

International Organization for Standardization (ISO) Digital Therapeutic Definition—June 2023

In June 2023, the International Organization for Standardization (ISO) published *ISO/TR 11147: Health informatics—Personalized digital health—Digital therapeutics health software systems*. This [publication](#) was developed by ISO's *Technical Committee (TC) 215—Health Informatics* and includes the definition of a digital therapeutic (DTx):

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.

The Digital Therapeutics Alliance (DTA) adopted this definition in June 2023 and developed a [briefing document](#) describing how DTA interprets this definition.