

Title: Quality Standard for Digital Therapeutics Products

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Abstract

Digital therapeutics (DTx) can be defined as 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 [1]. Many DTx products have been shown to have significant therapeutic impacts on various areas of medicine [2]. DTx products, have not, however, reached their full potential in the marketplace, partly due to lack of trust in them. For this reason, ISO/TC215 has started work on a quality standard for DTx products, the ISO/TS 24973 Digital therapeutics - Product requirements. The idea is that if a product passes the requirements of this technical specification, its quality is trustworthy.

Before starting the work on this technical specification, a technical report [1] was prepared to survey the DTx landscape. After the completion of the report, work begun on the technical specification under the leadership of a representative from the Digital Therapeutics Alliance.

The present committee draft contains requirements for the marketing claims, proof of clinical efficacy, safety, risk management, information security, usability, accessibility, and manufacturing quality. The document refers often to existing standards in these areas. The requirements resemble the requirements to medical device software in many countries.

After completion in 2027, the document needs marketing for widening its use to fulfil its purpose. The DTx providers need to know about it and the health care providers need to ask for the implementation of the document from the providers.

[1] ISO/TR 11147:2023 Health informatics - Personalized digital health - Digital therapeutics health software systems, <https://www.iso.org/standard/83767.html>

[2] Seo Y-C, Yong SY, Choi WW, Kim SH. Meta-Analysis of Studies on the Effects of Digital Therapeutics. *Journal of Personalized Medicine*. 2024; 14(2):157. <https://doi.org/10.3390/jpm14020157>