Navigating the Digital Health Ecosystem: a Review of Key Guidelines, Frameworks and Tools **Part 2:** *Digital Health Guidelines, Frameworks and Tools*

DIPC

State of the art digital health projects build on existing evidence, and normative guidelines, frameworks, and tools in various areas, ranging from software development to financing and equitable programing. In the context of the GIZ Digital Innovation in Pandemic Control (DIPC) Initiative, the Robert Koch Institute, Germany, has conducted a comprehensive analysis on key digital public health definitions and concepts, and on 75 normative resources for digital health programing across 11 digital health topics, published between 2012 and early 2024 [link]. Findings from the report have been summarized in form of 20 easy to use Factsheets. The current factsheet (18/20) summarizes the findings on the identified **Guidelines, Frameworks and Tools on Technical Standards for Developers** that are to ensure the safety, reliability, and interoperability of digital health products.

Factsheet 18

Technical Standards for Developers

Target Audience

Primary Users: Developers; DH Planners

Secondary Users: Donors.

Relevance

The commercialization of digital health products in global markets requires adherence to specific standards to ensure user safety.

More complex digital solutions deliver precise health information upon which medical decisions are based. Thus, strict regulations are necessary to ensure patient safety once we can label our digital intervention a Software as a Medical Device (FDA, 2018).

Findings

Number of resources identified: 4

Technical standards and frameworks, such as the ESF's tiered approach, ISO 82304-2, DiGA's certification process, and the FDA's guidelines, are critical for ensuring the reliability, safety, and efficacy of DH technologies. These resources offer clear guidance for developers, streamline regulatory approval processes, and foster innovation by providing pathways for navigating complex regulatory landscapes.

These frameworks play an important role in shaping the DH landscape, but their effectiveness depends on their ability to adapt to fast-paced advancements, harmonize across regions, and support innovation without compromising safety or efficacy.

Standards

FDA Digital Health quality regulations
The U.S. FDA, responsible for public health safety, established by the Digital Health Center of Excellence in 2020 to support high-quality digital health innovations.
Published by: Digital Health Centre of Excellence (DICE)
Year: 2020
Language: English

ISO-82304-2
A European standard enabling developer self-certification and guiding assessment process with accrediting bodies.
Published by: ISO
Year: 2021
Language: English

Frameworks

Evidence Standards Framework for Digital Health Technologies (ESF)
A tiered framework that categorizes digital health products based on functionality and specifies evidence requirements for developers.
Published by: National Institute for Clinical Excellence (NICE)
Year: NA
Language: English

Digital Health Applications (DiGA) process
A process framework which mandates specific criteria for healthcare tools to qualify as medical products under the German Digital Healthcare Act.
Published by: DiGA
Year: 2020
Language: English, German

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This is based on *"Navigating the Digital Health Ecosystem: A Review of Key Guidelines, Frameworks, and Tools"*

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