DIGITAL THERAPEUTICS ALLIANCE

Digital Therapeutics in Australia

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 optimise patient care and health outcomes.

DTx Value in Patient Care

Digital therapeutics equip patients, clinicians, and payors (including private health insurance and government agencies) 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 personalised medical interventions to patients in their preferred environments
- ✓ Are provided to patients through prescription or non-prescription authorisation
- ✓ Provide secure, meaningful results and insights on patient goals, engagement, and outcomes
- ✓ Extend the reach of clinical care and improve health equity through standardising therapy and enabling easier access

DTx Intervention Types

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

- ✓ Provide personalised 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 optimise current in-person and medication treatments
- ✓ Deliver responsive physical exercises and behavioural 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, analyse, and apply real world evidence and/or product performance data

Regulatory & Product Access Pathways

The Therapeutic Goods Administration (TGA) regulates DTx products under the Software as a Medical Device (SaMD) framework. When a DTx product qualifies as a medical device, it must be included in the Australian Register of Therapeutic Goods (ARTG) before it can be legally supplied in Australia.

Increased DTx Recognition & Utilisation

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.