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Health informatics — Personalized digital health — Digital therapeutics health software systems

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ISO copyright office

CP 401 • Ch. de Blandonnet 8

CH-1214 Vernier, Geneva

Phone: +41 22 749 01 11

Email: copyright@iso.org

Website: www.iso.orgwww.iso.org

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared by Technical Committee ISO/TC 215, *Health informatics*.

~~A list of all parts in the ISO 11147 series can be found on the ISO website.~~

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

As the healthcare sector evolves, there is an increasing demand for the production and appropriate use of digital health technologies (DHTs) across patient care settings. DHTs represent a broad spectrum of products ranging from clinician-facing electronic prescribing systems, telemedicine platforms, and decision support systems, to patient-facing wellness apps, diagnostic tools, monitoring products, biomarkers, and therapeutics.

Given the diversity of digital product types available, it is important for patients, clinicians, and healthcare decision makers to have the ability to clearly distinguish between the numerous types of DHTs on the market. Without harmonized internationally recognized guidance, users are often unable to differentiate between DHTs based on products' intended use.

Digital therapeutics (DTx) ~~–~~as defined in this document~~–~~ represent a decade-old category of medicine that can be used as standalone therapies or integrate into clinical care pathways alongside pharmaceuticals, clinician-delivered therapies, and other medical devices.

~~ISO~~ Standards exist for various non-DTx DHT product categories and varying DTx product definitions and best practices are emerging at the industry level (see Annex A), yet no DTx-specific ~~international standards~~publication exist. This document ~~serves as an internationally recognisable reference for patients, clinicians, healthcare decision makers, and product manufacturers to identify DHTs that qualify as a DTx. It~~ centres on DTx's use of software to generate and deliver validated and measurable medical interventions directly to patients. It is relevant to patients, clinicians, healthcare decision makers, and product manufacturers

~~Digital Therapeutics (DTx) —~~ Health informatics ~~–~~ Personalized digital health ~~–~~ Digital therapeutics health software systems

~~2~~1 ~~1~~ Scope

This document lists characteristics of a category of health software: digital therapeutics (DTx). DTx provides medical interventions that are based on clinical evidence and produce real-world outcomes. Product use cases (see Annex B) demonstrate the variety of products represented in this quickly growing industry.

This document provides an overview of how DTx relates to other ecosystem constructs, including medical devices, software as a medical device (SaMD), software in a medical device (SiMD), and digital health technologies (DHT). It also addresses relevant health and medical device software standards that have various degrees of applicability to DTx.

The focus of this document is on therapeutic products for human use and that are used in the context of a disease, disorder, condition, or injury. It does not address products that are intended for veterinary uses or for general wellbeing. Additional exclusions of this document include DTx market access pathways (i.e~~,~~ prescription, non-prescription pathways), medical device requirements, product risk assessment, clinical evidence requirements, data security and patient privacy considerations, and product authorization pathways.

~~4~~2 ~~2~~ Normative references

There are no normative references in this document.

~~6~~3 ~~3~~ Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
digital health technology
DHT
system that uses computing platforms, connectivity, software, and sensors for healthcare and related uses

Note 1 to entry: These technologies span a wide range of uses, from applications in general wellness to applications as a medical device. They include technologies intended for use as a medical product, in a medical product, or as an adjunct to other medical products (devices, drugs, and biologics). They can also be used to develop or study medical products.

[SOURCE: BEST ~~(Biomarkers, EndpointS, and other Tools)~~ Resource[1]]

3.2
user
person using the system for a health-related purpose

Note 1 to entry: The user can be the subject of care directly, or an individual assisting (as proxy for) the subject of care.

[SOURCE: ISO 81001-1:2021 ~~[2]~~]

, 3.1.14]

3.3
intended use
intended purpose
use for which a product, process~~,~~ or service is intended according to the specifications, instructions and information provided by the manufacturer

Note 1 to entry: The intended medical indication, patient population, part of the body or type of tissue interacted with, user profile, use environment, and operating principle are typical elements of the intended use.

[SOURCE: ISO/IEC Guide 63:2019, 3.4, modified — Added admitted term "intended purpose~~.~~ ~~[3]~~".]

3.4
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: DTx software can integrate with ancillary components to form a DTx system by:

— using general purpose hardware (i.e~~,~~ smartphone, tablet, computer, watch, headset), input or output components (i.e~~,~~ wearables, sensors, platforms), or pharmaceuticals necessary for DTx functioning;

— using patient- and context-specific data to generate a medical intervention;

— integrating with tandem medical interventions (i.e~~,~~ clinician-delivered therapies, pharmaceuticals, SiMD, other DHT components).

Note 2 to entry: DTx can function independently or in addition to other interventions.

Note 3 to entry: Includes secondary prevention and tertiary prevention.

Note 4 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.

3.5
medical device
instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one of more of the specific medical purpose(s) of

— diagnosis, prevention, monitoring, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury,

— investigation, replacement, modification, or support of the anatomy or of a physiological process,

— supporting or sustaining life,

— control of conception,

— disinfection of medical devices,

— providing information by means of in vitro examination of specimens derived from the human body,

and which does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which can be assisted in its intended function by such means

Note 1 to entry: Products which can be considered to be medical devices in some jurisdictions but not in others include:

— disinfection substances,

— aids for persons with disabilities,

— devices incorporating animal and human tissues,

— devices for in-vitro fertilization or assisted reproductive technologies.

[SOURCE: ISO/IEC Guide 63:2019~~[.]~~ 3~~]~~.7]

3.6
medical intervention
activity intended to maintain or to 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, or to assist an individual with activities of daily living, or to support physical and mental well-being

3.7
health software
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.

[SOURCE: IEC 82304-1:2016 [4], 3.6, modified — Note 2 to entry deleted.]

3.8
evidence
directly measurable characteristics of a process or product that represent objective, demonstrable proof that a specific activity satisfied a specified requirement

[SOURCE: ISO/IEC 21827:2008 [5], 3.19]

3.9
software as a medical device
SaMD
software intended to be used for one or more medical purposes that performs these purposes without being part of a hardware medical device

Note 1 to entry: SaMD is a medical device and includes in-vitro diagnostic (IVD) medical device

Note 2 to entry: SaMD is capable of running on general purpose (non-medical purpose) computing platforms

Note 3 to entry: "without being part of" means software not necessary for a hardware medical device to achieve its intended medical purpose

Note 4 to entry: Software does not meet the definition of SaMD if its intended purpose is to drive a hardware medical device

Note 5 to entry: SaMD can be used in combination (e.g., as a module) with other products including medical devices

Note 6 to entry: SaMD can be interfaced with other medical devices, including hardware medical devices and other SaMD software, as well as general purpose software

Note 7 to entry: Mobile apps that meet the definition above are considered SaMD

[SOURCE: IMDRF 2013 [6], modified — 'may' changed to 'can' [6].]

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