

DTA's Adoption & Interpretation of ISO's DTx Definition

In 2017, the Digital Therapeutics Alliance's (DTA) founding members set out to develop the definition of a digital therapeutic (DTx). It was important for the industry to be able to identify products that qualify as a DTx, while also creating a reliable reference point for patients, clinicians, policymakers, and payors.

While DTA's 2018 definition still accurately reflects a large portion of products across the DTx ecosystem, policymakers and payors have increasingly sought greater clarity from an external perspective on how digital therapeutics differ from other digital health product types (i.e., wellness, clinical decision support, monitoring, diagnostic) and relate to subsets of medical devices (i.e., software as a medical device [SaMD], software in a medical device [SiMD]).

Consequently, in 2020, DTA engaged with the International Organization for Standardization (ISO) to join their effort to formally define the term digital therapeutic. This effort began with the development of a Technical Report (TR) and will progress to the development of a Technical Specification (TS), which will provide specific standards for DTx products.

To ensure industry and global alignment, DTA is adopting ISO's new definition of a digital therapeutic, as defined by [ISO/TR 11147: Health informatics—Personalized digital health—Digital therapeutics health software systems](#).

This briefing document provides insights on how DTA interprets this definition.

According to ISO/TR 11147: *Health informatics—Personalized digital health—Digital therapeutics health software systems* (2023), a digital therapeutic (DTx) is:

health software intended to treat or alleviate a disease, disorder, condition, or injury by generating and delivering a medical intervention that has a demonstrable positive therapeutic impact on a patient's health.

Note 1 to entry: Many jurisdictions consider DTx a medical device.

Note 2 to entry: DTx can integrate with ancillary components to form a DTx system by:

- using general purpose hardware or platforms (i.e. smartphone, tablet, computer, watch, headset), input or output components (i.e. wearables, sensors), pharmaceuticals, or patient or clinician support components necessary for DTx functioning;
- using patient- and context-specific data to generate a medical intervention.

Note 3 to entry: DTx can function independently or in addition to other interventions, such as integrating with:

- other digital health technology (DHT) components (i.e. monitoring, diagnostic, clinical decision support) as part of a multi-functional DHT product;
- tandem medical interventions (i.e. clinician-delivered therapies, pharmaceuticals, medical devices, DHTs).

Note 4 to entry: DTx includes secondary prevention and tertiary prevention.

Note 5 to entry: DTx is produced in compliance with good product life cycle (PLC) management practices, through use of a quality management system which encompasses demonstrated safety and effectiveness, and post-market surveillance.

DTA's interpretation of specific terms used in the DTx definition:

Health software

- The use of the term *health software* builds on principles introduced in the [IEC 82304-1:2016](#) standard, *Health software — Part 1: General requirements for product safety*. In this standard, *health software* is formally defined as:
 - software intended to be used specifically for managing, maintaining or improving health of individual persons, or the delivery of care
 - Note 1 to entry: Health software fully includes what is considered software as a medical device.
 - Note 2 to entry: The scope of this document refers to the subset of health software that is intended to run on general computing platforms.

Treat or alleviate

- The definition of a medical device includes the following intended uses for a product:
 - diagnosis, prevention, monitoring, treatment, alleviation, compensation, investigation, replacement, modification, support, sustaining, control, disinfection
- ISO retained the words *treat* and *alleviate* in the DTx definition to appropriately align with the definition of a medical device. They determined this by eliminating indications from the medical device definition that are not specifically therapeutic.
- DTA believes that *managing*, *modifying*, *rehabilitating*, and *slowing* the progression of a disease or disorder are included under the term treat or alleviate in this definition.
- Wellness products that deliver interventions to patients but do not claim to *treat* or *alleviate* a disease do not qualify as a DTx.

Disease, disorder, condition, or injury

- To align the DTx definition with the definition of a medical device, ISO retained the words *disease*, *disorder*, *condition*, and *injury* in the DTx definition.
- A patient who is displaying symptoms of a *disease*, *disorder*, *condition*, or *injury* does not require a formal diagnosis in order to begin receiving DTx therapy.

- DTA believes that patients with certain or suspected *diseases*, *disorders*, or *conditions* should be eligible to utilize a DTx product even if the *disease*, *disorder*, or *condition* has not been formally diagnosed by a qualified clinician. For example, a child who has undergone an evaluation for autism does not require a formal diagnosis from a qualified clinician in order to begin receiving DTx therapy.

Generating and delivering

- ISO's definition acknowledges the difference between software operating in a therapeutic space (i.e., wellness, monitoring, diagnostic, decision support) versus software that generates and delivers a therapeutic intervention (i.e., digital therapeutic).
- DTx software products have varying levels of risk depending on the types of interventions that are generated and delivered to a patient. The International Medical Devices Regulators Forum (IMDRF) and national regulatory agencies have various methods to assess and regulate, as appropriate, DTx product risk levels.
- In some cases, as part of *generating* and *delivering* a medical intervention to a patient, the DTx product itself may function as the medical intervention itself.
- Clinicians have varying levels of engagement with different DTx products. Clinician actions range from prescribing and authorizing DTx products, to leveraging actionable real-world outcomes that are generated by the product to optimize a patient's care. Regardless of the type and level of clinician engagement with a DTx, the DTx product retains the responsibility for *generating* and *delivering* the therapeutic intervention to a patient.

Medical intervention

- ISO defines *medical intervention* in TR 11147 as an:
 - activity intended to maintain or improve an individual's health or functioning, or to alter the course of a disease, disorder, or condition for the better, or to restore function lost through disease or injury
- DTx products typically leverage patient- and/or context-specific data to generate a medical intervention.
- The presence of a *medical intervention* in a DTx product does not explicitly or implicitly require that formal authorization or engagement from a qualified clinician is necessary.

Demonstrable positive therapeutic impact

- The word *demonstrable* indicates that DTx products require product-specific clinical evaluations to verify that each DTx product is able to accomplish in real-world settings what it claims to do.
- While a *demonstrable positive therapeutic impact* can refer to a directly measurable impact on a patient's health, it also can refer to other forms of improvement for conditions such as cognition or mental health.

Patient's health

- Digital therapeutics' primary focus is to deliver care to patients.
- DTx products may provide clinicians and caregivers with actionable insights on how a patient's care is progressing through product-generated outcomes, but DTx products are primarily therapeutic in nature and are not primarily clinical decision support tools.
- Digital therapeutics can yield population health impacts when care for individual patients is delivered at scale.

Note 1 to entry

- Digital therapeutics are medical devices. This includes:
 - All classifications of medical devices (i.e., class I, II, IIa, IIb, or III).
 - Both prescription and non-prescription products.
- Regulatory agencies may determine if a DTx product requires a prescription by a qualified clinician before it can be provided to a patient in that jurisdiction.

Note 2 to entry

- While this definition focuses primarily on DTx software, other product components may be required or used to generate and deliver medical interventions to patients. DTx software plus necessary components can be called a DTx system or a DTx product.
- Although certain product components that enable the DTx product to function are listed in the ISO definition, this list is not all inclusive, nor are each of the elements listed in the definition required for DTx functioning.
- DTx software integration with ancillary components is typically defined during pre-market product development phases.

- While certain DTx software may be used on general purpose computing platforms, other DTx software may require fit-for-purpose components.

Note 3 to entry

- The term *digital health technology* (DHT) represents the full spectrum of digital health products that are available to patients, caregivers, clinicians, and health-systems.
- The DHT product spectrum includes various medical device categorization sub-classifications (i.e., health software, digital medical device [DMD]), in addition to various product indication types (i.e., health-system tools, clinician-facing tools, and patient-facing wellness, care support, monitoring, diagnostic, and therapeutic products).
 - DTx represents one pillar of the DHT indication categorization, while also qualifying as a subset of the medical device, health software, and DMD categories too.
- DTx products may be standalone or multi-functional.
- Any *multi-functional DHT product* that includes a DTx component will be identified as a digital therapeutic, and consequently, as a medical device.
- Regulatory agencies may assess products with one or more DHT components differently, especially if the DTx component is paired with another regulated component (i.e., diagnostic).

Note 4 to entry

- Digital therapeutics are used in the presence of a confirmed or suspected disease, disorder, condition, or injury. DTx products can therefore be deployed in the secondary and tertiary prevention of medical conditions.
- Since primary prevention suggests that a disease, disorder, condition, or injury is not yet present, products operating in this space likely do not qualify as a DTx.

Note 5 to entry

- As referenced above, the ISO definition is part of a Technical Report (TR). Since TRs are non-normative, it is not possible for this type of document to outline specific standards and requirements for DTx products. Instead, these types of requirements will be developed during the Technical Specification (TS) phase.

- In 2018, the industry adopted a series of baseline principles that all DTx products should adhere to in protecting and serving patients. Still upheld today, these include:
 - Incorporate design, manufacturing, 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.