CDRH) division to enforcement discretion.

Increased DTx Recognition & Utilization

The global pandemic highlighted existing gaps in care and the increased need for remote care options. Digital therapeutic use cases have become increasingly clear for policymakers, clinicians, payors, and patients across the world. Many stakeholders are working with urgency to build appropriate regulatory, reimbursement, and access pathways for digital therapeutic products.

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Visit www.dtxalliance.org to learn more about digital therapeutics.