Demystifying DTx

The future of patient care will unquestionably include software-based products that generate and deliver medical interventions directly to patients to treat, manage, and prevent diseases and disorders. To fully realize digital therapeutics' value and impact across all health settings, it is important to provide clarity on common questions about how DTx products fit in the broader digital health continuum and how to distinguish between DTx products and other DHTs.

MYTH: All digital health products are basically the same.

Just as medications serve different purposes, so do digital health products. Each digital health technology has a different purpose—such as health and wellness apps, digital diagnostics, remote monitoring, clinical support tools, and digital therapeutics.

MYTH: Every product that is called a digital therapeutic meets industry standards.

An increasing number of apps are being called a digital therapeutic on the basis that they are digital products and used in a healthcare environment. However, to truly qualify, all DTx products should align with the industry's definition and core principles.

MYTH: Like general health and wellness apps, digital therapeutics are only available via an app store download for immediate use.

Although patients may sometimes download the shell of a DTx product from an app store, they typically gain full access to the product's content after they receive an authorization code from a clinician, payor, employer, or other entity and enter it into the product.

MYTH: All digital therapeutic products require a prescription to use.

DTx products are provided to patients in a variety of ways, including:

- Formal prescription (Rx) from a qualified clinician
- Clinician referral for a non-prescription DTx product

- Direct authorization by an employer or payor for a non-prescription DTx product
- 'Authorized clinical protocol' established by a HCDM to authorize automatic patient access when necessary qualification requirements are met
- 'Clinically-validated screening tool' that patients utilize to determine whether they qualify for the therapy
- 'Over-the-counter' model where no form of third-party authorization is necessary

Individual countries often set different requirements for which products require a formal prescription.

MYTH: DTx products do not have sufficient evidence to be scaled as an effective therapy in clinical practice.

While most digital health apps do not require clinical evidence, DTx products do. Digital therapeutics must complete multiple levels of clinical evidence, including trial results inclusive of clinically meaningful outcomes that are published in peer-reviewed journals. Additional forms of evidence may include the generation of real-world data, product performance data, real-world evidence, and health economic outcomes.

MYTH: All DTx products deliver their clinical impact and value in the same way.

DTx products utilize a variety of mechanisms to deliver their clinical impact, including, but not limited to:

- Behavioral therapy
- Biofeedback
- Cognitive training

- Neurological stimulation
- Physiologic stimulation
- Software-determined medication dose modification
- Software-directed disease management
- Software-led clinical rehabilitation

MYTH: DTx products make their own determinations as to whether they want or need to undergo regulatory review.

Digital therapeutics are reviewed and cleared by regulatory bodies as required to support product claims of risk, efficacy, and intended use. Regulatory bodies in different regions and jurisdictions may set varying levels of regulatory and market authorization requirements for digital therapeutics based on the product's intended use and level of risk.

DTx products are generally recognized as medical devices in jurisdictions with relevant regulatory frameworks. According to the level of claims each DTx product is making and its associated level of risk, DTx products must submit to the necessary regulatory requirements that are set in place for the device.

MYTH: Digital therapeutic products do not protect patient data security or privacy.

DTx products incorporate patient privacy and security protections according to each region and jurisdiction they are used within. Regulations that protect patient privacy and data rights include Health Insurance Portability and Accountability Act (HIPAA) in the United States and General Data Protection Regulation (GDPR) in Europe.

Additionally, types of third-party certifications that DTx products may undergo to protect the security of each product include ISO/IEC 27001, HITRUST, and SOC 2.

MYTH: All digital therapeutics must have the same level of ongoing engagement as popular consumer use platforms (i.e., social media and streaming services).

DTx products are designed to deliver a therapy that is appropriate to patient needs and must therefore be appropriately engaging. Just as medications are used for specific durations and purposes, DTx products must be used according to product requirements in order to deliver the optimal therapeutic intervention at the right time, and for the right duration. Given their role in clinical therapy, digital therapeutics are not used in the same manner as non-clinical platforms, such as social media, gaming, and entertainment sites.

MYTH: DTx products may negatively impact clinician workflows, time requirements, and practice liability.

DTx products that have undergone service design processes in advance of and during clinical evaluations are able to more seamlessly integrate into the appropriate real-world environments. DTx products must meet the needs of patients, clinicians, and other end users during each phase of product use.

In clinical practice, DTx products do not require daily oversight and input from clinical teams. Clinicians, should they want access to this data in line with patient privacy requirements, are typically given access to dashboards that provide insights on patient trends and insights developed over specific periods of time.

MYTH: Clinicians cannot get paid for their time engaging with DTx products.

Clinician payment continues to grow in the United States and Europe. In the U.S., clinicians may use various CPT codes to account for the time they spend educating and onboarding patients, prescribing DTx products, and conducting necessary follow up efforts. In Germany and France, for example, clinicians are increasingly receiving payment for their direct engagement with digital health technologies as payment models move toward quarterly payments to optimize patient visits.

MYTH: Clinical teams are resistant to using this relatively new category of medicine out of fear that digital therapeutics will replace clinicians.

Digital therapeutics support clinicians in the delivery of high-quality patient care by extending clinicians' ability to care for patients, addressing existing gaps in care, and providing new therapy options for previously un- or undertreated conditions.

MYTH: DTx products increase patient disparities.

Digital therapeutics introduce an entirely new degree of product scalability and patient access. Payors and policymakers are now able to deliver care to entire populations that have previously been outside the reach of traditional care – either due to geographic limitations, cultural and language boundaries, well-documented disparities, or health condition severity. Patients who have previously not received care now have the opportunity to receive personalized therapeutic interventions based on their specific needs and abilities, in an engaging way, with familiar languages and cultural references, in the privacy and safety of their own environment, with access to actionable insights that convey patient movement toward clinical improvement, and often through the use of patient-owned smartphones or devices.

MYTH: All digital therapeutics require uninterrupted broadband internet access.

DTx products are able to deliver interventions, collect patient-generated data, and display necessary insights using a variety of internet connection types, including: intermittent WiFi access, sustained basic internet access, and broadband internet access.